HHS:PHS:FDA:CFSAN:OFS:DPDFS:DEB:MST

5100 Paint Branch Parkway
College Park, MD 20740-3835

November 8, 2013

IMS-a-49

To: All Regional Food and Drug Directors
Attn: Regional Milk Specialists

From: Dairy and Egg Branch (HFS-316)

Subject: Actions of the 2013 National Conference on Interstate Milk Shipments

The 34th National Conference on Interstate Milk Shipments (NCIMS) was held in Indianapolis, Indiana, April 19-24, 2013. A total of sixty-three (63) Proposals were submitted and deliberated at the Conference. During the Conference, the State delegates approved several changes to the *Grade "A" Pasteurized Milk Ordinance* (PMO) and related NCIMS documents. Following is a table showing the Actions taken by the voting delegates:

COUNCIL	# OF PROPOSALS	NO ACTION	PASSED AS SUBMITTED	PASSED AS AMENDED	TABLED
I	25	15	2	8	0
II	31	10	13	8	0
III	7	3	2	2	0
TOTAL	63	28	17	18	0

The following Proposals were passed and addressed changes to the PMO: 104, 105, 106, 107, 108, 109, 113, 116, 117, 119, 201, 203, 205, 206, 207, 208, 210, 211, 228, 303, 304 and 305.

The following Proposals were passed and addressed changes to the *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments* (Procedures): 301 (Identified as a new Procedure.), 303, 304 and 305 (All were identified as Procedures changes.).

The following Proposals were passed and addressed changes to the *Methods of Making Sanitation Ratings of Milk Shippers* (MMSR): 206, 207, 304 and 305.

The following Proposals were passed and addressed changes to the *Constitution* and/or the *Bylaws of the National Conference on Interstate Milk Shipments* (Constitution and Bylaws): 304 and 305

The following Proposals were passed and addressed changes to the *Evaluation of Milk Laboratories* (EML): 215, 216, 218, 303, 304 and 305.

The following Proposals were identified as FDA 2400 Forms and were voted on as a block to be handled by FDA and the NCIMS Laboratory Committee following the procedures for issuing and updating FDA 2400 Forms: 211, 223, 224, 225, 226, 227, 228 (**NOTE**: This Proposal also included a PMO change.), 229 and 231 (FDA non-concurred).

The following Proposals were passed and addressed changes to the Inspection and Rating Forms utilized in the Program:

- FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT (10/11): 304 and 305
- FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (Page 2) (10/11): 304
- FORM FDA 2359k-STATUS OF RAW MILK FOR PASTERUIZATION: 304
- FORM FDA 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT (10/10): 305
- FORM FDA 2359n-NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT (10/11): 304 and 305
- FORM FDA 2359o-PERMISSION FOR PUBLICATION (10/11): 305
- FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM CRITICAL LISTING ELEMENTS for Low-Acid (pH greater than 4.6) Aseptic Milk and Milk Products (10/11): 304

The following Proposals were passed and addressed the formation of a Study Committee or were assigned to a Standing Committee(s):

Proposal 220: The NCIMS Chair is to appoint a study committee or assign to a standing committee to examine the issue when drug residue screening is conducted with an unapproved test for contractual or export obligations and at a testing level different than the safe/tolerance level, when a Food and Drug Administration (FDA) approved test does exist.

The appointed study committee or assigned standing committee will provide a report on the topic at the 35th National Conference on Interstate Milk Shipments in 2015. The report will examine current obligations under the Grade "A" Pasteurized Milk Ordinance and may propose additional requirements via a formal proposal.

NOTE: The NCIMS Chair assigned this Proposal to the Appendix N Modification Committee.

Proposal 222: Assign a committee to review the EPA Final Revised Total Coliform Rule signed by the EPA administrator on December 20, 2012 for publication in the federal register and report to 2015 Conference on any suggested changes to the PMO.

NOTE: The NCIMS Chair assigned this Proposal to the Laboratory Committee.

Proposal 301: FDA requests the NCIMS Chair to assign the following charges to the identified NCIMS standing committee(s) and to report back to the 2015 NCIMS Conference:

- SSCC and Methods Committees Jointly: To develop listing and withdrawal of listing criteria for SSCC manufacturers. Consultants that currently have SSCC listings on the IMS List shall participate on these Committees.
- SSCC Committee: To develop qualifications, authorization, certification/recertification procedures, etc. for consultants that currently certify or wish to certify SSCC manufacturers located outside the geographical boundaries of NCIMS Member States. Consultants that currently have SSCC listings on the IMS List shall participate on this Committee.

NOTE: The NCIMS Chair assigned this Proposal to the SSCC and MMSR Committees, respectively.

Proposal 304: The Aseptic Program Committee (APC) requests a two (2) year extension of the NCIMS Aseptic Pilot Program to specifically address Grade "A" acidified and fermented high-acid milk and/or milk products. The additional two (2) years will be utilized to evaluate the effectiveness of regulating and rating milk plants producing Grade "A" acidified and/or fermented high-acid milk and/or milk products.

As part of the NCIMS Aseptic Program addressing aseptically processed and packaged Grade "A" low-acid milk and/or milk products and retort processed after packaged Grade "A" low-acid milk and/or milk products; and the Aseptic Pilot Program addressing aseptically processed and packaged Grade "A" acidified and fermented high-acid milk and/or milk products, an NCIMS Aseptic Program Committee (APC) shall be formed in accordance with NCIMS *Procedures*. The APC shall be responsible for the oversight of the NCIMS Aseptic Program addressing aseptically processed and packaged Grade "A" low-acid milk and/or milk products and retort processed after packaged Grade "A" low-acid milk and/or milk products; and the Aseptic Pilot Program addressing aseptically processed and packaged Grade "A" acidified and fermented high-acid milk and/or milk products in consultation with FDA, including the development of forms, documents and guidance necessary to implement, evaluate and provide training as well as study current and new aseptic technology and its application. The APC shall provide a report to the 2015 NCIMS.

NOTE: The NCIMS Chair assigned this Proposal to the Aseptic Program Committee.

Proposal 305: The International Certification Pilot Program Committee (ICPPC) requests the NCIMS Chair to assign the following charge to the SSCC Committee and report back to the 2015 NCIMS Conference:

Develop qualifications, authorization, certification/recertification procedures, etc. for consultants that currently certify or wish to certify SSCC manufacturers located outside the geographical boundaries of NCIMS Member States. Consultants that currently have SSCC listings on the IMS List shall participate on this Committee.

NOTE: The NCIMS Chair assigned this Proposal to the SSCC Committee.

The following Proposals were passed and did not reference any documents or Forms: 220 and 222.

The following Proposals were passed and are of significance to the Grade "A" Milk Safety Program:

Proposal 304: Contains modifications to the PMO, Methods, Procedures and Bylaws documents that address the regulation and rating of milk plants producing Grade "A" low-acid retort processed after packaging milk and/or milk products. It will incorporate the Aseptic Program Committee's findings and determination for milk plants that produce Grade "A" low-acid retort processed after packaging milk and/or milk products into the NCIMS documents.

This Proposal addresses the regulation of Grade "A" low-acid retort processed after packaging milk and/or milk products manufactured in accordance with the Low Acid Canned Foods (LACF) regulations contained in 21 CFR 108, 110, and 113 while regulating the areas of the milk plant that are outside the low-acid retort processed after packaging system (RPPS) in accordance with the PMO. It provides for a separate IMS listing for Grade "A" milk plants producing Grade "A" low-acid retort processed after packaging milk and/or milk products.

Proposal 305: Contains modifications to the PMO, MMSR, Procedures, and the EML documents that the International Certification Pilot Program Committee (ICPPC) deemed necessary for the regulatory oversight, rating and IMS listing of milk shippers and milk laboratories located outside the geographic boundaries of the National Conference on Interstate Milk Shipments (NCIMS) Member States.

This Proposal incorporates the findings of the ICPPC into the NCIMS documents and transform the International Certification Pilot Program (ICPP) into the International Certification Program (ICP) making it a permanent part of the NCIMS Grade "A" Milk Safety Program.

The program will utilize Third Party Certifiers (TPCs) who will act as regulatory, rating, and laboratory evaluation agencies in the regulation of foreign milk companies (MCs) and their associated farms, haulers, receiving stations, transfer stations, laboratories etc. FDA will conduct check ratings, laboratory evaluations and program evaluations in accordance with "Methods" and "Procedures".

The ICPPC has concluded that TPCs have the capability to operate as the regulatory, rating, and laboratory evaluation agencies as required to comply with the PMO and related NCIMS documents.

FDA responded in writing to the NCIMS Conference Chair on September 3, 2013 and met with the NCIMS Executive Board on October 9-10, 2013 concerning the Proposals passed during the 2013 Conference. Within FDA's letter dated September 3, 2013, FDA concurred with all of the passed Proposals with the exception of Proposal 231. During the October 9-10, 2013 NCIMS Executive Board meeting, FDA and the Executive Board did not reach mutual

concurrence with Proposal 231; therefore, Proposal 231 in accordance with Section IX-Application of Conference Agreements, A-Implementation of Changes, 4. of the *Procedures* will be referred to the next Conference for discussion. The NCIMS Executive Board mutually concurred with FDA on all of the Proposals that were concurred with by FDA.

All Proposals that were passed and concurred with by FDA and the NCIMS Executive Board, with the exception of the ones noted below, will become effective within one (1) year of the electronic publication of the affected document(s); or by the official notification to the States through the transmittal of this IMS-a, as applicable, following the Conference at which the changes were passed. For States that can legally enforce the new regulations based on the issuance of this IMS-a, the effective date will be November 8, 2014.

The following Proposals are exceptions to the effective dates cited above:

- **Proposal 206**: Adds wording to define the inspection frequency interval for bulk milk hauler, industry plant and dairy plant samplers to be the designated period plus the remaining days of the month in which the inspection is due.

- **Proposal 207:** Adds appropriate references to M-a-98 into the PMO and the MMSR.

- **Proposal 304**: Incorporates the Aseptic Program Committee's findings and determination for milk plants that produce Grade "A" low-acid retort processed after packaging milk and/or milk products into the NCIMS documents.

- **Proposal 305:** Makes the voluntary NCIMS International Certification Pilot Program (ICPP) a permanent part of the Grade "A" Milk Safety program.

NOTE: *All of these Proposals shall take immediate effect upon the issuance of the IMS-a, Actions from the 2013 National Conference on Interstate Milk Shipments, following FDA concurrence with the NCIMS Executive Board.*

NOTE: Some of the language as adopted by the delegates was editorialized in order to maintain continuity with the present language and to ensure compatibility with existing sections of the affected NCIMS document(s). The edits have not changed the intent of the voted actions. Deletions to the current document's language are identified by ~~strikeout~~ and additions are identified by underlined text, unless otherwise noted.

Proposal: 305
Document: 2011 PMO (Entire Document)
Pages: Entire document

*Make the following changes to the **2011 PMO**:*

Cover Page:

~~2011~~ 2013 Revision

Page ii:

2013. *Grade "A" Pasteurized Milk Ordinance, Including Provisions from the Grade "A" Condensed and Dry Milk Products and Condensed and Dry Whey--Supplement I to the Grade "A" Pasteurized Milk Ordinance. Public Health Service/Food and Drug Administration.*

PREFACE …

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To assist States and Municipalities in initiating and maintaining effective programs for the prevention of milkborne disease, the USPHS, in 1924, developed a model regulation known as the *Standard Milk Ordinance* for voluntary adoption by State and Local Milk Control Agencies. To provide for the uniform interpretation of this *Ordinance*, an accompanying *Code* was published in 1927, which provided administrative and technical details as to satisfactory compliance. This model milk regulation, now titled the *Grade "A" Pasteurized Milk Ordinance* (Grade "A" PMO), ~~2011~~ 2013 Revision, incorporates the provisions governing the processing, packaging, and sale of Grade "A" milk and milk products, including buttermilk and buttermilk products, whey and whey products, and condensed and dry milk products and represents the 29th revision and incorporates new knowledge into public health practice. …

The USPHS/FDA's recommended *Grade "A" PMO* is the basic standard used in the voluntary Cooperative State-USPHS/FDA Program for the Certification of Interstate Milk Shippers, a program participated in by all fifty (50) States, the District of Columbia and U.S. Trust Territories. The National Conference on Interstate Milk Shipments (NCIMS) in accordance with the Memorandum of Understanding with the Food and Drug Administration (FDA) has at its biennial conferences recommended changes and modifications to the *Grade "A" PMO*. These changes have been incorporated into this ~~2011~~ 2013 revision. The counsel and guidance rendered by the Conference in preparation of this edition of the *Grade "A" PMO* is deeply appreciated. …

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Within the ~~2011~~ 2013 *Grade "A" PMO*, the administrative and technical requirements for the manufacture of condensed and dry milk products and condensed and dry whey included in the *Grade "A" Condensed and Dry Milk Ordinance--Supplement I to the Grade "A" Pasteurized Milk Ordinance* have been incorporated as directed by the 2001 NCIMS.

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INTRODUCTION

The following *Grade "A" PMO,* with Appendices, is recommended for legal adoption by States~~, Counties, and Municipalities,~~ in order to encourage a greater uniformity and a higher

level of excellence of milk sanitation practice in the United States. An important purpose of this recommended standard is to facilitate the shipment and acceptance of milk and milk products of high sanitary quality in interstate and intrastate commerce. …

The following form is suggested for adoption by States~~, Counties, and Municipalities~~ subject to the approval of the appropriate legal authority. Adoption of this form will reduce the cost of publishing and printing, and will enable the *Grade "A" PMO* to be easily kept current. The adoption of this form is considered legal in many States and has been so adopted. The Council of State Governments has prepared a model State law, *Milk and Food Codes Adoption-by-Reference Act*,[1] which is recommended for enactment by States to enable communities to adopt milk and food ordinances by reference.

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The USPHS/FDA does not have legal jurisdiction in the enforcement of milk sanitation standards, except on interstate carriers and milk and milk products shipped in interstate commerce. It serves solely in an advisory and stimulative capacity and its program is designed primarily to assist ~~State and Local~~ Regulatory Agencies. Its aim is to promote the establishment of effective and well-balanced milk sanitation programs in each State; to stimulate the adoption of adequate and uniform ~~State and Local~~ milk control legislation; and to encourage the application of uniform enforcement procedures through appropriate legal and educational measures.

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When this *Ordinance* is adopted ~~locally~~, its enforcement becomes a function of the ~~Local or State authorities~~ Regulatory Agencies. Consequently, the *Ordinance* should be adopted only if adequate provisions can be made for qualified personnel and for suitable laboratory facilities. ~~Small Municipalities which cannot afford to provide these services should arrange for supervision by the County or State Health Department, or seek cooperation with neighboring Municipalities in organizing a milk control district or area.~~

Adoption: In the interest of national uniformity, it is recommended that ~~no~~ not any changes be made in this *Ordinance* when adopted by a State ~~or Local community~~, unless changes are necessary to avoid conflict with State law. Modifications should be contemplated with extreme caution so as not to render the *Ordinance* unenforceable. In order to promote uniformity, it is recommended that all of the **ADMINISTRATIVE PROCEDURES** be adopted as well.

Amendment of Existing Regulations: States ~~and Communities~~ that have adopted the ~~2009~~ 2011 or earlier editions of the USPHS/FDA recommended *Grade "A" PMO* are urged to bring such *Ordinance* up-to-date in order to take advantage of the most current developments in milk sanitation and administration. States ~~and Communities~~ whose milk sanitation law or regulations are not based on a previous USPHS/FDA recommended *Grade "A" PMO* are urged to consider the attendant public health benefits, as well as those economic in nature, which can accrue upon the adoption and implementation of the *Grade "A" PMO*. …

Page 1:

GRADE "A" PASTEURIZED MILK ORDINANCE
(*GRADE "A" PMO*)--~~2011~~ 2013 REVISION ...

Page 2:

D. **AUTOMATIC MILKING INSTALLATION (AMI):** The term ~~automatic milking installation~~ Automatic Milking Installation (AMI) covers the entire installation of one (1) or more automatic milking units, including the hardware and software utilized in the operation of individual automatic milking units, the animal selection system, the automatic milking machine, the milk cooling system, the system for cleaning and sanitizing the automatic milking unit, the teat cleaning system, and the alarm systems associated with the process of milking, cooling, cleaning and sanitation.

E. **BULK MILK HAULER/SAMPLER:** A bulk milk hauler/sampler is any person who collects official samples and may transport raw milk from a farm and/or raw milk products to or from a milk plant, receiving station or transfer station and has in their possession a permit from any ~~State~~ Regulatory Agency to sample such products. …

I. **CLEAN-IN-PLACE (CIP) CLEANING:** The removal of soil from product contact surfaces in their process position by circulating, spraying, or flowing chemical solutions and water rinses onto and over the surfaces to be cleaned. Components of the equipment, which are not designed to be cleaned-in-place, are removed from the equipment to be ~~cleaned-out-of-place~~ Cleaned-Out-Of-Place (COP) or manually cleaned. Product contact surfaces shall be inspectable, except when the cleanability by Cleaned-In-Place (CIP) has been documented and accepted by the Regulatory Agency. In such accepted equipment, all product and solution contact surfaces do not have to be readily accessible for inspection, i.e., permanently installed pipelines and silo tanks. …

Page 3:

N. **DAIRY PLANT SAMPLER:** A person responsible for the collection of official samples for regulatory purposes outlined in Section 6 of this *Ordinance*. This person is an employee of the Regulatory Agency and is evaluated at least once every two (2)-year period by a ~~State~~ Sampling Surveillance Officer (SSO) or a properly delegated Sampling Surveillance Regulatory Agency Official (dSSO). Sampling Surveillance Officers (SSOs) or properly delegated Sampling Surveillance Regulatory Agency Officials (dSSO) are not required to be evaluated for sampling collection procedures. …

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S. **HACCP DEFINITIONS:** (For use in conjunction with Appendix K.)

S-2. **CENTRALIZED DEVIATION LOG:** A centralized log or file identifying data detailing any deviation of ~~critical limits~~ Critical Limits (CLs) and the corrective actions

taken as required in Appendix K. …

S-4. **CONTROL MEASURE:** Any action or activity that can be used to prevent, eliminate, or reduce a significant hazard that is managed at a Critical Control Point (CCP).
…
S-6. **CRITICAL CONTROL POINT (CCP):** A step at which control can be applied and is essential to prevent or eliminate a milk and/or milk product safety hazard or reduce it to an acceptable level.
S-7. **CRITICAL LIMIT (CL):** A maximum and/or minimum value to which a biological, chemical, or physical parameter ~~must~~ shall be controlled at a ~~CCP~~ Critical Control Point (CCP) to prevent, eliminate, or reduce to an acceptable level the occurrence of a milk and/or milk product safety hazard.
S-8.**CRITICAL LISTING ELEMENT (CLE):** An item on FORM FDA 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT identified with a double star (**). The marking of a CLE by a ~~State~~ Milk Sanitation Rating Officer (SRO) or FDA auditor, indicates a condition that constitutes a major dysfunction likely to result in a potential compromise to milk and/or milk product safety, or that ~~violate~~ violates NCIMS requirements regarding drug residue testing and trace back and/or raw milk sources, whereby a listing may be denied or withdrawn. …

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S-11. **DEVIATION:** A failure to meet a ~~CL~~ Critical Limit (CL).
S-12. **HAZARD ANALYSIS CRITICAL CONTROL POINT (HACCP):** A systematic approach to the identification, evaluation, and control of significant milk and/or milk product safety hazards. …

S-14. **HACCP SYSTEM:** The implemented HACCP Plan and Prerequisite ~~Program~~ Programs (PPs), including other applicable NCIMS requirements. …

S-16. **HAZARD:** A biological, chemical, and/or physical agent that is reasonably likely to cause illness or injury in the absence of its control.
S-17. **HAZARD ANALYSIS:** The process of collecting and evaluating information on hazards associated with the milk and/or milk product under consideration, to decide which are reasonably likely to occur and ~~must~~ shall be addressed in the HACCP Plan.
S-18. **MONITOR:** To conduct a planned sequence of observations or measurements to assess whether a ~~CCP~~ Critical Control Point (CCP) is under control or to assess the conditions and practices of all required Prerequisite Programs (PPs). …
S-21. **PREREQUISITE PROGRAMS (PPs):** Procedures, including Good Manufacturing Practices (GMPs), which address operational conditions that provide the foundation for the HACCP System. The required ~~PPs~~ Prerequisite Programs (PPs) specified in Appendix K. are sometimes called Sanitary Standard Operating Procedures (SSOPs) in other HACCP Systems. …

U. **INDUSTRY PLANT SAMPLER:** A person responsible for the collection of official samples for regulatory purposes at a milk plant, receiving station or transfer station as outlined in Appendix N. This person is an employee of the milk plant, receiving station or transfer station and is evaluated at least once every two (2) year period by a ~~State~~ Sampling Surveillance Officer (SSO) or a properly delegated Sampling Surveillance Regulatory Agency Official (dSSO).

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V. **INTERNATIONAL CERTIFICATION PROGRAM (ICP):** The International Certification Program (ICP) means the NCIMS voluntary program designed to utilize Third Party Certifiers (TPCs) authorized by the NCIMS Executive Board in applying the requirements of the NCIMS Grade "A" Milk Safety Program for Milk Companies (MCs) located outside the geographic boundaries of NCIMS Member States that desire to produce and process Grade "A" milk and/or milk products for importation into the United States.

W. **LETTER OF INTENT (LOI):** A formal written signed agreement between a Third Party Certifier (TPC), authorized under the NCIMS voluntary International Certification Program (ICP), and a Milk Company (MC) that intends to be certified and IMS Listed under the NCIMS voluntary International Certification Program (ICP). A copy of each written signed agreement shall be immediately submitted to the International Certification Program (ICP) Committee following the signing by the Third Party Certifier (TPC) and Milk Company (MC).

X. **LETTER OF UNDERSTANDING (LOU):** A formal written signed agreement between a Third Party Certifier (TPC) and the NCIMS Executive Board that acknowledges the NCIMS' authorization of the Third Party Certifier (TPC) to operate under the NCIMS voluntary International Certification Program (ICP). It also states the Third Party Certifier's (TPC's) responsibilities under the NCIMS voluntary International Certification Program (ICP); their agreement to execute them accordingly; and their understanding of the consequences for failing to do so. The Letter of Understanding (LOU) shall include, but is not limited to, the issues and concerns addressed in all documents involved in the NCIMS voluntary International Certification Program (ICP).

~~V~~Y. **LOW-ACID ASEPTIC MILK AND MILK PRODUCTS:** …

Z. **MEMORANDUM OF AGREEMENT (MOA):** A formal written signed memorandum that states the requirements and responsibilities of each party (Third Party Certifier (TPC) and Milk Company (MC)) to participate and execute the NCIMS voluntary International Certification Program (ICP). The Memorandum of Agreement (MOA) shall include, but is not limited to, the issues and concerns addressed in all documents involved in the NCIMS voluntary International Certification Program (ICP). This agreement shall be considered the Milk Company's (MC's) permit to operate in the context of the NCIMS Grade "A" Milk Safety Program and shall be renewed (signed and dated) on an annual basis.

AA. **MILK COMPANY (MC):** A Milk Company (MC) is a private entity that is listed on the IMS List by a Third Party Certifier (TPC) including all associated dairy farms, bulk milk

haulers/samplers, milk tank trucks, milk transportation companies, milk plants, receiving stations, transfer stations, dairy plant samplers, industry plant samplers, milk distributors, etc. and their servicing milk and/or water laboratories, as defined in the *Grade "A" PMO*, located outside the geographic boundaries of NCIMS Member States.

~~W~~BB. **MILK DISTRIBUTOR:** …

Re-letter the remaining DEFINITIONS accordingly.

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OO. **RATING AGENCY:** A Rating Agency shall mean a State Agency, which certifies interstate milk shippers (BTUs, receiving stations, transfer stations, and milk plants) as having attained the Sanitation Compliance and Enforcement Ratings necessary for inclusion on the *IMS List*. The ratings are based on compliance with the requirements of the *Grade "A" PMO* and were conducted in accordance with the procedures set forth in the *Methods of Making Sanitation Ratings of Milk Shippers (MMSR)*. Ratings are conducted by FDA certified Milk Sanitation Rating Officers (SROs). They also certify single-service containers and closures for milk and/or milk products manufacturers for inclusion on the *IMS List*. The certifications are based on compliance with the requirements of the *Grade "A" PMO* and were conducted in accordance with the procedures set forth in the *Methods of Making Sanitation Ratings of Milk Shippers (MMSR)*. The definition of a Rating Agency also includes a Third Party Certifier (TPC) that conducts ratings and certifications of Milk Companies (MCs) located outside the geographic boundaries of NCIMS Member States that desire to produce and process Grade "A" milk and/or milk products for importation into the United States. …

Re-letter the remaining DEFINITIONS accordingly.

~~LL~~RR. **REGULATORY AGENCY:** The Regulatory Agency shall mean the ... of the …[1]or their authorized representative. The term, "Regulatory Agency", whenever it appears in the *Ordinance* shall mean the appropriate agency, including a Third Party Certifier (TPC) authorized under the NCIMS voluntary International Certification Program (ICP), having jurisdiction and control over the matters embraced within this *Ordinance*. …

Re-letter the remaining DEFINITIONS accordingly.

UU. THIRD PARTY CERTIFER (TPC): A Third Party Certifier (TPC) is a non-governmental individual(s) or organization authorized under the NCIMS voluntary International Certification Program (ICP) that is qualified to conduct the routine regulatory functions and enforcement requirements of the *Grade "A" PMO* in relationship to milk plants, receiving stations, transfer stations, associated dairy farms, bulk milk hauler/samplers, milk tank trucks, milk transportation companies, dairy plant samplers, industry plant samplers, milk distributors, etc. participating in the NCIMS voluntary International Certification Program (ICP). The Third Party Certifier (TPC) provides the means for the rating and listing of milk plants, receiving stations, transfer stations and their related raw milk sources. They also conduct the certification and IMS listing of related milk and/or water laboratories and related

single-service container and closure manufacturers on the *Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers (IMS) List*. To be authorized under the NCIMS voluntary International Certification Program (ICP), a valid Letter of Understanding (LOU) shall be signed between the NCIMS Executive Board and the Third Party Certifier (TPC). …

Re-letter the remaining DEFINITIONS accordingly.

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SECTION 2. ADULTERATED OR MISBRANDED MILK AND/OR MILK PRODUCTS

~~No~~ Not any person shall, within the ... of ...[1], or its jurisdiction, produce, provide, sell, offer, or expose for sale or have in possession with intent to sell any milk or milk product, which is adulterated or misbranded. Provided, that in an emergency, the sale of pasteurized milk and/or milk products, which do not fully meet the requirements of this *Ordinance*, may be authorized by the Regulatory Agency.

NOTE: The option for the emergency sale of pasteurized milk and/or milk products as cited above, shall not be applicable to a Milk Company (MC) IMS listed under the NCIMS voluntary International Certification Program (ICP).

Any adulterated and/or misbranded milk and/or milk products may be impounded by the Regulatory Agency and disposed of in accordance with applicable laws or regulations.

NOTE: Adulterated and/or misbranded milk and/or milk products from MCs IMS listed under the ICP shall not gain entry into the U.S.

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ADMINISTRATIVE PROCEDURES

This Section of the *Ordinance* shall be used in impounding the milk and/or milk products of, or preferring charges against, persons who adulterate and/or misbrand their milk and/or milk products; or label them with any grade designation not authorized by the Regulatory Agency under the terms of this *Ordinance*; or who sell or deliver ungraded milk and/or milk products, except as may be permitted under this Section in an emergency. An emergency is defined as a general and acute shortage in the milk shed, not simply one (1) distributor's shortage.

NOTE: The option for the emergency sale of pasteurized milk and/or milk products as cited above, shall not be applicable to a MC IMS listed under the ICP.

SECTION 3. PERMITS …

The term "permit", whenever it appears in this *Ordinance* shall also mean a MC operating

under the ICP possessing a valid Memorandum of Agreement (MOA) with a Third Party Certifier (TPC).

It shall be unlawful for any person who does not possess a permit from the Regulatory Agency of the ... of ...[1] to manufacture, bring into, send into or receive into the ... of ...[1] or its jurisdiction, for sale, or to sell, or offer for sale therein or to have in storage any milk and/or milk products, defined in this *Ordinance*. Provided, that grocery stores, restaurants, soda fountains and similar establishments where milk and/or milk products are served or sold at retail, but not processed may be exempt from the requirements of this Section. Provided further, that brokers, agents, and distributors representing, buying from, and/or selling condensed and dry milk products from or to a milk plant having a valid permit are not required to have a permit. …

It shall be unlawful for any person to manufacture in a milk plant under a permit for Grade "A" condensed or dry milk products in the...of...[1] or its jurisdiction any condensed and dry milk products which do not meet the requirements of this *Ordinance* for Grade "A" condensed or dry milk products without a permit from the Regulatory ~~Authority~~ Agency who shall require that such condensed and dry milk products be processed, packaged and stored separately from Grade "A" condensed or dry milk products and that each container of such products be plainly marked in such a manner as to prevent confusion of the product with Grade "A" condensed or dry milk products. …

SUSPENSION OF PERMIT: When any requirement(s) of this *Ordinance* is violated, the permit holder is subject to the suspension of their permit.

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The Regulatory Agency may forego suspension of the permit, provided the milk and/or milk product in violation is not sold or offered for sale as a Grade "A" milk and/or milk product. A Regulatory Agency may allow the imposition of a monetary penalty in lieu of a permit suspension, provided the milk and/or milk product in violation is not sold or offered for sale as a Grade "A" milk and/or milk product. Except, that a milk producer may be assessed a monetary penalty in lieu of permit suspension for violative counts provided:

1. If the monetary penalty is due to a violation of the bacterial or cooling temperature standards, the Regulatory Agency shall conduct an inspection of the facility and operating methods and make the determination that the conditions responsible for the violation have been corrected. Samples shall then be taken at the rate of not more than two (2) per week on separate days within a three (3) week period in order to determine compliance with the appropriate standard as determined in accordance with Section 6 of this *Ordinance*.
2. If the monetary penalty is due to a violation of the somatic cell count standard, the Regulatory Agency shall verify that the milk supply is within acceptable limits as prescribed in Section 7 of this *Ordinance*. Samples shall then be taken at the rate of not more than two (2) per week on separate days within a three (3) week period in order to determine compliance with the appropriate standard as determined in accordance with Section 6 of this *Ordinance*.

NOTE: The option to issue a monetary penalty in lieu of a permit suspension as cited above, shall not be applicable to a TPC authorized under the ICP.

HEARINGS: If a State's Administrative Procedure Act (APA), which provides procedures for administrative hearings and judicial review of administrative determinations, is available, the APA shall be made applicable by reference to the hearings provided for in the *Ordinance*. If such APA is not available, appropriate procedures, including provision for notice, hearing officer, their authority, record of hearing, rules of evidence and court review shall be established by the appropriate authority.

NOTE: TPCs authorized under the ICP shall follow the hearing procedures and process addressed in this *Ordinance*.

SECTION 4. LABELING

Page 16:

ADMINISTRATIVE PROCEDURES …

LABELING OF EMERGENCY SUPPLIES: When the sale of ungraded milk or milk products is authorized during emergencies, under the terms of Section 2, the label ~~must~~ shall bear the designation "ungraded". When such labeling is not available, the Regulatory Agency shall take immediate steps to inform the public that the particular supply is "ungraded" and that the supply will be properly labeled as soon as the distributor can obtain the required labels.

NOTE: The option for the sale of "ungraded" milk and/or milk products as cited above, shall not be applicable to a MC IMS listed under the ICP. …

Page 17:

SECTION 5. INSPECTION OF DAIRY FARMS AND MILK PLANTS …

3. Inspect each milk plant and receiving station at least once every three (3) months, provided that, for those milk plants and receiving stations that have HACCP Systems, which are regulated under the NCIMS voluntary HACCP Program, regulatory audits shall replace the regulatory inspections described in this Section. The requirements and minimum frequencies for these regulatory audits are specified in Appendix K. Provided further, that regulatory inspections of a milk plant or portion of a milk plant that is IMS listed to produce aseptically processed and packaged milk or milk products shall be conducted by the ~~State~~ Regulatory Agency in accordance with this *Ordinance* at least once every six (6) months. (Refer to Appendix S.) The milk plant's APPS shall be inspected by FDA, or ~~the State~~ a Regulatory Agency ~~when~~ designated by FDA under the FDA LACF Program, in accordance with the applicable requirements of 21 CFR Parts 108, 110 and 113 at a frequency determined by FDA.
…

Page 20:

ENFORCEMENT PROCEDURES - ASEPTIC PROCESSING AND PACKAGING MILK PLANTS: The ~~State~~ Regulatory Agency shall take appropriate regulatory action, in coordination with FDA when applicable, to assure that the Grade "A" aseptic milk plant and the Grade "A" aseptic milk and milk products meet the applicable requirements of this *Ordinance*. …

Page 22:

INSPECTION/AUDIT REPORTS: A copy of the inspection/audit report shall be filed as directed by the Regulatory Agency and retained for at least twenty-four (24) months. The results shall be entered on appropriate ledger forms. The use of a computer or other information retrieval system may be used. Examples of field inspection/audit forms are identified in Appendix M.

NOTE: The option to use Certified Industry Inspection as cited in this Section, shall not be applicable to a TPC authorized under the ICP.

Page 23:

SECTION 6. THE EXAMINATION OF MILK AND MILK PRODUCTS

Samples of milk and/or milk products shall be taken while in the possession of the producer, milk plant or distributor at any time prior to delivery to the store or consumer.
Samples of milk and/or milk products from dairy retail stores, food service establishments, grocery stores and other places where milk and/or milk products are sold shall be examined periodically as determined by the Regulatory Agency and the results of such examination shall be used to determine compliance with Sections 2, 4 and 10. Proprietors of such establishments shall furnish the Regulatory Agency, upon request, with the names of all distributors from whom milk and/or milk products are obtained.

NOTE: The sampling of milk and/or milk products from locations where milk and/or milk products are sold as cited above, shall not be applicable to a TPC authorized under the ICP. …

ITEM 7r. TOILET …

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

Page 42:

1. There is at least one (1) flush toilet connected to a public sewer system, or to an individual sewage-disposal system, or a chemical toilet, earth pit privy or other type of privy. Such sewage systems shall be constructed and operated in accordance with the standards outlined in

Appendix C., or when a Regulatory Agency has more effective standards designed specifically for that region, these standards may apply, provided, there is ~~no~~ not any mixing of animal and human waste.

NOTE: The text "or when a Regulatory Agency has more effective standards designed specifically for that region, these standards may apply" as cited in 1. above, shall not be applicable to a TPC authorized under the ICP. …

ITEM 8r. WATER SUPPLY …

ADMINISTRATIVE PROCEDURES …

This Item is deemed to be satisfied when:

1. The water supply for milkhouse and milking operations is approved as safe by the ~~State~~ applicable Government Water Control Authority and, in the case of individual water systems, complies with the specifications outlined in Appendix D~~,~~ and the Bacteriological Standards outlined in Appendix G. …

ITEM 10r. UTENSIL AND EQUIPMENT – CLEANING …

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

Page 46:

3. There shall ~~be no~~ not be any partial removal of milk from milk storage/holding tanks by the bulk milk hauler/sampler, except partial pickups may be permitted when the milk storage/holding tank is equipped with a seven (7) day recording device complying with the specifications of Appendix H. or other recording device acceptable to the Regulatory Agency, provided the milk storage/holding tank shall be clean and sanitized when empty and shall be emptied at least every seventy-two (72) hours. In the absence of a temperature-recording device, partial pickups may be permitted as long as the milk storage/holding tank is completely empty, clean and sanitized prior to the next milking. In the event of an emergency situation, such as inclement weather, natural disaster, etc., a variance may be permitted at the discretion of the Regulatory Agency.

NOTE: The text "In the event of an emergency situation" as cited in 3. above, shall not be applicable to a TPC authorized under the ICP. …

STANDARDS FOR GRADE "A" PASTEURIZED, ULTRA-PASTEURIZED AND ASEPTICALLY PROCESSED AND PACKAGED MILK AND MILK PRODUCTS

Page 61:

ITEM 7p. WATER SUPPLY

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when: …

2. The water supply is approved as safe by the ~~State~~ applicable Government Water Control Authority and, in the case of individual water systems, complies with the specification outlined in Appendix D. and the Bacteriological Standards outlined in Appendix G. …

ITEM 11p. CONSTRUCTION AND REPAIR OF CONTAINERS AND EQUIPMENT ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

Page 66:

11. The manufacture, packing, transportation and handling of single-service containers, closures, caps, gaskets and similar articles comply with the requirements of Appendix J. Standards for the Fabrication of Single-Service Containers and Closures for Milk and Milk Products. Provided, that all paper, plastics, foil, adhesives, and other components of containers used in the packaging of milk and/or milk products that have been condensed and/or dried shall be free from deleterious substances and comply with the requirements of the *FFD&CA*.
Inspections and tests shall be made by the Regulatory Agency or any Agency authorized by them.

NOTE: The option for "Inspections and tests" as cited in 11. above, shall only be made by a TPC authorized under the ICP. …

ITEM 12p. CLEANING AND SANTIZING OF CONTAINERS AND EQUIPMENT

ADMINISTRATIVE PROCEDURES

Page 71:

6. a. The residual bacteria count of multi-use containers and closures shall be conducted as …

c. When single-service containers or closures are fabricated in another plant that conforms to the Standards of Appendix J. and the Regulatory Agency has information that they do comply, the Regulatory Agency may accept the containers as being in conformance without additional testing. If there is reason to believe that containers do not conform to the bacteriological standards, additional testing may be required. If containers are fabricated in the milk plant, the Regulatory Agency shall collect, during any consecutive six (6) months, at least four (4) sample sets of containers, as defined in Appendix J., from each manufacturing line, as defined in Appendix J., in at least four (4)

separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days, and analyze the sample sets at an Official, Commercial or Industry Laboratory, approved by the ~~State~~ Milk Laboratory ~~Certifying~~ Control Agency specifically for the examinations required under Appendix J. …

ITEM 15p. PROTECTION FROM CONTAMINATION

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

Page 75:

15p.(A) …

2. Packaged milk and/or milk products, which have physically left the premises or the processing milk plant are not re-pasteurized for Grade "A" use. The Regulatory Agency may, on a specific individual request, authorize reprocessing of packaged milk and/or milk products, provided all other aspects of this Item, including proper storage temperature and container integrity are complied with. Provided, that the re-pasteurization of milk and/or milk products shipped in milk tank trucks, which have been pasteurized at another Grade "A" milk plant and have been handled in a sanitary manner and maintained at 7ºC (45ºF) or less is permitted. Equipment, designated areas or rooms utilized for handling, processing and storage of returned packaged milk and/or milk products are maintained, operated, cleaned and sanitized so as to preclude the contamination of Grade "A" milk and/or products and equipment and the Grade "A" operations.

NOTE: The option for the authorizing of the reprocessing of packaged milk and/or milk products on an individual request, as cited in 2. above, shall not be applicable to a TPC authorized under the ICP. …

ITEM 16p.(D) PASTEURIZATION RECORDS, EQUIPMENT TESTS AND EXAMINATIONS

1. **PASTEURIZATION RECORDS:** …

Page 100:

a. **Batch Pasteurizers**: …

(5) Reading of the airspace thermometer, at the start of the holding period and at the end of the holding period, at a given time or reference point as indicated on the chart; provided, if the airspace thermometer is a digital combination airspace/recording thermometer, which provides a continuous recording of the airspace temperature and has been calibrated by the ~~State~~ Regulatory Agency in accordance with Appendix I, Test 4, the recording of the airspace temperature on the chart shall only be required at

the start of the holding period; …

Page 101:

2. **EQUIPMENT TESTS AND EXAMINATIONS:**
The Regulatory Agency shall perform the indicated tests on the following instruments and devices initially on installation; and at least once each three (3) months, including the remaining days of the month in which the equipment tests are due; and whenever any alteration or replacement is made which may affect the proper operation of the instrument or device. Provided, that the holding time test shall be conducted at least every six (6) months, including the remaining days of the month in which the equipment check is due.

NOTE: A TPC authorized under the ICP may utilize appropriately trained and TPC authorized in-country regulatory personnel to comply with 2. as cited above.

On an emergency basis, pasteurization equipment may be tested and temporarily sealed by a milk plant employee provided the following conditions are met: …

a. The individual applying the seal(s) ~~is~~ shall be employed by the milk plant in which the ~~seal~~ seal(s) was removed; …

d. The individual ~~is~~ shall be in possession of authorization from the Regulatory Agency to perform these tests;
e. The individual ~~will~~ shall immediately notify the Regulatory Agency of the time of the shutdown that would necessitate the breaking and removal of the regulatory seal(s). Permission to test and ~~seal~~ reseal the equipment ~~must~~ shall be obtained for each specific incident. The individual ~~will~~ shall also notify the Regulatory Agency of the identity of the controls affected, the cause, if known, of the equipment failure, the repairs made and the results of the testing. Test results for Pasteurization Equipment Testing shall be recorded on a similar document for all milk plants. (Refer to the reference in Appendix M. for an example.) The individual ~~will~~ shall provide to the Regulatory Agency the identity and volume of milk and/or milk products processed during the period that the temporary ~~seals were~~ seal(s) was applied ~~to the Regulatory Agency~~;
f. If regulatory ~~tests reveal~~ testing reveals that the equipment or controls are not in compliance with the provisions of this *Ordinance*, all milk and/or milk products that were processed during ~~that~~ this period may be recalled by the Regulatory Agency;
g. The Regulatory Agency or a properly trained regulatory official, commissioned by the responsible ~~State~~ Regulatory Agency, of each participating non-U.S. country or political subdivision thereof, ~~will~~ shall remove the temporary seal(s), retest the equipment and apply the regulatory seal(s) within ten (10) working days of the notification by ~~industry~~ the milk plant; and
h. ~~No~~ Grade "A" milk and/or milk products ~~will~~ shall not be processed after ten (10) working days of the notification by the milk plant without the affected equipment being tested and sealed by the Regulatory Agency or a properly trained regulatory official, commissioned by the responsible ~~State~~ Regulatory Agency, of each participating non-U.S. country or political subdivision thereof. …

SECTION 8. ANIMAL HEALTH …

Page 118:

5. Records supporting the tests required in this Section shall be available to the Regulatory Agency and be validated with the signature of a licensed and accredited veterinarian or an accredited veterinarian in the employ of an official Agency.

NOTE: For the ICP, references to USDA and/or State in Items 1 through 5 above, shall mean the Government Agency responsible for animal disease control in the Country or region of that Country. The term "accredited veterinarian" shall mean an individual veterinarian authorized for those activities in said Country or region of that Country. …

AMINISTRATIVE PROCEDURES

BOVINE TUBERCULOSIS: All tuberculin tests and retests shall be made, and any reactors disposed of, in accordance with the current edition of *Uniform Methods and Rules; Bovine Tuberculosis Eradication, Uniform Methods and Rules for Establishment and Maintenance of Tuberculosis-Free Accredited Herds of Cattle, Modified Accredited Areas and Areas Accredited Free of Bovine Tuberculosis in the Domestic Bovine*, as published by USDA. For tuberculosis test purposes, the herd is defined as all adult cattle twenty-four (24) months of age and over, including any commingled beef animals. Dairy cattle less than two (2) years of age and already milking shall be included in the herd test. A letter or other official correspondence attesting to the accreditation status of the locality in which the herd is located, including the date of accreditation, or a certificate identifying the animals tested, the date of injection, the date of reading of the test and the results of the test signed by a USDA accredited veterinarian, shall be evidence of compliance with the above requirements and shall be filed with the Regulatory Agency. (Refer to Appendix A.)

NOTE: For the ICP, an official letter or other official correspondence attesting to the accreditation status of the locality in which the herd is located, including the date of accreditation or recertification, or certificate identifying the animals tested, the date of injection, the date of the reading of the test and the results of the test signed by the Country's Veterinary Services shall be provided as directed by the TPC.

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BOVINE BRUCELLOSIS: All brucellosis tests, retests, disposal of reactors, vaccination of calves and certification of herds and areas shall be in accordance with the current edition of *Brucellosis Eradication, Recommended Uniform Methods and Rules,* as published by USDA. All reactors disclosed on blood agglutination tests shall be separated immediately from the milking herd and the milk of these reactors shall not be used for human consumption.
A certificate identifying each animal, signed by the veterinarian and the director of the laboratory making the test, shall be filed as directed by the Regulatory Agency. Provided, that in the event the herd is subject to the milk ring test, the record shall be required to show only the date and results of such test. Within thirty (30) days following the expiration of an official

milk ring testing program, or in the case of a herd subject to annual blood tests, thirteen (13) months following the last annual blood tests, the Regulatory Agency shall notify the herd owner or operator of the necessity to comply with the brucellosis requirements. The failure of the herd owner or operator to comply with the brucellosis requirements within thirty (30) days of written notice shall result in immediate suspension of the permit. (Refer to Appendix A.)

NOTE: For the ICP, a certificate identifying each animal signed by the Country's Veterinary Services and director of the laboratory conducting the testing, shall be provided as directed by the TPC.

SECTION 9. MILK AND MILK PRODUCTS WHICH MAY BE SOLD

From and after twelve (12) months from the date on which this *Ordinance* is adopted, only Grade "A" pasteurized, ultra-pasteurized, or aseptically processed and packaged milk and milk products shall be sold to the final consumer, to restaurants, soda fountains, grocery stores or similar establishments. Provided, only Grade "A" milk and milk products shall be sold to milk plants for use in the commercial preparation of Grade "A" milk and milk products. Provided further, that in an emergency, the sale of pasteurized, ultra-pasteurized or aseptic processed and packaged milk and milk products, which have not been graded, or the grade of which is unknown, may be authorized by the Regulatory Agency, in which case, such milk and milk products shall be labeled "ungraded".

NOTE: The option for the sale of "ungraded" milk and/or milk products as cited above, shall not be applicable to a MC IMS listed under the ICP. …

SECTION 11. MILK AND MILK PRODUCTS FROM POINTS BEYOND THE LIMITS OF ROUTINE INSPECTION …

Page 121:

ADMINISTRATIVE PROCEDURES …

7. All ratings are made on the basis of procedures outlined in the *Methods of Making Sanitation Ratings of Milk Shippers* (MMSR).

NOTE: Names of interstate milk shippers and their ratings, as reported by ~~State~~ Rating Agencies, are contained in the *IMS List-Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers* (IMS List), issued electronically by FDA. This list may be obtained from the FDA web site at www.fda.gov.

8. The supplies have been awarded, by a SRO, certified by FDA, a satisfactory listing under the NCIMS voluntary HACCP Program as specified in Appendix K. of this *Ordinance*.
9. The foreign supplies have been awarded a satisfactory listing, by ~~an NCIMS Certified Third Party~~ a TPC Rating Officer ~~standardized~~ certified by the FDA, under the ~~NCIMS International Certification Pilot Program~~ ICP. ~~This provision will expire December 31, 2013, unless extended by future conference action.~~

Page 122:

11. Aseptically processed and packaged milk and milk products in Definition Z of this *Ordinance* shall be considered to be Grade "A" milk or milk products. The sources(s) of the milk and milk products used to produce aseptically processed and packaged milk and milk products shall be IMS listed. Aseptically processed and packaged milk and milk products shall be labeled "Grade "A"" and meet Section 4 labeling requirements of the ~~PMO~~ *Grade "A" PMO*. The milk plant or portion of the milk plant that is producing aseptically processed and packaged milk and milk products shall be awarded a Milk Sanitation Compliance Rating of at least ninety percent (90%) and an Enforcement Rating equal to the local supply, or equal to ninety percent (90%) or higher, or if the Enforcement Rating is below ninety percent (90%) on a rating, a re-rating ~~must~~ shall occur within (6) months of this rating. Both the Milk Sanitation Compliance and Enforcement Ratings ~~must~~ shall be equal to ninety percent (90%) or higher on the re-rating or the supply is considered in violation of this Section. In the case of HACCP/Aseptic listings, an acceptable HACCP listing by a SRO is required. For milk plants that produce aseptically processed and packaged Grade "A" milk and/or milk products, prior to the milk plant participating in the NCIMS Aseptic Processing and Packaging Program, or the Aseptic Pilot Program, the ~~State's regulatory~~ Regulatory Agency's and ~~rating~~ Rating Agency's personnel shall have completed a training course that is acceptable to the NCIMS and FDA addressing the procedures for conducting regulatory inspections and ratings under the NCIMS Aseptic Processing and Packaging Program or Aseptic Pilot Program. The NCIMS Aseptic Pilot Program addressing aseptically processed and packaged acidified and fermented high acid milk and milk products regulated under 21 CFR Parts 108, 110, and/or 114 will expire on December 31, 2013, unless extended by future conference action.

12. Retort processed after packaging milk and milk products as addressed in Definition Z of this *Ordinance* shall be considered to be Grade "A" milk or milk products if they are used as an ingredient to produce any milk or milk product defined in Definition Z of this *Ordinance*; or if they are labeled as Grade "A" as described in Section 4 of this *Ordinance*. Retort processed after packaging milk and milk products shall be labeled "Grade "A"" and meet Section 4 labeling requirements of this *Ordinance* whenever they meet the provisions cited within Definition Z of this *Ordinance*. The source(s) of the milk and/or milk products used to produce retort processed after packaging Grade "A" milk and/or milk products shall be IMS listed. The milk plant or portion of the milk plant that is producing retort processed after packaging Grade "A" milk and/or milk products shall be awarded a Milk Sanitation Compliance Rating of at least ninety percent (90%) and an Enforcement Rating equal to the local supply, or equal to ninety percent (90%) or higher; or if the Enforcement Rating is below ninety percent (90%) on a rating, a re-rating ~~must~~ shall occur within (6) months of this rating. Both the Milk Sanitation Compliance and Enforcement Ratings ~~must~~ shall be equal to ninety percent (90%) or higher on the re-rating; or the supply is considered in violation of this Section. In the case of HACCP/Retort listings, an acceptable HACCP listing by a SRO is required. For milk plants that produce retort processed after packaging Grade "A" milk and/or milk products and prior to the milk plant participating in the NCIMS Retort Pilot Program, the ~~State's regulatory~~ Regulatory Agency's and ~~rating~~ Rating Agency's personnel shall have completed a training course that is acceptable to the NCIMS and FDA addressing the procedures for conducting regulatory inspections and ratings under the NCIMS Retort Pilot Program. The NCIMS Retort Pilot Program addressing retort processed after packaging

Grade "A" milk and milk products regulated under 21 CFR Parts 108, 110, and 113 will expire on December 31, 2013, unless extended by future conference action.

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SECTION 13. PERSONNEL HEALTH …

ADMINISTRATIVE PROCEDURES

Milk plant operators who have received reports, under this Section, from employees who have handled pasteurized milk or milk products or associated milk or milk product-contact surfaces shall immediately report these facts to the appropriate ~~Milk~~ Regulatory Agency. …

Page 124:

SECTION 14. PROCEDURE WHEN INFECTION OR HIGH RISK OF INFECTION IS DISCOVERED

When a person who may have handled pasteurized, ultra-pasteurized or aseptically processed and packaged milk or milk products or pasteurized, ultra-pasteurized or aseptically processed and packaged milk or milk product-contact surfaces meets one (1) or more of the conditions specified in the **ADMINISTRATIVE PROCEDURES** of Section 13, the ~~Milk~~ Regulatory Agency is authorized to require any or all of the following measures:

Page 127:

FOOTNOTES

4. Where State law does not permit the sale of reconstituted or recombined milk and/or milk products, Definition ~~KK~~QQ and other corresponding references ~~should~~ shall be omitted.

   NOTE: This option, as cited in 4. above, shall not be applicable to a TPC authorized under the ICP. …

Page 128:

16. A certified copy may be secured from the Food and Drug Administration, HFS-626, 5100 Paint Branch Parkway, College Park, MD 20740-3835.

NOTE: In reference to Footnotes 2, 7, 8, 9, 10, 11, 12, and 13, for the purposes of the ICP, cottage cheese, dry curd cottage cheese and reduced fat or low fat cottage cheese shall be Grade "A" and shall be regulated under the terms of this *Ordinance*. …

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APPENDIX B. MILK SAMPLING, HAULING AND TRANSPORTATION

I. MILK SAMPLING AND HAULING PROCEDURES …

The bulk milk hauler/sampler is any person who collects official samples and may transport raw milk from a farm and/or raw milk products to or from a milk plant, receiving station or transfer station and has in their possession a permit from any ~~State~~ Regulatory Agency to sample such products. The bulk milk hauler/sampler occupies a unique position making this individual a critical factor in the current structure of milk marketing. ….

Page 131:

EVALUATION OF BULK MILK HAULER/SAMPLER PROCEDURES: …

The bulk milk hauler/sampler's technique is best determined when the regulatory agent is able to observe the bulk milk hauler/sampler at one (1) or more farms. Each bulk milk hauler/sampler ~~must~~ shall be inspected by the Regulatory Agency prior to the issuance of a permit and at least once every twenty-four (24) months thereafter as referenced in Section 5 of this *Ordinance*. The bulk milk hauler/sampler ~~must~~ shall hold a valid permit prior to the collection of official samples. ~~States~~ Regulatory Agencies may use inspections from any Regulatory Agency as a means of maintaining record requirements and enforcement.

NOTE: The option to utilize inspections of bulk haulers/samplers conducted by other Regulatory Agencies, as cited above, shall not be applicable to a TPC authorized under the ICP. …

Page 132:

5. **Universal Sampling System:** …. The following are sampling procedures: …

   b. The milk ~~must~~ shall be agitated a sufficient time to obtain a homogeneous blend. Follow the ~~State~~ Regulatory Agency and/or manufacturer's guidelines or when using an approved aseptic sampling device, follow the ~~speicified~~ specified protocol and SOP for that device. …

Page 135:

V. MILK TANK TRUCK PERMITTING AND INSPECTION …

PERMITTING: Each milk tank truck shall bear a permit for the purpose of transporting milk and/or milk products. (Refer to Section 3 of this *Ordinance.*) The permit shall be issued to the owner of each milk tank truck by an authorized Regulatory Agency. The permit identification and ~~State~~ Regulatory Agency issuing the permit shall be displayed on the milk tank truck. It is recommended that this permit be renewed each year pending satisfactory completion of an inspection as outlined in the following **INSPECTION** Section. …

Page 136:

INSPECTION: …

When significant defects or violations are encountered by a Regulatory Agency, a copy of the report shall be forwarded to the permitting ~~agency~~ Regulatory Agency and also carried on the milk tank truck until the violations are corrected. …

Page 137:

5. **Wash and Sanitize Record:**
   a. The bulk milk hauler/sampler shall be responsible for assuring that the milk tank truck has been properly cleaned and sanitized at a permitted milk plant, receiving station, transfer station, or milk tank truck cleaning facility. A milk tank truck without proper cleaning and sanitizing documentation shall not be loaded or unloaded until the proper cleaning and sanitization can be verified.

   NOTE: The option to use non-IMS listed milk tank truck cleaning facilities, as cited in a. above, shall not be applicable to a TPC authorized under the ICP. …

Page 138:

   e. ~~State will~~ States shall submit to the NCIMS Executive Secretary an updated list of all currently permitted non-IMS listed milk tank truck cleaning facilities. The list is to be submitted for publication on the NCIMS ~~or other easily accessible~~ web site.

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APPENDIX C. DAIRY FARM CONSTRUCTION STANDARDS AND MILK PRODUCTION

I. TOILET AND SEWAGE DISPOSAL FACILITIES

FLUSH TOILETS

Flush toilets are preferable to pit privies, earth closets or chemical toilets at both dairy farms and milk plants. Their installation shall conform to the ~~Local or State~~ applicable Government plumbing regulations. Toilets shall be located in a well-lighted and well-ventilated room. Fixtures shall be protected against freezing. The following shall be considered defects in flush-toilet installations: …

SEPTIC TANKS

Disposal of the wastes from toilets should preferably be into a sanitary-sewer system. Where such systems are not available to a dairy farm or milk plant, the minimum satisfactory method should include treatment in a septic tank, with the effluent discharged into the soil. Where soil of satisfactory permeability is not available, the effluent shall be disposed of in accordance with the rules of the ~~Local or State Health~~ applicable Government Authority. It is preferable

to treat floor drainage, wastes from washing of utensils, etc., in separate systems. When such wastes are combined with toilet wastes in the septic tank system, careful consideration ~~must~~ shall be given to the expected flow in the design of both the septic tank and the leaching system. …

Page 141:

DISPOSAL FIELDS FOR SEPTIC TANKS …

Information as to methods of making percolation tests to determine absorptive quality of the soil may be obtained from ~~Local and/or State Health Departments~~ applicable Government Agencies. From the same sources, advice may be obtained as to trench areas needed for various numbers of users, in relation to observed percolation rates. In view of their close knowledge of local conditions, it is recommended that such assistance be requested before an absorption system is constructed. …

EARTH-PIT PRIVY …

Page 142:

4. **Floor and Riser:** Impervious materials, such as concrete, are believed to be most suitable for the floor and riser. Because privy units are commonly used as urinals, the use of impervious materials for risers is desirable in the interest of cleanliness. In cold climates, wood treated with a preservative, such as creosote, has been found to be durable and to reduce the problem of condensation. Therefore, in some sections of the country, wood may be used if approved by the ~~Local or State Health~~ applicable Government Authority. …

Page 145:

CONSTRUCTION PLANS

Detailed construction drawings for septic tanks, pit privies, masonry-vault privies and chemical toilets complying with ~~State~~ applicable Government regulations may be secured from the ~~Local and State Health~~ applicable Government Authority. …

Page 160:

APPENDIX D. STANDARDS FOR WATER SOURCES

The *Grade "A" PMO*, formal FDA interpretations of the *Grade "A" PMO* and other written USPHS/FDA opinions ~~will~~ shall be used in evaluating the acceptability of individual water supplies and water system construction requirements at dairy farms, milk plants, and single-service container manufacturing facilities.

~~State~~ The applicable Government Water Control Authority requirements, which are less stringent than the *Grade "A" PMO*, shall be superseded by the *Grade "A" PMO*. ~~State~~ The applicable Government Water Control Authority requirements, which are more strict than the *Grade "A" PMO*, shall not be considered in determining the acceptability of water supplies during ratings,

check ratings, single-service listing evaluations and audits. For example, the *Grade "A" PMO* requires a satisfactory farm water sample every three (3) years. If State law required such samples to be taken annually, a SRO conducting a sanitation rating, which includes that farm, ~~will~~ shall give that farm full credit for water sample frequency, if the *Grade "A" PMO* three (3) year requirement is met, even though, the State required annual frequency is not met.
Supplies other than individual water supplies, which have been approved as safe by the ~~State~~ applicable Government State Water Control Authority, shall be considered to be acceptable sources as provided in Section 7 of this *Ordinance* for Grade "A" inspections, as well as for all other IMS purposes without further inspection of the spring, well or reservoir treatment facility(ies), testing records, etc.

I. LOCATION OF WATER SOURCES

DISTANCE FROM SOURCES OF CONTAMINATION …

When a properly constructed well penetrates an unconsolidated formation, with good filtering properties, and when the aquifer itself is separated from sources of contamination by similar materials, research and experience have demonstrated that 15 meters (50 feet) is an adequate distance separating the two. Lesser distances should be accepted, only after a comprehensive sanitary survey, conducted by qualified ~~Local or State~~ ~~Agency~~ applicable Government Water Control Authority Officials, has determined such lesser distances are both necessary and safe.

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If it is proposed to install a properly constructed well in formations of unknown character, the ~~State or U.S. Geological Survey and the Local or State Health~~ applicable Government Agency should be consulted.
When wells must be constructed in consolidated formations, extra care should always be taken in the location of the well and in setting "safe" distances, since pollutants have been known to travel great distances in such formations. The owner should request assistance from the ~~Local or State Health~~ applicable Government Agency …

II. CONSTRUCTION

SANITARY CONSTRUCTION OF WELLS …

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Well Pits and Drainage: Because of the pollution hazards involved, the well head, well casing, pump, pumping machinery, valve connected with the suction pump or exposed suction pipe shall not be permitted in any pit, room or space extending below ground level, or in any room or space above the ground, which is walled-in or otherwise enclosed, so that it does not have free drainage by gravity to the surface of the ground. Provided, that a dug well properly constructed, lined and covered, as herein prescribed, shall not be construed to be a pit. Provided further, that pumping equipment and appurtenances may be located in a residential basement, which is not subject to flooding. And provided further, that in the case of existing water supplies which otherwise comply with the applicable requirements of this Appendix, pit

installations may be accepted, under the following conditions, when permitted by the ~~State~~ applicable Government Water Control Authority: …

Page 168:

SURFACE WATER …

The milk producer and/or milk plant operator, who is considering surface sources of water for milking, milkhouse and milk plant, receiving station and/or transfer station operations shall receive the advance approval of the Regulatory Agency and shall comply with all applicable requirements of the ~~State~~ applicable Government Water Control Authority on the construction, protection and treatment of the chosen supply. …

APPENDIX E. EXAMPLES OF 3-OUT-OF-5 COMPLIANCE ENFORCEMENT PROCEDURES …

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Table 12. Example of Enforcement Procedures for Raw Milk Laboratory Examinations

11/14/2011	1,200,000	Violative (3 of last 5 counts exceed the standard); Required Regulatory Actions: 3. Impose monetary penalty in lieu of permit suspension, provided … Samples shall then be taken at the rate of not more than two (2) per week on separate days within a three (3) week period in order to determine compliance with the appropriate standard as determined in accordance with Section 6 of this *Ordinance*. (Refer to Section 3.) **NOTE:** The option to issue a monetary penalty in lieu of a permit suspension, as cited in 3. above, shall not be applicable to a TPC authorized under the ICP.

…

VI. CRITERIA FOR THE EVALUATION OF COMPUTERIZED SYSTEMS FOR GRADE "A" PUBLIC HEALTH CONTROLS …

CRITERIA …

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9. The public health computer program access ~~must~~ shall be sealed. … Public health controls in pasteurizers that may be compromised by such a challenge, ~~must~~ shall be altered or re-programmed so this compromise is prevented and the access to this computer program ~~must~~

shall be sealed by the Regulatory A~~uthority~~ Agency. Similar challenges may be performed on other required public health functions that are computer controlled. …

14. When the public health computer prints the holding tube temperature trace at specific intervals, rather than a continuously changing line, temperature readings shall be printed not less than once every five (5) seconds. In addition, during the recorder/controller thermometric response test, the temperature shall be printed or indicated at a time rate sufficient to allow the Regulatory Agency ~~official~~ to measure the 7ºC (12ºF) rise in temperature as described in TEST 8. RECORDER/CONTROLLER-THERMOMETRIC RESPONSE. …

Page 276:

APPENDIX I. PASTEURIZATION EQUIPMENT AND CONTROLS - TESTS
I. TESTING APPARATUS SPECIFICATIONS
TEST THERMOMETER …

2. **Digital Test Thermometer:** Hand-held; high accuracy digital thermometer; and battery or AC line powered. Calibration is protected from unauthorized changes. …
Accuracy: System accuracy of: … This calibration shall be performed annually by a properly trained representative of an "Official Laboratory" or an "Officially Designated Laboratory"; or by a qualified representative of a thermometer manufacturer; or by a properly trained ~~State~~ Regulatory Agency representative. The calibration protocol/SOP shall be developed by the Regulatory Agency in cooperation with the thermometer manufacturer and FDA. Documentation of the identity of the properly trained ~~State~~ Regulatory Agency representative shall be maintained by the ~~State~~ Regulatory ~~Authority~~ Agency. A signed certificate of calibration for the digital thermometer shall be maintained with the unit. …

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C. BACTERIAL STANDARDS AND EXAMINATION OF SINGLE-SERVICE CONTAINERS AND CLOSURES …

3. During any consecutive six (6) months, at least four (4) sample sets shall be collected in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days, and analyzed at an Official, Commercial or Industry Laboratory approved by the ~~State~~ Milk Laboratory ~~Certifying~~ Control Agency specifically for the examinations required under these Standards. (Refer to Item 12p of this *Ordinance* for sampling of containers and closures in milk plants.) …

D. FABRICATION PLANT STANDARDS …

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6. TOILET FACILITIES - SEWAGE DISPOSAL

a. Disposal of sewage and other wastes shall be in a public sewage system or in a manner in compliance with ~~Local and State~~ applicable Government regulations.

b. All plumbing shall comply with the ~~Local and State~~ applicable Government plumbing regulations. …

7. WATER SUPPLY

a. The water supply, if from a public system, shall be approved as safe by the ~~State~~ applicable Government Water Control Authority responsible for water quality, and in the case of individual water systems, comply with at least the specifications outlined in Appendix D. and the bacteriological standards outlined in Appendix G. of this *Ordinance*. …

Page 320:

E. CRITERIA FOR LISTING CERTIFIED SINGLE-SERVICE MANUFACTURERS IN THE IMS LIST …

Page 326:

The following procedures shall be followed for listing certified single-service manufacturers in the *IMS List*:

1. For domestic firms, ~~Triplicate~~ triplicate copies or PHS/FDA's electronic version (transmitted via computer) of FORM FDA 2359d-REPORT OF CERTIFICATION (*Fabrication of Single-Service Containers and Closures for Milk and Milk Products)* shall be submitted by the ~~State Rating Officer~~ SRO to the appropriate Regional Office of the PHS/FDA for single-service manufacturers who desire to be listed ~~in~~ on the *IMS List*.

2. For foreign firms, duplicate copies or PHS/FDA's electronic version (transmitted via computer) of FORM FDA 2359d-REPORT OF CERTIFICATION (*Fabrication of Single-Service Containers and Closures for Milk and Milk Products)* shall be submitted by the TPC or private consultant conducting the certification to CFSAN's Milk Safety Team (HFS-316), Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740-3835 for single-service manufacturers who desire to be listed ~~in~~ on the *IMS List*.

3. The Certified Single-Service Manufacturer is not listed ~~in~~ on the *IMS List* unless the "PERMISSION TO PUBLISH" SECTION of FORM FDA 2359d is signed by an officer of the firm authorizing the release.

a. For the submission of PHS/FDA's electronic version, a signed copy of FORM FDA 2359d, including Section 12, shall be maintained on file by the Rating Agency and ~~will~~ shall be reviewed as part of the Single-Service Listing Audit and/or the ~~State~~ Regulatory/Rating Agency Program Evaluation. …

4. The Certified Single-Service Manufacturer may be listed ~~in~~ on the *IMS List* as a "PARTIAL" listing. A "PARTIAL" listing shall mean that only specific production rooms, or fabrication lines or machines have been evaluated in regard to specific containers or closures or specific size of containers or closures and conform to the specifications contained within Appendix J.

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APPENDIX K. HACCP PROGRAM

I. THE HACCP SYSTEM INTRODUCTION …

VOLUNTARY PARTICIPATION: This Appendix describes a ~~voluntary,~~ NCIMS voluntary HACCP Program alternative to the traditional inspection system. ~~No~~ A milk plant, receiving station or transfer station may not participate in the ~~voluntary~~ NCIMS voluntary HACCP Program unless the Regulatory Agency responsible for the oversight of the facility agrees to participate with the ~~dairy~~ milk plant(s), receiving station(s) and transfer station(s) in the NCIMS voluntary HACCP Program. Both parties ~~must~~ shall provide written commitment to each other that the necessary resources to support participation in the NCIMS voluntary HACCP Program ~~will~~ shall be made available. Management responsible for both the ~~State~~ Regulatory Agency and milk plant, receiving station and/or transfer station ~~must~~ shall be willing to provide the resources ~~needed~~ required to develop and implement a successful HACCP System. …

Page 335:

IV. TRAINING AND STANDARDIZATION …

Industry, ~~State~~ Regulatory Agency, Rating Agency and ~~Federal regulatory and listing~~ FDA personnel should be trained together. …

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V. HACCP AUDITS AND FOLLOW-UP ACTIONS

~~STATE~~ REGULATORY AGENCY AUDITS, ENFORCEMENT AUDITS, ACTIONS AND FOLLOW-UP: Audits shall be conducted of the milk plant, receiving station, or transfer station facility, and the NCIMS voluntary HACCP Program to ensure compliance with the HACCP System and other associated NCIMS regulatory requirements. …

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~~STATE~~ REGULATORY AGENCY ENFORCEMENT ACTION/FOLLOW-UP: The ~~State~~ Regulatory Agency shall: …

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APPENDIX N. DRUG RESIDUE TESTING AND FARM SURVEILLANCE

I. INDUSTRY RESPONSIBILITIES

MONITORING AND SURVEILLANCE: …

The bulk milk pickup tanker shall be sampled after the last producer has been picked up and before any additional commingling. … All presumptive positive test results for drug residues from analysis done on commingled raw milk tanks, bulk milk pickup tankers, farm raw milk

tanks (only milk offered for sale) or finished milk or milk product samples ~~must~~ shall be reported to the Regulatory Agency ~~of the State~~ in which the testing was conducted.

REPORTING AND FARM TRACE BACK:

When a bulk milk pickup tanker is found to be positive for drug residues, the Regulatory Agency ~~of the~~ ~~State~~ in which the testing was conducted, shall be immediately notified of the results and the ultimate disposition of the raw milk. …

Page 343:

II. REGULATORY AGENCY RESPONSIBILITIES

Upon receipt of notification from industry of a bulk milk pickup tanker, which contains milk from another ~~State(s)~~ Regulatory Agency's jurisdiction, is found to be presumptive positive for drug residues it is the responsibility of the receiving Regulatory Agency ~~of the receiving State~~ to notify the Regulatory Agency(ies) ~~of all States of origin~~ from which the milk originated. …

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2. **Screening Test Positive (Load Confirmation):** A screening test positive result is obtained when the presumptive positive sample is tested in duplicate, using the same or equivalent (M-I-96-10, latest revision) test as that used for the presumptive positive, with a positive and negative control, and either or both of the duplicates are positive and the controls give the proper results. A screening test positive (load confirmation) is to be preformed by an Official ~~State~~ Laboratory, Officially Designated Laboratory or Certified Industry Supervisor using the same or an equivalent test (M-I-96-10, latest revision).

3. **Producer Trace Back/Permit Action:** A producer trace back/permit action test is performed after a screening test positive load is identified by an Official ~~State~~ Laboratory, Officially Designated Laboratory or Certified Industry Supervisor using the same or an equivalent (M-I-96-10, latest revision) test as was used to obtain the screening test positive (load confirmation). …

7. **Certified Industry Supervisor:** An Industry Supervisor who is evaluated and listed by a ~~State~~ LEO as certified to conduct drug residue screening tests at industry drug residue screening sites for *Grade "A" PMO*, Appendix N. regulatory actions (confirmation of tankers, producer trace back and/or permit actions).

CERTIFIED INDUSTRY SUPERVISORS; EVALUATION AND RECORDS:
Reference: *EML*

1. **Certified Industry Supervisors/Industry Supervisors/Industry Analysts:** Regulatory Agencies may choose to allow Industry Supervisors to be certified. Under this program, these Certified Industry Supervisors may officially confirm presumptive positive tanker loads and confirm producer milk for regulatory purposes (producer trace back/permit action). In the implementation of Appendix N. of this *Ordinance,* the LEO ~~will~~ shall use the appropriate Appendix N. FDA 2400 Series Form when evaluating Official ~~State~~ Laboratories, Officially

Designated Laboratories or Certified Industry Supervisors, Industry Supervisors and Industry Analysts.
The Certified Industry Supervisor/Industry Supervisor shall report to the LEO the result of all competency evaluations performed on Industry Analysts. The names of all Certified Industry Supervisors, Industry Supervisors and Industry Analysts, as well as their training and evaluation status, shall be maintained by the ~~State~~ LEO and updated as replacement, additions and/or removals occur. The ~~State~~ LEO shall verify (document) that each Certified Industry Supervisor and/or Industry Supervisor has established a program that ensures the proficiency of the Industry Analysts they supervise. The ~~State~~ LEO shall also verify that each Industry Supervisor and Industry Analyst has demonstrated proficiency in performing drug residue analysis at least biennially. Verification may include an analysis of split samples and/or an on-site performance evaluation or another proficiency determination that the ~~State~~ LEO and the Laboratory Proficiency Evaluation Team (LPET) agree is appropriate. …

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BULK MILK PICKUP TANKER SCREENING TEST: …

2. **Initial Drug Testing Procedures:** …

a. Industry Presumptive Positive Options: There are two (2) industry options for the milk represented by a presumptive positive sample:

(1) The Regulatory Agency involved (origin and receipt) shall be notified. … Testing for confirmation of that presumptive positive load shall be in an Official ~~State~~ Laboratory, Officially Designated Laboratory or by a Certified Industry Supervisor at a location acceptable to the Regulatory Agency. Documentation of prior testing shall be provided to the analyst performing the load confirmation. …

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4. **Producer Trace Back:** All screening test positive (confirmed) loads ~~must~~ shall be broken down (producer trace back) using the same or an equivalent test method (M-I-96-10, latest revision). Confirmation tests (load and producer trace back/permit action) shall be performed in an Official ~~State~~ Laboratory, or Officially Designated Laboratory or by a Certified Industry Supervisor. Positive producers shall be handled in accordance with this Appendix. …

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SCREENING TESTS NECESSARY TO IMPLEMENT THE PROVISIONS OF APPENDIX N. FOR BULK MILK PICKUP TANKERS:

1. **Performance Tests/Controls (+/-):** …

c. All NCIMS Approved Bulk Milk Pickup Tanker Screening Tests Include The Following Format: All presumptive positive test results ~~are to~~ shall be repeated in duplicate as soon as possible at the direction of the Regulatory Agency on the same sample with

single positive (+) and negative (-) controls by a certified analyst (Official ~~State~~ Laboratory, Officially Designated Laboratory or Certified Industry Supervisor) using the same or equivalent test (M-I-96-10, latest revision). If the duplicate tests, with appropriate control (+/-) results are negative (-), the tanker is reported as negative. If one or both duplicate test(s) is positive (+), the test result is reported to the Regulatory Agency ~~of the State~~ in which the testing was conducted, as a screening positive. …

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7. **Screening Test Volumetric Measuring Devices:** …

b. NCIMS Certified Laboratories require calibrated pipetting/dispensing devices. These devices may be calibrated at another location acceptable to the ~~State~~ LEO. …

IV. ESTABLISHED TOLERANCES AND/OR SAFE LEVELS OF DRUG RESIDUES

"Safe levels" are used by FDA as guides for prosecutorial discretion. They do not legalize residues found in milk that are below the safe level. In short, FDA uses the "safe levels" as ~~prosecutional~~ prosecutorial guidelines and in full consistency with CNI v. Young stating, in direct and unequivocal language, that the "safe levels" are not binding. They do not dictate any result; they do not limit ~~the Agency's~~ FDA's discretion in any way; and they do not protect milk producers, or milk from court enforcement action.
"Safe levels" are not and cannot be transformed into tolerances that are established for animal drugs under Section 512 (b) of the *FFD&CA* as amended. "Safe levels" do not:

1. Bind the courts, the public, including milk producers, or ~~the Agency~~ FDA, including individual FDA employees; and …

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APPENDIX P. PERFORMANCE-BASED DAIRY FARM INSPECTION SYSTEM

PREFACE

A performance-based inspection system is an option to the traditional routine inspection frequency of at least once every six (6) months on Grade "A" dairy farms. This option provides ~~States~~ Regulatory Agencies with a choice. For some ~~States~~ Regulatory Agencies, inspecting every farm routinely twice a year may provide effective regulatory oversight and make efficient use of inspection resources. ~~In other States, however~~ For other Regulatory Agencies, an optional system, which determines routine farm inspection frequency based on producer milk quality and inspection performance may be more desirable, equally effective, and make the most efficient use of limited inspection resources. The overall inspection effort devoted to a performance-based farm inspection system may be more or less than the traditional inspection system, which requires a routine inspection at least once every six (6) months per farm. …

APPENDIX R. DETERMINATION OF TIME/TEMPERATURE CONTROL FOR SAFETY MILK AND MILK PRODUCTS

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A milk or milk product designated PA (further product assessment required) in either Table A or B should be considered TCS until sufficient information is provided to demonstrate the safety of the product. The PA ~~will~~ shall be an evaluation of the ~~product~~ milk or milk product group's ability to not support pathogenic growth. Means to evaluate this assessment include (but are not limited to): literature review of similar milk products, inoculation studies, expert risk assessment, and/or ~~state regulatory~~ Regulatory Agency assessment.

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APPENDIX S. ASEPTIC PROCESSING AND PACKAGING PROGRAM …
ASEPTIC PROCESSING AND PACKAGING PROGRAM CFR/*GRADE "A" PMO* COMPARISON SUMMARY REFERENCE …

16p. Pasteurization and Aseptic Processing and Packaging (A) through (D)*	The APPS is exempt, but shall comply with the CFR. The ~~State~~ Regulatory Agency is not required to conduct the quarterly equipment testing and sealing of aseptic processing equipment. Records and recording charts are not required to be reviewed during routine inspections, ~~State~~ ratings or check ratings.	CFR

…

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LETTER OF INTENT ……..
MEMORANDUM OF AGREEMENT …….

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SECTION III. DEFINITIONS …

E. **CERTIFIED MILK LABORATORY EVALUATION OFFICER (LEO):** A Regulatory Agency or Milk Laboratory Control Agency employee who has been certified by the Public Health Service/Food and Drug Administration (PHS/FDA) Laboratory Proficiency Evaluation Team (LPET) using the Evaluation of Milk Laboratories (EML) to evaluate milk laboratories for the purpose of accrediting or approving laboratories that conduct official NCIMS milk testing and has a valid certificate of qualification.

~~E~~F. **CERTIFIED MILK SANITATION RATING OFFICER (SRO):** A ~~State~~ Regulatory Agency employee who has been ~~standardized~~ certified by the Public Health Service/Food and Drug Administration (PHS/FDA), has a valid certificate of qualification~~,~~ and does not have direct responsibility for the routine regulatory inspection and enforcement or regulatory auditing of the shipper to be rated or listed. Directors, administrators, supervisors, etc. may be certified as Milk Sanitation Rating Officers (SROs). A Milk Sanitation Rating Officer (SRO) may be certified to make HACCP milk plant, receiving station or transfer station listings.

~~F~~G. **CERTIFIED SAMPLING SURVEILLANCE OFFICER (SSO):** A ~~State~~ Regulatory Agency employee who has been ~~standardized~~ certified by the Public Health Service/Food and Drug Administration (PHS/FDA) and has a valid certificate of qualification. Directors, administrators, supervisors, etc., Milk Sanitation Rating Officers (SROs), Laboratory Evaluation Officers (LEOs), etc. may be certified as Sampling Surveillance Officers (SSOs).

Page 3:

~~G~~H. **CHECK RATING:** The designated PHS/FDA and NCIMS *Procedures* method to ensure that the published ~~State~~ rating of a milk shipper on the *IMS LIST-Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers* (*IMS List*) is valid and maintained during the interval between ~~State~~ ratings. …

Re-Letter remaining DEFINTIONS accordingly.

~~J~~K. **IMS LISTED SHIPPER:** An interstate milk shipper (BTU, receiving station, transfer station, or milk plant), which has been certified by ~~the State~~ a Rating Agency as having attained the Sanitation Compliance and Enforcement Ratings necessary for inclusion ~~in~~ on the *IMS List*. The ratings are based on compliance with the requirements of the *Grade "A" PMO* and were made in accordance with the procedures set forth in the *Methods of Making Sanitation Ratings of Milk Shippers (MMSR)*. For milk plants that produce aseptically processed and packaged Grade "A" milk and/or milk products, prior to the milk plant participating in the NCIMS Aseptic Processing and Packaging Program, the ~~State's~~ Regulatory Agency's regulatory and Rating Agency's rating personnel shall have completed a training course that is acceptable to the NCIMS and PHS/FDA addressing the procedures for conducting regulatory inspections and ratings under the NCIMS Aseptic Processing and Packaging Program**.**

L. **INTERNATIONAL CERTIFICATION PROGRAM (ICP):** The International Certification Program (ICP) means the NCIMS voluntary program designed to utilize Third Party Certifiers (TPCs) authorized by the NCIMS Executive Board in applying the requirements of the NCIMS Grade "A" Milk Safety Program for Milk Companies (MCs) located outside the geographic boundaries of NCIMS Member States that desire to produce and process Grade "A" milk and/or milk products for importation into the United States.

M. **LETTER OF INTENT (LOI):** A formal written signed agreement between a Third Party Certifier (TPC), authorized under the NCIMS voluntary International Certification Program (ICP), and a Milk Company (MC) that intends to be certified and IMS Listed under the NCIMS voluntary International Certification Program (ICP). A copy of each written signed agreement shall be immediately submitted to the International Certification Program (ICP) Committee following the signing by the Third Party Certifier (TPC) and Milk Company (MC).

N. **LETTER OF UNDERSTANDING (LOU):** A formal written signed agreement between a Third Party Certifier (TPC) and the NCIMS Executive Board that acknowledges the NCIMS' authorization of the Third Party Certifier (TPC) to operate under the NCIMS voluntary International Certification Program (ICP). It also states the Third Party Certifier's (TPC's) responsibilities under the NCIMS voluntary International Certification Program (ICP); their agreement to execute them accordingly; and their understanding of the consequences for failing to do so. The Letter of Understanding (LOU) shall include, but is not limited to, the issues and concerns addressed in all documents involved in the NCIMS voluntary International Certification Program (ICP).

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O. **MEMORANDUM OF AGREEMENT (MOA):** A formal written signed memorandum that states the requirements and responsibilities of each party (Third Party Certifier (TPC) and Milk Company (MC)) to participate and execute the NCIMS voluntary International Certification Program (ICP). The Memorandum of Agreement (MOA) shall include, but is not limited to, the issues and concerns addressed in all documents involved in the NCIMS voluntary International Certification Program (ICP). This agreement shall be considered the Milk Company's (MC's) permit to operate in the context of the NCIMS Grade "A" Milk Safety Program and shall be renewed (signed and dated) on an annual basis.

~~L~~P. **MEMORANDUM OF CONFERENCE ACTIONS (IMS-a):** A memorandum issued by PHS/FDA providing the transmittal of information related to the actions taken at NCIMS Conferences and between PHS/FDA and the NCIMS Executive Board to PHS/FDA Regional staff and Regulatory/Rating Agencies.

~~M~~Q. **MEMORANDUM OF INFORMATION (M-I):** A memorandum issued by PHS/FDA providing the transmittal of administrative and miscellaneous information by PHS/FDA to PHS/FDA Regional staff and ~~State~~ Regulatory/Rating Agencies.

~~N~~R. **MEMORANDUM OF INTERPRETATION (M-a):** A memorandum issued by PHS/FDA, following the *Procedures* document, providing clarification of the intent or meaning of wording related to the *Grade "A" PMO* and the *Evaluation of Milk Laboratories (EML)* to PHS/FDA Regional staff and Regulatory/Rating Agencies.

~~O~~S. **MEMORANDUM OF MILK ORDINANCE EQUIPMENT COMPLIANCE (M-b):** A memorandum issued by PHS/FDA that provides a notice of PHS/FDA's review of equipment related to compliance with the *Grade "A" PMO* to PHS/FDA Regional staff and Regulatory/Rating Agencies.

T. **MILK COMPANY (MC):** A Milk Company (MC) is a private entity that is listed on the *IMS List* by a Third Party Certifier (TPC) including all associated dairy farms, bulk milk haulers/samplers, milk tank trucks, milk transportation companies, milk plants, receiving stations, transfer stations, dairy plant samplers, industry plant samplers, milk distributor, etc., and their servicing milk and/or water laboratories, as defined in the *Grade "A" PMO*, located outside the geographic boundaries of NCIMS Member States.

U. **RATING AGENCY:** A Rating Agency shall mean a State Agency, which certifies interstate milk shippers (BTUs, receiving stations, transfer stations, and milk plants) as having attained the Sanitation Compliance and Enforcement Ratings necessary for inclusion on the *IMS List*. The ratings are based on compliance with the requirements of the *Grade "A" PMO* and were conducted in accordance with the procedures set forth in the *Methods of Making Sanitation Ratings of Milk Shippers (MMSR)*. Ratings are conducted by FDA certified Milk Sanitation Rating Officers (SROs). They also certify single-service containers and closures for milk and/or milk products manufacturers for inclusion on the *IMS List*. The certifications are based on compliance with the requirements of the *Grade "A" PMO* and were conducted in accordance with the procedures set forth in the *Methods of Making Sanitation Ratings of Milk Shippers (MMSR)*. The definition of a Rating Agency also includes a Third Party Certifier (TPC) that conducts ratings and certifications of Milk Companies (MCs) located outside the geographic boundaries of NCIMS Member States that desire to produce and process Grade "A" milk and/or milk products for importation into the United States.

Re-letter remaining DEFINITIONS accordingly.

~~S~~X. **REGULATORY AGENCY:** A Regulatory Agency shall mean an agency which has adopted an ordinance, rule or regulation in substantial compliance with the current edition of the *Grade "A" PMO* ~~or two (2) agencies which have mutually agreed to share the~~ and is ~~responsibilities~~ responsible for the enforcement of ~~an~~ such ordinance, rule or regulation, which is in substantial compliance with the *Grade "A" PMO* for a listed interstate milk shipper. ~~The mutual agreement shall specify the details of how the rating will be made so long as the details do not conflict with the basic intent of this document.~~ The term, "Regulatory Agency", whenever it appears in the *Procedures* shall also mean the appropriate Third Party Certifier (TPC) having jurisdiction and control over the matters cited within these *Procedures*.

~~T~~Y. ~~**STATE**~~ **REGULATORY/RATING AGENCY PROGRAM EVALUATION:** An evaluation of a ~~State~~ Regulatory/Rating Agency's program by PHS/FDA. This shall include check ratings of IMS Listed Shippers, an assessment of a ~~State~~ Regulatory/Rating Agency's administrative procedures and records, adoption of the *Grade "A" PMO* (or equivalent laws and regulations), and compliance with NCIMS *Procedures*.

Z. **THIRD PARTY CERTIFIER (TPC):** A Third Party Certifier (TPC) is a non-governmental individual(s) or organization authorized under the NCIMS voluntary International Certification Program (ICP) that is qualified to conduct the routine regulatory functions and enforcement requirements of the *Grade "A" PMO* in relationship to milk plants, receiving stations, transfer stations, associated dairy farms, bulk milk hauler/samplers, milk tank trucks, milk transportation companies, dairy plant samplers, industry plant samplers, milk distributors, etc. participating in the NCIMS voluntary International Certification Program (ICP). The Third Party Certifier (TPC) provides the means for the rating and listing of milk plants, receiving stations, transfer stations and their related raw milk sources. They also conduct the certification and IMS listing of related milk and/or water laboratories and related single-service container and closure manufacturers on the *Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers (IMS) List*. To be authorized under the NCIMS voluntary International Certification Program (ICP), a valid Letter of Understanding (LOU) shall be signed between the NCIMS Executive Board and the Third Party Certifier (TPC).

Re-letter remaining DEFINITIONS accordingly.

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SECTION IV. OVERSIGHT AND RESPONSIBILITIES

A. PHS/FDA RESPONSIBILITIES

1. Standardization of Personnel …

   a. PHS/FDA Regional personnel who: …

      2.) Comply with the directives of the PHS/FDA Milk Safety Program as administered by the PHS/FDA Milk Safety Team (MST); and …

   c. PHS/FDA shall standardize, in accordance with Section V., F. and G., the evaluation procedures of ~~State Milk~~ LEOs and SSOs.

2. Training

   a. PHS/FDA shall extend to ~~State~~ Regulatory and Rating Agencies and educational institutions assistance in the training of ~~representatives of State, Regional and Local Governmental Units~~ personnel, including ~~Milk~~ SROs, ~~Milk~~ LEOs, SSOs and dairy industry personnel.

b. In order to coordinate ratings and evaluation procedures and interpretations, PHS/FDA shall sponsor seminars annually or biennially for the ~~state~~ milk rating and milk laboratory personnel in each of its regions. The content and agenda of the seminar shall be mutually concurred with by PHS/FDA MST and appropriate PHS/FDA Regional Milk Specialist. Each seminar shall be open to representatives of ~~State, Regional and Local Government Units~~ Regulatory/Rating Agencies, including SROs, LEOs and SSOs. Dairy industry personnel ~~should~~ shall be permitted to attend appropriate sessions of such seminars.

c. PHS/FDA ~~should~~ shall provide consultation and training in order to correct any deficiency in ~~State~~ Regulatory/Rating Agency's programs. Reasonable action shall be taken to resolve any dispute between PHS/FDA and the ~~State~~ Regulatory/Rating Agency over interpretations and implementation of any program components.

3. ~~State~~ Regulatory/Rating Agency Program Evaluations

a. A PHS/FDA Regional Milk Specialist or PHS/FDA MST personnel shall conduct a triennial written program evaluation of the IMS program administered by each Member State and TPC, respectively. This triennial written program evaluation ~~will~~ shall be submitted to the ~~State Milk~~ Regulatory Agency, the ~~State Milk~~ Rating Agency, if applicable, and PHS/FDA MST. The evaluation shall concentrate on the following areas: …

Page 6:

3.) ~~State laws~~ Laws and regulations to include a review of ~~State~~ laws and regulations with an explanation of any areas not compatible with the *Grade "A" PMO*. …

5.) Regulatory compliance with Appendix N. of the *Grade "A" PMO* ~~will~~ shall be determined by the PHS/FDA Regional Milk Specialist and/or PHS/FDA MST personnel for TPCs through check ratings or the triennial evaluation and will be reported as part of the written triennial evaluation. The review shall include: …

Page 7:

6.) Regulatory compliance with Appendix B. and other *Grade "A" PMO* milk sampling, hauling, and transportation requirements ~~will~~ shall be determined by the PHS/FDA Regional Milk Specialist and/or PHS/FDA MST personnel for TPCs and ~~will~~ shall be reported as part of the written triennial evaluation. This portion of the evaluation shall include a review of: …

b. Any State or TPC in substantial non-compliance as determined by PHS/FDA ~~will~~ shall be referred to the NCIMS Executive Board for determination of listing on a separate page ~~in~~ on the *IMS List*. The State or TPC, upon notification of PHS/FDA and the Executive Board ~~will~~ shall have an opportunity to address the Executive Board to explain why they believe they should not be so listed. If such listing is required, annual

evaluations shall be conducted until substantial compliance, as determined by PHS/FDA, is achieved. Any State or TPC not in substantial compliance a second consecutive year ~~will~~ shall be notified by PHS/FDA and provided an opportunity for a hearing by the NCIMS Executive Board. The NCIMS Executive Board, as a result of the hearing, may determine that the State or TPC ~~should~~ shall not be an active participant in future NCIMS Conferences until substantial compliance is achieved.

Page 8:

4. Laboratory Evaluations

a. PHS/FDA shall evaluate and approve the laboratory facilities and procedures of ~~State~~ Milk Laboratory ~~Approval~~ Control Agencies and TPCs to assure compliance with FDA 2400 Series Evaluation Forms and, where appropriate, the current edition of *Official Methods of Analysis of AOAC INTERNATIONAL (OMA)*.

b. PHS/FDA shall periodically evaluate milk laboratories of participating States and TPCs to assure compliance with FDA 2400 Series Evaluation Forms, and where appropriate, the current edition of *OMA*. Evaluations conducted during the recertification of LEOs shall be submitted, but it shall be the option of the LEO as to whether or not the evaluation is submitted for official action regarding laboratory status, except when the LEO is conditionally approved. All laboratory evaluations conducted by conditionally approved LEOs are official.

5. Electronic Publication of Sanitation Compliance and Enforcement Ratings

a. PHS/FDA shall provide an electronic publication of the *IMS List* on their web site. The electronic *IMS List* is available at http://www.fda.gov/Food/Food Safety/Product-SpecificInformation/MilkSafety/FederalStatePrograms/InterstateMilkShippersList/default.htm. The Sanitation Compliance Ratings of IMS listed milk shippers, ~~and~~ the Enforcement Ratings of Regulatory Agencies and the IMS Listed shippers' expiration rating dates contained in the electronic publication are certified by the ~~State~~ Rating Agency to be those established by ratings conducted in accordance with the *MMSR* by certified SROs when FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT is signed and submitted to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs for publication.

b. PHS/FDA shall list ratings only from ~~States~~ Rating Agencies, and/or shippers, which are in substantial compliance with the *Procedures*. …

d. PHS/FDA shall identify ~~in~~ on the *IMS List* milk laboratories approved by PHS/FDA Laboratory Proficiency Evaluation Team (LPET), ~~or State~~ Milk Laboratory Control Agencies or TPCs to perform official examinations of Grade "A" raw milk and milk products, pasteurized milk and milk products, condensed and dry milk products, and whey and whey products; as well as milk containers and closures.

Page 9:

6. Electronic Publication of Qualified PHS/FDA Regional Milk Specialists, ~~and~~ State and TPC Personnel …

7. Interpretations and Editorial Updates

a. Interpretations of the PHS/FDA recommended *Grade "A" PMO* and related documents as referenced in Section VI. of these *Procedures* shall be issued to the ~~State Milk~~ Regulatory and Rating Agencies in accordance with the following procedure:

Procedure for Issuing Interpretations of the *Grade "A" PMO* and Related Documents

3. PHS/FDA disseminates the draft M-a to all ~~State Milk~~ Regulatory and Rating Agencies and the Executive Board with provisions for a thirty (30) day written comment period from the date of dissemination. The date the draft M-a was actually distributed by PHS/FDA to all ~~State Milk~~ Regulatory and Rating Agencies and the Executive Board shall be the date of dissemination from which all timelines are calculated. When calculating the timelines, the date of dissemination is not counted as one (1) of the days. …

5. The Executive Secretary shall forward comments to PHS/FDA~~,~~ MST~~,~~ and the Executive Board within fifteen (15) days of the end of the comment period. …

Page 10:

9. ~~No~~ An M-a shall not become effective unless it receives the approval from a simple majority of the returned ballots of the NCIMS voting delegates. …

8. PHS/FDA Check Ratings of the Sanitation Compliance Status of Listed Interstate Shippers

a. PHS/FDA shall conduct, each year, check ratings of the Sanitation Compliance status of listed interstate milk shippers. To conduct check ratings of aseptic milk plants, the PHS/FDA Regional Milk Specialist and/or PHS/FDA MST personnel for TPCs shall have completed a training course that is acceptable to the NCIMS and PHS/FDA addressing the procedures for conducting check ratings under the NCIMS Aseptic Processing and Packaging Program. Within a State or a TPC's jurisdiction, check ratings ~~will~~ shall be ~~made~~ conducted of a representative number of IMS Listed shippers. The selection of shippers ~~for~~ to be check ~~rating~~ rated in a given State or a TPC's jurisdiction ~~will~~ shall be made randomly.

b. In order to make effective use of PHS/FDA Regional Office personnel, the random selection of shippers to be check rated ~~will~~ shall be selected in advance and assignments scheduled in each State and/or TPC's jurisdiction. Selection of dairy

farms ~~will~~ shall be made from records provided at the time of the check rating.

c. The number of shippers selected ~~for~~ to be check ~~rating~~ rated ~~will~~ shall be based on consideration of the number of shippers in the State or TPC's jurisdiction as well as the demonstrated validity of the State or TPC program. Validity ~~will~~ shall be measured by estimating the number of adverse actions (re-inspections, re-ratings, or withdrawals of certification) in the ~~States~~ State or a TPC's jurisdiction based on the results of previous check ratings. This approach ~~will~~ shall shift attention from States or TPCs with demonstrated validity to problem States or TPCs while still preserving an adequate level of monitoring.

Page 11:

d. In ~~no~~ any case ~~can~~ a check rating cannot be ~~made~~ conducted with a greater frequency than the official rating or listing.

e. For action to be taken if the PHS/FDA check rating indicates the listed rating is not justified, refer to Section IV., B., 7.c. For the purpose of these *Procedures* and all related forms, the terms "listed rating", "official rating" and "published rating" shall mean the most recent rating, which is accompanied by written permission ~~by~~ from the shipper to publish, and submitted to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs by the ~~State~~ Rating Agency.

f. Except as provided in Section IV., B., 7.c., PHS/FDA shall release the detailed results of its check ratings of listed individual interstate shippers only to the Rating Agency, which originally certified the shipper for listing, and the shipper's ~~State~~ Regulatory Agency. …

B. **STATE AND TPC RESPONSIBILITIES**

1. ~~State~~ Ratings

a. The ~~State~~ Rating Agency of the shipping State or TPC shall certify the results of ratings of each interstate milk shipper to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs, which~~,~~ in turn~~,~~ ~~will~~ shall transmit the ratings to the PHS/FDA Headquarters Office for inclusion ~~in~~ on the *IMS List*. (Refer to Section IV., A., 5) The rating results, together with other pertinent information, shall be forwarded on an appropriate form (FORM FDA 2359i).

b. If both an area and individual rating are available on an individual supply of milk, the most recent rating of the two (2) shall be reported. The Rating Agency shall immediately send a completed copy of FORM FDA 2359i and all applicable rating/listing Forms used to complete the rating/listing to the ~~State~~ Regulatory Agency upon completion of any ~~Milk Sanitation Rating~~ rating. …

d. When a certified interstate milk shipper's supply, raw or pasteurized, changes status because of degrading, permit revocation, significant change in the number of ~~producers~~ dairy farms, or change in the Sanitation Compliance or Enforcement Rating to less than ninety percent (90%), the shipping State or TPC shall immediately notify all known receiving States and/or TPCs and the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs.

Page 12:

e. When a certified interstate milk shipper's supply, raw or pasteurized, receives an Enforcement Rating of less than ninety percent (90%), the State or TPC shall re-rate the supply within six (6) months of that rating. Should this re-rating result in either a Sanitation Compliance and/or Enforcement Rating of less than ninety percent (90%), the shipping State or TPC shall immediately withdraw the shipper from the IMS List and notify all known receiving States and/or TPCs and the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs. If a re-rating of the original rating is not requested and conducted within six (6) months of the earliest rating date of the rating with the Enforcement Rating not equal to ninety percent (90%) or greater, the shipper shall be immediately withdrawn from the IMS List and the shipping State or TPC shall immediately notify all receiving States and/or TPCs and the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs.

f. When an existing rating is no longer valid because a listed milk plant, receiving station and/or transfer station's permit is revoked, the State or TPC shall within five (5) days request PHS/FDA to withdraw the shipper from the IMS List.

g. Receiving States or TPCs shall notify shipping States and/or TPCs of any irregularities in the supply received. (Refer to Section IV., B., 7.)

h. The Rating Agency shall furnish their Regulatory ~~Agencies~~ Agency with copies of coded memoranda, including interpretations of the PHS/FDA recommended *Grade "A" PMO* and HACCP listing procedures received from PHS/FDA.

i. The Rating Agency shall keep current the ratings of all certified shippers within its State or a TPC's jurisdiction.

j. The State Rating Agency shall certify U.S. manufacturers of containers and closures in accordance with Appendix J. STANDARDS FOR THE FABRICATION OF SINGLE-SERVICE CONTAINERS AND CLOSURES FOR MILK AND MILK PRODUCTS in the *Grade "A" PMO* for inclusion ~~in~~ on the *IMS List*. …

3. Lab Evaluation

a. If written split sample results of the laboratories/Certified Industry Supervisor (CIS) used by certified interstate milk shippers are not received by PHS/FDA LPET within sixteen (16) months of the last previous split sample date, PHS/FDA LPET ~~will~~

shall notify the appropriate PHS/FDA Regional Office in writing to send a written withdrawal of the accreditation of the laboratory(ies) concerned. A copy of the PHS/FDA Regional Office notice or PHS/FDA LPET notice for TPCs to the ~~State~~ Milk Laboratory Control Agency to withdraw accreditation shall be sent to the ~~State~~ Regulatory and/or Rating Agency. The ~~State~~ Milk Laboratory Control Agency shall then inform the laboratory(ies), ~~and~~ the Regulatory Agency and/or Rating Agency in writing of the action.

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b. If written results of the official evaluations are not received by PHS/FDA LPET within twenty-six (26) months of the previous evaluation date, PHS/FDA LPET ~~will~~ shall notify the appropriate PHS/FDA Regional Office, in writing, to inform the ~~State~~ Milk Laboratory Control Agency to send a written withdrawal of accreditation of the laboratory(ies) concerned. A copy of the PHS/FDA Regional Office notice or PHS/FDA LPET notice for TPCs to the ~~State~~ Milk Laboratory Control Agency to withdraw accreditation shall be sent to the Regulatory Agency and/or Rating Agency. The ~~State~~ Milk Laboratory Control Agency shall then inform the laboratory(ies), ~~and~~ the Regulatory Agency and/or Rating Agency in writing, of the action.

4. Response to ~~State~~ Regulatory/Rating Agency Program Evaluations

The State or TPC shall cooperate with PHS/FDA in order to correct any deficiencies identified in the State or TPC Milk Safety ~~programs~~ Program, including regulatory, rating and laboratory.

5. Request for Emergency Consideration

In the event of a declared public health emergency or natural or man made disaster, including the activation of the State Emergency Response Plan, if the State is not in a position to operate the program in full compliance with NCIMS program requirements, the State shall immediately contact PHS/FDA. PHS/FDA shall immediately conduct discussions with the State to reach a mutually acceptable resolution.

NOTE: This request for emergency consideration is not applicable to TPCs. …

7. Challenges and Remedies

a. Complaints from Receiving States ~~and Municipalities~~ or TPCs

1.) Complaints as to the sanitary quality of milk and/or milk products being received and challenges of the validity of certified ratings shall be made in writing by the receiving State ~~or municipality~~ and/or TPC to the Rating Agency of the shipping State or TPC, with a copy to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs. …

3.) The Rating Agency of the shipping State or TPC shall make a preliminary investigation of the complaints within fifteen (15) days and notify the receiving State and/or TPC in writing of the action being taken, with a copy to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs.

4.) After an investigation, and based on the facts disclosed, the shipping State or TPC shall:

A.) Notify the receiving State(s) and/or TPC and appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs that the complaint ~~was~~ has been resolved;
B.) Withdraw the certification of the shipper and notify the receiving State(s) and/or TPC and appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs of such action; or
C.) Make a new rating within sixty (60) days, and with the written permission of the shipper, forward the new rating and a copy of the shipper's written permission to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs for listing ~~in~~ on the *IMS List*. The receiving State(s) and/or TPC(s) shall also be notified of the action being taken by the shipping State or TPC.

5.) If the Rating Agency of the shipping State or TPC for any reason cannot make a prompt investigation called for in 7.a.3.) above, or the new rating called for in 7.a.4.) above, it shall:

A.) Notify PHS/FDA, ~~and~~ the State and/or TPC making the complaint. Such notification shall be considered by PHS/FDA as tantamount to the withdrawal of the present ~~State~~ certification of the interstate shipper involved.
B.) Notify the shipper involved, and any other interested parties, that in accordance with Conference agreements, the current ~~State~~ certification is being withdrawn until such time as the complaint may be investigated or a new rating made.

b. Complaints from Shipping States ~~and Municipalities~~ and/or TPCs

1.) Complaints from shipping States ~~and municipalities~~ and/or TPCs shall be made in writing to the Rating Agency of the receiving State(s) and/or TPC(s) with a copy to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs.

2.) The Rating Agency of the receiving State(s) and/or TPC(s) ~~will~~ shall make a preliminary investigation of the complaint(s) within fifteen (15) days and notify the shipping State or TPC in writing of the action being taken, with a copy to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs.

c. Action to be Taken if the PHS/FDA Check Rating or Single-Service Containers and Closures Manufacturer's Audit Indicates the Listed Rating is Not Justified:

1.) ~~Producer Dairies~~ Dairy Farms (Raw Milk) …

A.) Action to be Taken

The following table shall be used to determine action to be taken if the ~~PHS/FDA raw milk~~ Sanitation Compliance Rating from a check rating of a listed shipper's dairy farms indicates the listed ~~raw milk rating~~ Sanitation Compliance Rating is not justified:

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~~PRODUCER DAIRIES~~ DAIRY FARMS (RAW MILK) …

B.) Re-Rating

When check rating data indicates that the Sanitation Compliance Rating of a listed shipper's ~~producer dairies~~ dairy farms requires a re-rating, PHS/FDA shall formally notify the ~~State~~ Rating Agency that a re-rating of the ~~producer dairies~~ dairy farms ~~will~~ shall be required within sixty (60) days.

C.) Withdrawal of Certification

When check rating data indicates that the Sanitation Compliance Rating of a listed shipper's ~~producer dairies~~ dairy farms requires a withdrawal of certification, the ~~State~~ Rating Agency, upon written recommendation of PHS/FDA, shall immediately withdraw the current certification of the shipper and notify such shipper, PHS/FDA, and all known receiving States and/or TPCs thereof, in accordance with Section IV., B., 1.d. In case of withdrawal, a new rating shall be made in not less than thirty (30) days and not to exceed sixty (60) days, unless the ~~State~~ Rating Agency has reason to believe a new rating within a lesser time period, would result in an acceptable rating. The effective date for action shall be determined from the date of the letter of notification by the ~~State~~ Rating Agency. Such letter shall be dated within five (5) working days following the date of the official notification.

2.) Milk Plants, Receiving Stations and/or Transfer Stations

A.) Action to be Taken

The following table shall be used to determine action to be taken if the ~~PHS/FDA~~ Sanitation Compliance Rating from a check rating of a milk plant, receiving station and/or transfer station indicates the listed ~~rating~~ Sanitation Compliance Rating is not justified: …

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B.) Reinspection

When check rating data indicates that the Sanitation Compliance Rating of the milk plant, receiving station and/or transfer station requires a reinspection, PHS/FDA shall formally notify the ~~State~~ Rating Agency that a reinspection of the milk plant, receiving station and/or transfer station ~~will~~ shall be required within thirty (30) days. If the reinspection indicates a level of sanitation compliance below that of the published rating, the ~~State~~ Rating Agency shall submit such new rating for publication, provided that if the reinspection indicates a level of sanitation compliance equal to or better than the published rating, the PHS/FDA Regional Office or PHS/FDA MST for TPCs shall be so advised by the ~~State~~ Rating Agency and no further action ~~will~~ shall be necessary.

C.) Withdrawal of Certification

When check rating data indicates that the Sanitation Compliance Rating of a milk plant, receiving station and/or transfer station requires a withdrawal of certification, the ~~State~~ Rating Agency, upon written recommendation of PHS/FDA, shall immediately withdraw the current certification of the shipper and notify such shipper, PHS/FDA, and all known receiving States and/or TPCs thereof, in accordance with Section IV., B., 1.d. In case of withdrawal, a new rating shall be made in not less than thirty (30) days and not to exceed sixty (60) days, unless the ~~State~~ Rating Agency has reason to believe a new rating within a lesser time period would result in an acceptable rating. The effective date for action shall be determined from the date of the letter of notification by the ~~State~~ Rating Agency. Such letter shall be dated within five (5) working days following the date of the official notification. A withdrawal of certification is also required if an aseptic milk plant has any Aseptic Critical Listing Element (ACLE) identified as not being in compliance on FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM CRITICAL LISTING ELEMENTS for Low-Acid (pH greater than 4.6) Aseptic Milk and Milk Products following the procedures cited above.

3.) If a Rating Agency fails to take the required action outlined in Section IV., B., 7.c.1.) and 7.c.2.), calling for immediate notification of all known receiving States and/or TPCs when the current certification of a listed shipper is to be withdrawn as recommended by PHS/FDA, PHS/FDA after a reasonable lapse of time (not to exceed five (5) days), shall provide all participating States and TPCs with the check rating ~~scores~~ results. The State or TPC which failed to take the required action shall be identified in the next listing of the *IMS List* as not being in compliance with Section IV., B., 7.c.1.) and 7.c.2.).

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4.) Should ~~the~~ a Rating Agency indicate that it is not in a position to make a new rating within a sixty (60) day period or a reinspection within thirty (30) days, PHS/FDA shall identify those States or TPCs in the next listing of the *IMS List* as not being in compliance with the provisions of this paragraph.

5.) If ~~the~~ a Rating Agency informs PHS/FDA that it is unable to make arrangements for PHS/FDA to check rate the sanitation compliance status of listed shippers, PHS/FDA shall identify those States or TPCs in the next listing of the *IMS List* as not being in compliance with the provisions of this paragraph.

6.) If a Rating Agency fails to request removal of a milk plant, receiving station and/or transfer station from the *IMS List* as provided for in Section IV., B., 1.f., PHS/FDA shall, after five (5) days, provide this information to all receiving ~~states~~ States and/or TPCs.

SECTION V. QUALIFICATIONS AND CERTIFICATIONS

A. **SUPERVISION REQUIREMENTS** …

2. The shipper to be rated shall be under the full-time supervision of a State or TPC ~~Regional or Local Milk~~ Regulatory Agency. …

B. **PROCEDURES FOR REQUESTING A MILK SANITATION RATING**

A shipper desiring a rating of their supply for the purpose of interstate certification shall submit a request to the Rating Agency in their own State or to their TPC. …

C. **SANITATION COMPLIANCE AND ENFORCEMENT RATINGS REQUIRED**

Ratings to be made on each shipper who desires certification shall include:

Page 18:

1. Sanitation Compliance Rating on ~~producer~~ dairy farms, transfer stations, receiving stations, pasteurization plants, condensed and dry milk plants and whey plants. …

D. **MILK SANITATION RATING PERSONNEL**

~~Milk~~ Sanitation Compliance and Enforcement Ratings shall be made by certified SROs and the certification of U.S. manufacturers of containers and closures for milk and/or milk products shall be made by certified State SROs who meet the following requirements: …

2. Have been ~~standardized~~ certified by PHS/FDA as a SRO and hold a valid certificate of qualification in one (1) or any combination of the following categories: milk pasteurization plants, including HACCP and/or aseptic processing and packaging if appropriate, dairy farms and transfer/receiving stations, including HACCP if appropriate. The PHS/FDA ~~will~~

shall issue a certificate, valid for three (3) years, to each individual who meets the criteria listed below, as applicable. Certification of a SRO shall qualify that SRO to perform ratings or HACCP listings, if applicable, ~~in any State,~~ upon the request of that State's or TPC's Regulatory/Rating Agency as long as the ~~Officer's~~ SRO's certification is valid.

3. A SRO applicant for initial ~~standardization~~ certification shall be evaluated by PHS/FDA personnel in an independent side-by-side comparison of dairy facilities using the items listed on the appropriate inspection or evaluation report form. The applicant and PHS/FDA personnel shall be in agreement at least eighty percent (80%) of the time on each listed item. Comparison evaluations shall be performed on at least the following number of dairy facilities: …

Page 19:

7. Applicants shall demonstrate the ability to conduct and compute ~~Milk~~ Sanitation Compliance and Enforcement Ratings by completing all of the necessary forms.

8. A certified SRO shall be ~~re-standardized~~ re-certified once each three (3) years by PHS/FDA personnel in an independent side-by-side comparison of dairy facilities using the items listed on the appropriate inspection or evaluation report form. The applicant and PHS/FDA personnel shall be in agreement at least eighty percent (80%) of the time on each listed item. Comparison evaluations shall be performed on at least the following number of dairy facilities: …

d. If HACCP certified for milk plants, receiving or transfer stations, in addition to meeting the requirements listed above for pasteurization milk plants for a SRO, one (1) recertification audit is required. The recertification audit can be done independent as a mock-listing audit or as part of an official HACCP listing audit, at the discretion of the PHS/FDA ~~Regional Milk Specialist~~ personnel and SRO. (Refer to Section VIII., E.6. for additional HACCP certification procedures.) …

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10. To be ~~re-standardized~~ re-certified, a certified SRO shall have during the three (3) year period attended at least one (1) PHS/FDA Regional Milk Seminar, attended at least one (1) training course, which includes the auditing of milk plant HACCP Systems and NCIMS listing, if applicable, and attended at least one (1) PHS/FDA training course on "Special Problems in Milk Protection" or other training judged by PHS/FDA to be equivalent and appropriate.

11. Should PHS/FDA determine that a certified SRO has failed to demonstrate proficiency in the above ~~re-standardization~~ re-certification procedures; PHS/FDA may require the certified SRO to perform the initial ~~standardization~~ certification procedures. …

F. **SAMPLING SURVEILLANCE PERSONNEL** …

2. Have been ~~standardized~~ certified by PHS/FDA as a SSO and hold a valid certificate of qualification. The PHS/FDA ~~will~~ shall issue a certificate, valid for three (3) years, to each individual who meets the criteria listed in 3. and 4. below.

3. A SSO applicant for initial ~~standardization~~ certification shall be evaluated by PHS/FDA personnel in an independent side-by-side comparison of sampling procedure observations using the items listed on the appropriate inspection or evaluation report form. The applicant and PHS/FDA personnel shall be in agreement at least eighty percent (80%) of the time on each listed item. Comparison evaluations shall be performed on at least the following number of bulk milk hauler/samplers and plant samplers at dairy facilities: …

Page 21:

d. Hold a valid certificate of qualification ~~for~~ as a SRO, LEO, or, in the case of a State or TPC Regulatory Supervisor, hold a valid certificate as a SSO.

4. A certified SSO shall be ~~re-standardized~~ re-certified once each three (3) years by PHS/FDA personnel in an independent side-by-side comparison of sampling procedure observations using the items listed on the appropriate inspection or evaluation report form. The applicant and PHS/FDA personnel shall be in agreement at least eighty percent (80%) of the time on each listed item. Comparison evaluations shall be performed in accordance with 3. above.

5. The SSO may delegate the inspection of bulk milk hauler/samplers, who collect samples of raw milk for pasteurization from individual ~~producers~~ dairy farms, to other qualified State~~,~~ or TPC ~~Regional or Local~~ Regulatory Agency personnel or certified industry personnel as outlined in Section 5 of the *Grade "A" PMO*.

NOTE: The delegation to industry certified personnel is not applicable to TPCs.

The SSO may delegate the inspection of Dairy Plant Samplers and Industry Plant Samplers to other qualified State~~,~~ or TPC ~~Regional or Local~~ Regulatory Agency personnel. **…**

a. Initial ~~Standardization~~ Certification: …

Page 22:

c. ~~Re-standardization~~ Re-certification: A certified applicant for the delegation of sampling surveillance responsibilities shall be ~~re-standardization~~ re-certification once each three (3) years by a PHS/FDA certified SSO in an independent side-by-side comparison of sampling procedure observations using the items listed on the appropriate inspection or evaluation report form. The applicant and SSO shall be in agreement at least eighty percent (80%) of the time on each listed item. Comparison evaluations shall be performed on at least the following number of bulk milk hauler/samplers and plant samplers at dairy facilities: …

G. **MILK LABORATORY EVALUATION PERSONNEL**

Milk laboratory evaluations may be made ~~in any State,~~ upon the request of that State's or TPC's Regulatory Agency~~,~~ and shall be made by certified LEOs who:

1. Have been ~~standardized~~ certified and approved by PHS/FDA as a LEO per the requirements and criteria listed in the most recent edition of the *EML*. (Refer to Section 3 of the *EML*.) …

H. **THE HEARING PROCEDURE FOR REVOKING THE CERTIFICATION OF A SRO, SSO, OR LEO** …

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2. Notification of Intent to Revoke PHS/FDA Certification and an Opportunity for a Hearing

If the PHS/FDA Standard (Regional Milk Specialist, or MST personnel, or member of LPET, respectively) makes an initial determination to revoke certification, PHS/FDA ~~will~~ shall notify the SRO, SSO, or LEO in writing of its intent to revoke his or her certification. The notification shall specify: …

Page 24:

I. **AREA RATING** …

2. If a shipper's supply is included in an area rating which has received a Sanitation Compliance Rating of ninety percent (90%) or more, the shipper may be listed without an individual rating, provided that an individual rating shall be furnished upon request of the receiving State(s) ~~or Local jurisdiction(s)~~ and/or TPC(s). …

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J. **INDIVIDUAL RATINGS** …

3. If an aseptic milk plant has any ACLE identified by a SRO, ~~or~~ PHS/FDA Regional Milk Specialist, or PHS/FDA MST personnel as not being in compliance on FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM CRITICAL LISTING ELEMENTS for Low-Acid (pH greater than 4.6) Milk and Milk Products, the listing shall be immediately denied or withdrawn.

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SECTION VI. STANDARDS

A. **POINTS BEYOND THE LIMITS OF THE ROUTINE INSPECTION**

Milk and/or milk products from points beyond the limits of the routine inspection shall be acceptable under the principles of reciprocity ~~for sale in the State or Local area concerned~~, provided they are produced and pasteurized under regulations which are substantially equivalent to the current edition of the *Grade "A" PMO* and have been awarded an acceptable ~~Milk~~ Sanitation Compliance and Enforcement Rating by a SRO certified by PHS/FDA. …

E. **MILK SANITATION STANDARDS**

The current edition of the *Grade "A" PMO* shall be used as the basic sanitation standards in making ~~Milk~~ Sanitation Compliance Ratings of interstate milk shippers. …

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SECTION VII. PROCEDURES GOVERNING A STATE's OR THIRD PARTY CERTIFIER's PARTICIPATION IN THE COOPERATIVE PROGRAM FOR THE CERTIFICATION OF IMS LISTED SHIPPERS

~~STATE~~ REGULATORY/RATING AGENCY PROGRAM EVALUATIONS …

B. Any State or TPC in substantial non-compliance as determined by PHS/FDA ~~will~~ shall be referred to the NCIMS Executive Board for determination of listing on a separate page ~~in~~ on the *IMS List*. The State or TPC upon notification of PHS/FDA and the NCIMS Executive Board ~~will~~ shall have an opportunity to address the NCIMS Executive Board to explain why they believe they ~~should~~ shall not be so listed. If such listing is required, annual evaluations shall be conducted until substantial compliance as determined by PHS/FDA is achieved. Any State or TPC not in substantial compliance a second consecutive year ~~will~~ shall be notified by PHS/FDA and provided an opportunity for a hearing by the NCIMS Executive Board. The NCIMS Executive Board, as a result of the hearing, may determine that the State or TPC ~~should~~ shall not be an active participant in future NCIMS Conferences until substantial compliance is achieved. …

SECTION VIII. PROCEDURES GOVERNING THE CERTIFICATION OF MILK PLANT, RECEIVING STATION AND TRANSFER STATION NCIMS HACCP SYSTEMS FOR IMS LISTED SHIPPERS

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8. **~~STATE~~ REGULATORY/RATING AGENCY PROGRAM EVALUATION:** Definition ~~T~~Y. in Section III shall apply as written, except that for purposes of this Section the words "check ratings of IMS Listed Shippers" shall include "PHS/FDA audits of IMS Listed Shippers".

C. **PHS/FDA HACCP RESPONSIBILITIES** …

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a. PHS/FDA Regional personnel who: …

2.) Comply with the directives of the PHS/FDA Milk Safety Program as administered by the PHS/FDA MST; and …

4.) PHS/FDA personnel responsible for PHS/FDA HACCP audits and ~~State~~ Regulatory/Rating Agency Program Evaluations in States and TPCs participating in the NCIMS HACCP Program shall, at a minimum, be required to meet the same level of training and ~~standardization~~ certification required for SROs who make HACCP listing audits. …

2. HACCP Training …

b. Regulatory Agency ~~Personnel~~ personnel responsible for the evaluation, licensing and regulatory auditing of facilities using the ~~voluntary~~ NCIMS voluntary HACCP Program ~~will~~ shall have equivalent training to the training required to perform traditional NCIMS functions. They shall also have specialized training in conducting HACCP System audits. …

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3. ~~State~~ Regulatory/Rating Agency Program Evaluations

In the event a State or TPC has a participating HACCP milk plant, receiving station, or transfer station, PHS/FDA shall conduct an evaluation of ~~the State's~~ their NCIMS HACCP Program, as a part of the ~~State~~ Regulatory/Rating Agency Program Evaluation. …

5. Electronic Publication of Sanitation Compliance and Enforcement Ratings

a. PHS/FDA shall provide an electronic publication of the *IMS List* on their web site. The electronic *IMS List* is available at http://www.fda.gov/Food/Food Safety/Product-SpecificInformation/MilkSafety/FederalStatePrograms/InterstateMilkShippersList/default.htm. The HACCP listings and IMS Listed shippers' expiration listing dates contained in the electronic publication are certified by the ~~State~~ Rating Agency to be those established by HACCP audits conducted in accordance with the *MMSR* by certified SROs when FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT is signed and submitted to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs for electronic publication. …

b. PHS/FDA shall identify listings only from ~~States~~ Rating Agencies, and/or shippers, which are in substantial compliance with the *Procedures*.

6. Electronic Publication of Qualified PHS/FDA Regional Milk Specialists, ~~and~~ State and TPC Personnel …

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8. PHS/FDA Audits of HACCP Listings

a. PHS/FDA shall conduct, each year, PHS/FDA audits of HACCP listed shippers. To conduct audits of HACCP/aseptic processing and packaging milk plants, the PHS/FDA Regional Milk Specialist and/or PHS/FDA MST personnel for TPCs shall have completed a training course that is acceptable to the NCIMS and PHS/FDA addressing the procedures for conducting ~~the audit~~ audits and the implementation of the NCIMS Aseptic Processing and Packaging Program. Within a State or a TPC conducting the NCIMS voluntary HACCP Program, PHS/FDA audits ~~will~~ shall be ~~made~~ conducted of a representative number of IMS HACCP listed shippers. The selection of shippers ~~for auditing~~ to be audited in a given State or a TPC's jurisdiction ~~will~~ shall be made randomly.

b. In order to make effective use of PHS/FDA Regional Office personnel, the random selection of shippers to be audited ~~will~~ shall be selected in advance and assignments scheduled in each State and/or TPC's jurisdiction.

c. The number of shippers selected ~~for~~ to be PHS/FDA ~~audit~~ audited ~~will~~ shall be based on consideration of the number of shippers in the State or TPC's jurisdiction as well as the demonstrated validity of the State or TPC program. Validity ~~will~~ shall be measured by estimating the number of adverse actions (re-audits or withdrawals of certification) in the State or a TPC's jurisdiction based on the results of previous PHS/FDA audits. This approach ~~will~~ shall shift attention from States or TPCs with demonstrated validity, to problem States or TPCs, while still preserving an adequate level of monitoring.

d. Except as provided for in Sections VIII., C. 8. i., VIII., D. 2., and VIII., D. 7. c.2.)A.) ~~an~~ a PHS/FDA HACCP audit ~~will~~ shall not be ~~made~~ conducted with a greater frequency than the official HACCP listing.

e. For action to be taken when a PHS/FDA audit indicated that a HACCP listing is not justified, refer to Section VIII., D. 7.c. For the purpose of these *Procedures* and all related forms, the terms "listed/listing", "official listing" and "published listing" shall mean the most recent listing, which is accompanied by written permission ~~by~~ from the shipper to publish, and submitted to the PHS/FDA Regional Office or PHS/FDA MST for TPCs by the ~~State~~ Rating Agency.

f. Except as provided in Sections VIII., C.8.i., VIII., D.2., and VIII., D.7.c.2.), PHS/FDA shall release the detailed results of its ~~check ratings or~~ PHS/FDA HACCP audits of listed individual interstate shippers only to the Rating Agency, which originally certified the shipper for listing, and the ~~State~~ shipper's Regulatory Agency.
…

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h. PHS/FDA shall conduct on-site milk plant, receiving station and transfer station audits of the HACCP compliance status of listed interstate milk shippers. These PHS/FDA HACCP audits shall be conducted using the procedures for ~~State~~ HACCP listing audits as described in the *MMSR*. These audits ~~will~~ shall be used in the overall ~~State~~ Regulatory/Rating Agency Program Evaluation. …

i. PHS/FDA shall review the Regulatory Agency records for the milk plant, receiving station or transfer station being audited. In the event that there is reason to doubt the safety of any ~~State's~~ Regulatory Agency's milk and/or milk products that are HACCP listed, PHS/FDA shall immediately investigate the ~~State's~~ Milk Safety Program and may evaluate/audit the milk plants, receiving stations or transfer stations affected. This applies even if the HACCP listing of the milk plant, receiving station or transfer station being audited is sustained.

Based on this investigation, if there are substantial milk and/or milk product safety program weaknesses, PHS/FDA shall send a written notice requiring corrections to the ~~State~~ Regulatory Agency with a copy to the Rating Agency. If after thirty (30) days, PHS/FDA determines that the corrections were not made, PHS/FDA shall notify the affected industry and receiving States and/or TPCs.

If after this investigation of HACCP listings ~~in the State~~, PHS/FDA determines that the State or TPC is not able to fulfill its obligations under the NCIMS voluntary HACCP Program and milk and/or milk products safety remains in doubt, PHS/FDA shall provide written notification to the State or TPC specifying the reasons this determination was made.

This written notification ~~will~~ shall specify that the State or TPC has 180 days from the date of the written notification to show to PHS/FDA's satisfaction that the State or TPC has made appropriate corrections and is once again able to fulfill its obligations under the NCIMS voluntary HACCP Program.

After the 180 days, if the State or TPC is still unable to fulfill its obligations under the NCIMS voluntary HACCP Program and milk and/or milk product safety remains in doubt PHS/FDA ~~will~~ shall not accept new HACCP listings from the State or TPC and PHS/FDA may audit the existing listings as necessary to protect the public health.

D. ~~**STATE**~~ **NCIMS HACCP RESPONSIBILITIES**

1. ~~State~~ NCIMS HACCP Listings for Milk Plants, Receiving Stations and Transfer Stations.

Section IV., B. 1.) shall apply as written, except that for purposes of this Section:

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a. The Rating Agency of the shipping State or TPC shall certify the results of HACCP listing audits of each interstate milk shipper to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs, which in turn~~, will~~ shall transmit the HACCP listing audits to the PHS/FDA Headquarters Office for inclusion ~~in~~ on the *IMS List*. (Refer to Section IV., A., 5.) The HACCP listing audit results, together with other pertinent information, shall be forwarded on an appropriate form (FORM FDA 2359i). …

d. When a certified interstate milk shipper's supply, raw or pasteurized, changes status because of degrading, permit revocation, significant change in the number of ~~producers~~ dairy farms, change in the Sanitation Compliance or Enforcement Rating to less than ninety percent (90%), or a change in HACCP listing status, the shipping State or TPC shall immediately notify all known receiving States and/or TPCs and the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs.

f. When a HACCP listing is no longer valid because a listed milk plant, receiving station and/or transfer station's permit is revoked, the State or TPC shall within five (5) days request PHS/FDA to withdraw the shipper from the *IMS List*.

h. The Rating Agency shall furnish their Regulatory ~~Agencies~~ Agency with copies of coded memoranda, including interpretations of the PHS/FDA recommended *Grade "A" PMO* and HACCP listing procedures received from PHS/FDA.

i. The Rating Agency shall keep current the HACCP listings of all certified shippers within its State or TPC's jurisdiction

2. NCIMS HACCP Enforcement Responsibilities …

Based on this report, if PHS/FDA finds there may be reason to doubt the safety of the State's or TPC's milk and/or milk products that are NCIMS HACCP listed, PHS/FDA shall immediately investigate the State's or TPC's Milk Safety Program and may evaluate/audit the milk plants, receiving stations or transfer stations affected. This applies even if FORM FDA 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT finds that the listing of the milk plant, receiving station or transfer station is satisfactory.

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If there are substantial milk and/or milk product safety program weaknesses, PHS/FDA shall send a notice requiring corrections to the ~~State~~ Regulatory Agency with a copy to the ~~State~~ Rating Agency. If after thirty (30) days, PHS/FDA determines that the corrections were not made, PHS/FDA shall notify the affected industry and receiving States and/or TPCs.

If PHS/FDA determines that the State or TPC is not able to fulfill its obligations under the NCIMS voluntary HACCP Program and milk and/or milk product safety remains in

doubt, PHS/FDA shall provide written notification to the State or TPC specifying the reasons this determination was made.
This notification ~~will~~ shall specify that the State or TPC has 180 days from the date of the notification to show to PHS/FDA's satisfaction that the State or TPC has made appropriate corrections and is once again able to fulfill its obligations under the NCIMS voluntary HACCP Program.

After the 180 days, if the State or TPC is still unable to fulfill its obligations under the NCIMS voluntary HACCP Program and milk and/or milk product safety remains in doubt PHS/FDA ~~will~~ shall not accept new HACCP listings from the State or TPC and PHS/FDA may audit the existing listings as necessary to protect the public health. …

4. Response to ~~State~~ Regulatory/Rating Agency Program Evaluations

   The State or TPC shall cooperate with PHS/FDA in order to correct any deficiencies identified in the State or TPC Milk Safety ~~Programs~~ Program, including regulatory, rating and laboratory. …

7. Challenges and Remedies

   a. Complaints from Receiving States and/or TPCs ~~and Municipalities~~

      Section IV., B. 7.a. shall apply as written, except that for purposes of this Section:

      1.) Complaints as to the sanitary quality of milk and/or milk products being received and challenges of the validity of certified HACCP listing audits shall be made in writing by the receiving State ~~or municipality~~ and/or TPC to the Rating Agency of the shipping State or TPC, with a copy to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs.

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      3.) The Rating Agency of the shipping State or TPC shall make a preliminary investigation of the complaints within fifteen (15) days and notify the receiving State and/or TPC in writing of the action being taken, with a copy to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs.

      4.) After an investigation, and based on the facts disclosed, the shipping State or TPC shall:

         C.) Make a new listing audit within sixty (60) days and, with the written permission of the shipper, forward the new listing audit and a copy of the shipper's written permission to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs for publication ~~in~~ on the *IMS List*. The receiving State(s) and/or TPC(s) shall also be notified of the action being taken by the shipping State or TPC.

5.) If the Rating Agency of the shipping State or TPC for any reason cannot make a prompt investigation called for in 7.a.3.) above, or the new listing called for in 7.a.4.) above, it shall:

B.) Notify the shipper involved, and any other interested parties, that in accordance with Conference agreements, the current ~~State~~ certification is being withdrawn until such time as the complaint may be investigated or a new listing audit is made.

b. Complaints from Shipping States ~~and Municipalities~~ and/or TPCs

1.) Complaints from shipping States ~~and municipalities~~ and/or TPCs shall be made in writing to the Rating Agency of the receiving State(s) and/or TPC(s), with a copy to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs.

2.) The Rating Agency of the receiving State(s) and/or TPC(s) ~~will~~ shall make a preliminary investigation of the complaint(s) within fifteen (15) days and notify the shipping State or TPC in writing of the action being taken, with a copy to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs.

c. Action to be Taken if the PHS/FDA HACCP Audit Indicates the Listing is Not Justified: …

2.) Milk Plants, Receiving Stations and/or Transfer Stations

A.) Action to be Taken

Should a milk plant, receiving station or transfer station's HACCP System be found to be either invalid or improperly verified, PHS/FDA shall request that the State or TPC initiate regulatory action. In addition, PHS/FDA may request a re-audit or withdrawal of certification. When milk and/or milk product safety is in doubt, based on Regulatory Agency practices or concerns, PHS/FDA shall immediately investigate and may audit other milk plants, receiving stations and transfer stations affected.

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Based on this investigation, if there are substantial milk and/or milk product safety program weaknesses, PHS/FDA shall send a notice requiring corrections to the Regulatory Agency with a copy to the Rating Agency. If after thirty (30) days, PHS/FDA determines that the corrections were not made, PHS/FDA shall notify the affected industry and receiving States and/or TPCs.

If PHS/FDA determines that the State or TPC is not able to fulfill its obligations under the NCIMS voluntary HACCP Program and milk and/or milk product safety remains in doubt, PHS/FDA shall provide written notification to

the State or TPC specifying the reasons this determination was made.

This notification ~~will~~ shall specify that the State or TPC has 180 days from the date of the notification to show to PHS/FDA's satisfaction that the State or TPC has made appropriate corrections and is once again able to fulfill its obligations under the NCIMS voluntary HACCP Program.

After the 180 days, if the State or TPC is still unable to fulfill its obligations under the NCIMS voluntary HACCP Program and milk and/or milk product safety remains in doubt, PHS/FDA ~~will~~ shall not accept new HACCP listings from the State or TPC and PHS/FDA may audit the existing listings as necessary to protect the public health.

B.) Re-Audit

If deficiencies and/or non-conformities are significant to the point that timely correction is necessary, but do not require an immediate withdrawal of certification, the deficiencies and/or non-conformities shall be corrected and the correction confirmed by a re-audit by an appropriate listing official. The period of time allowed to correct the HACCP System deficiencies and/or non-conformities shall be specified by the PHS/FDA Regional Milk Specialist and/or PHS/FDA MST personnel for TPCs in writing to the State or TPC. ~~No~~ A re-audit is not required if the deficiencies and/or non-conformities are immediately corrected, or are minor and can be corrected within a time period, which will neither present a risk to the public health nor result in milk and/or milk product adulteration.

If after notice, as specified by PHS/FDA, the HACCP System deficiencies and/or non-conformities have not been corrected, the milk plant's, receiving station's or transfer station's listing shall be withdrawn by the State or TPC.

If the HACCP System deficiencies and/or non-conformities have been corrected, the Rating Agency shall notify the Regional Office of PHS/FDA or PHS/FDA MST for TPCs and ~~no~~ further action ~~will~~ shall not be necessary.

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C.) Withdrawal of Certification

1.) A HACCP listing shall be requested to be withdrawn when CLE's have been noted on FORM FDA 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT indicating that the milk plant, receiving station or transfer station has failed to recognize or correct a deficiency(ies) and/or nonconformity(ies) indicating:

i.) A major HACCP System dysfunction that is reasonably likely to result in a milk and/or milk product safety hazard or an adverse health consequence;

NOTE: A milk and/or milk product safety hazard that is reasonably likely to occur is one for which a prudent milk plant, receiving station or transfer station operator would establish controls because experience, illness data, scientific reports, or other information provide a basis to conclude that there is a reasonable likelihood that, in the absence of those controls, the milk and/or milk product hazard will occur in the particular type of milk and/or milk product being processed.

ii.) Series of observations that leads to a finding of a potential HACCP System failure that is likely to result in a compromise to milk and/or milk product safety; …

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1. **HAZARD ANALYSIS:** Flow Diagram and Hazard Analysis conducted and written for each kind or group of milk and/or milk products processed.
2. **HACCP PLAN:** HACCP Plan prepared for each kind or group of milk and/or milk products processed. …

4. **HACCP PLAN CORRECTIVE ACTION:** Corrective action taken for milk and/or milk products produced during a deviation from CL's defined in the HACCP Plan. …

8. **HACCP SYSTEM AUDIT FOLLOW-UP ACTIONS:** A series of observations that lead to a finding of a potential HACCP System failure that is likely to result in a compromise to milk and/or milk product safety. …

4.) When PHS/FDA audit data indicates that the milk plant, receiving station and/or transfer station requires a withdrawal of certification, the Rating Agency, upon written recommendation of the PHS/FDA, shall immediately withdraw the current certification of the shipper and notify such shipper, PHS/FDA, and all known receiving States and/or TPCs thereof. …

5.) If a Rating Agency fails to immediately notify all known receiving States and/or TPCs when the current certification of a listed shipper is to be withdrawn as recommended by PHS/FDA, the PHS/FDA, after a reasonable lapse of time, not to exceed five (5) days, shall provide all participating States and/or TPCs with the PHS/FDA audit conclusion. The State or TPC, which failed to take the required action, shall be identified in the next listing of the *IMS List* as not being in compliance with the provisions of this

paragraph.
6.) If a Rating Agency informs PHS/FDA that it is unable to make arrangements for PHS/FDA to audit HACCP listed shippers, PHS/FDA shall identify those States or TPCs in the next listing of the *IMS List* as not being in compliance with the provisions of this paragraph.

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7.) If a Rating Agency fails to request removal of a milk plant, receiving station and/or transfer station from the *IMS List* as provided for in this Section, PHS/FDA shall, after five (5) days, provide this information to all receiving States and/or TPCs.

D.) Imminent Health Hazard

1.) When an imminent health hazard is observed, PHS/FDA shall request the Regulatory Agency to take immediate action to prevent any further movement of such milk and/or milk products until such hazard(s) has been eliminated. If such a violation results in a milk and/or milk product that presents a public health risk, the Regulatory Agency shall take immediate action against all milk and/or milk products produced and/or processed that have already entered the distribution system. …

4.) If the Regulatory Agency fails to take immediate action to correct the identified hazard(s), or fails to notify PHS/FDA concerning actions taken within five (5) working days, PHS/FDA shall provide this information to all receiving States and/or TPCs.

E. QUALIFICATIONS AND CERTIFICATIONS

1. Supervision Requirements

   Section V., A. shall apply as written, except that for purposes of this Section: …

   b. The shipper to be audited shall be under the full-time supervision of a State or TPC~~, Regional or Local Milk~~ Regulatory Agency.

2. Procedure for Requesting a HACCP Listing

   A shipper desiring a HACCP listing of their supply for the purpose of interstate certification shall submit a request to the ~~State Milk Rating~~/Rating Agency in their own State or to their TPC. …

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3. HACCP Listing

b. Milk plants, receiving stations or transfer stations participating in the NCIMS voluntary HACCP Program shall receive dairy ingredients, including raw milk and/or milk products, for use in listed products only from IMS listed sources that have been awarded an acceptable HACCP listing or acceptable Sanitation Compliance and Enforcement Ratings.

4. HACCP Listing Personnel

HACCP listings shall be made by qualified SROs who:

a. Have been ~~standardized~~ certified by PHS/FDA as a SRO and hold a valid ~~SRO~~ certification of qualification to perform HACCP listing audits. …

c. Have, during the three (3) year period for which ~~standardized~~ certified, participated in at least one (1) Regional Milk Seminar and, in addition, attended at least one (1) training course on "Special Problems in Milk Protection" or other training course judged by the PHS/FDA to be equivalent. …

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NOTE: The cause shall be documented and provided to the Candidate and the ~~State~~ Rating Agency.

c. Continuous Certification

After the initial successful ~~Conditional~~ HACCP Certification, subsequent certification of a SRO to make NCIMS HACCP Listing Audits ~~will~~ shall be valid for three (3) years unless revoked for cause.

1.) Milk Plant Technical Knowledge …

During the three (3) year certification period, the SRO, certified to conduct NCIMS HACCP listings, ~~will~~ shall complete the minimum training requirements established to maintain proficiency regarding the NCIMS voluntary HACCP Program including having attended at least one (1) training course in the auditing of milk plant HACCP Systems and NCIMS listing for the period of qualification. The NCIMS HACCP Implementation Committee has developed and accepted for this required training both a comprehensive multi-day course presented by members of the NCIMS HACCP Implementation Committee and an abbreviated individual instruction that may be presented to individuals or small groups by any of the HACCP Certified FDA Regional Milk Specialists.

Small group training with practical exercises and other appropriate training that may include written examinations ~~will~~ shall be used to evaluate the SROs technical knowledge for continuing certification. …

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NOTE: The cause shall be documented and provided to the Candidate and the ~~State~~ Rating Agency.

d. Paperwork Review …

9. Milk Plant, Receiving Station and Transfer Station HACCP Listings …

b. If an audit for a HACCP listing is unsatisfactory, another audit shall be conducted after written notification from an authorized representative of the IMS Listed shipper to the ~~State~~ Rating Agency that the IMS Listed shipper is in substantial compliance. The audit shall be completed in ~~no~~ not more than fifteen (15) days from the date of receipt of the notification, unless the Rating Agency has a reason to believe a new listing within a lesser time would result in an acceptable listing. …

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F. **STANDARDS TO BE USED FOR THE NCIMS VOLUNTARY HACCP PROGRAM**

Section VI. shall apply as written, except that for purposes of this Section:

1. Points Beyond the Limits of Routine Inspection

Milk and/or milk products from points beyond the limits of the routine inspection shall be acceptable under the principles of reciprocity ~~for sale in the State or Local area concerned~~, provided they are produced and pasteurized under regulations which are substantially equivalent to the current edition of the *Grade "A" PMO* and have been awarded an acceptable HACCP listing by a SRO certified by PHS/FDA. …

G. **PROCEDURES GOVERNING A STATE's OR THIRD PARTY CERTIFIER's PARTICIPATION IN THE NCIMS HACCP PROGRAM FOR THE CERTIFICATION OF IMS LISTED SHIPPERS**

Section VII. shall apply as written, except that for purposes of this Section:

1. ~~State~~ Regulatory/Rating Agency Program Evaluations …

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SECTION IX. ~~APPLICATION OF CONFERENCE AGREEMENTS~~ PROCEDURES GOVERNING THE NCIMS VOLUNTARY INTERNATIONAL CERTIFICATION PROGRAM

In addition to complying with all of the other Sections of the *Procedures*, the following shall apply to the NCIMS voluntary International Certification Program (ICP):

A. **PURPOSE AND SCOPE**

This Section outlines the policies and procedures for the implementation, operation and maintenance of the NCIMS voluntary ICP. The NCIMS voluntary ICP is intended to provide an additional certification option for Milk Companies (MCs) located outside the United States seeking participation in the NCIMS Grade "A" Milk Safety Program and a listing on the *IMS List*. Previous to this additional option, MCs located outside the United States wishing to import Grade "A" milk and/or milk products, as defined in the *Grade "A" PMO,* into the United States were required to pursue one (1) of the three (3) options identified in M-I-00-4.

This additional option involves using Third Party Certifiers (TPCs) who are authorized by the NCIMS to offer regulatory and rating services to dairy and laboratory facilities in accordance with all of the procedures and requirements of the NCIMS Grade "A" Milk Safety Program. This Section defines the responsibilities and requirements of NCIMS voluntary ICP participants, including prospective TPCs, participating MCs and associated dairy farms, receiving stations, transfer stations, official laboratories, official designated laboratories, etc., the NCIMS and PHS/FDA. This Section also outlines the conditions under which the NCIMS voluntary ICP shall satisfy the requirements for obtaining and maintaining the IMS listing of dairy and laboratory facilities located outside of the geographic boundaries of the NCIMS Member States.

An NCIMS ICP Committee shall be responsible for the implementation, operation and maintaining the oversight of the NCIMS voluntary ICP.

The policies and procedures contained in this Section apply only to TPCs and MCs that are authorized by a signed and dated Letter of Understanding (LOU) with the NCIMS as participants in the NCIMS voluntary ICP. This Section does not apply to Member State and U.S. trust territory regulatory and rating programs that operate under the requirements of the NCIMS, nor does it apply to dairy facilities located within the geographic boundaries of those Member States and trust territories. The NCIMS voluntary ICP does not establish requirements for regulatory programs operated by any governmental agency within or outside of the United States.

TPCs authorized by the NCIMS for participation are required to conform to all of the policies and procedures of the NCIMS voluntary ICP and all of the applicable NCIMS Grade "A" Milk Safety Program requirements when providing regulatory and/or rating services to MCs that produce and process Grade "A" milk and/or milk products for importation into the United States. This includes related services provided to dairy farms, bulk milk hauler/samplers, milk tank trucks, milk transportation companies, milk plants, receiving stations, transfer stations, dairy plant samplers, industry plant samplers, distributors and servicing laboratories located outside the geographic boundaries of the NCIMS Member States that are a part of or serve a MC that desires to produce and process Grade "A" milk and/or milk products for importation into the United States.

B. **PROCEDURES**

1. Operation of the NCIMS voluntary ICP

The NCIMS voluntary ICP is to be implemented, operated and maintained so as to:

a. Comply with all of the applicable requirements of the *Grade "A" PMO* and related NCIMS documents. The regulation and rating of MCs shall be in accordance with the applicable requirements of the NCIMS Grade "A" Milk Safety Program for the purpose of listing those complying on the *IMS List*.

b. Continue to assure the same level of milk safety provided within the NCIMS Grade "A" Milk Safety Program.

c. Provide a means for NCIMS Member States to accept Grade "A" milk and/or milk products from NCIMS voluntary ICP IMS Listings.

2. Application by Prospective TPCs

a. The NCIMS Executive Board shall make an initial announcement seeking applications from non-governmental individuals or organizations wishing to participate in the NCIMS voluntary ICP as a TPC. Prospective TPCs shall complete and submit the official NCIMS voluntary ICP application form along with all of the appropriate documentation to the ICP Committee. The ICP Committee shall confirm with each applicant, the receipt of the application form and whether it is complete enough to be warranted for consideration as submitted or if additional information shall be required.

b. All documents that are utilized and exchanged within the NCIMS voluntary ICP shall be in English or translated into English by the submitter.

3. Review of Applications, Selection and Official Notification of TPCs

a. The ICP Committee is responsible to review all valid application forms from qualified prospective TPCs. This review shall evaluate the quality and strength of each application on the basis of the applicant's response to the requests for information on the application form. This review shall also evaluate each application based on the TPC identified personnel's knowledge and experience with the requirements of the NCIMS Grade "A" Milk Safety Program and the responsibilities and duties of a Regulatory/Rating/Laboratory Control Agencies providing the regulatory, rating and laboratory functions within the NCIMS Grade "A" Milk Safety Program. The ICP Committee shall make recommendations to the NCIMS Executive Board of qualified applicants for participation in the NCIMS voluntary ICP.

b. The NCIMS Executive Board may request additional information concerning the ICP Committee's recommendations. If the NCIMS Executive Board has a reason to dispute any of the ICP Committee's recommendations, they may request that the ICP

Committee reconvene to consider additional information that may be relevant to their recommendations.

c. All applicants shall be notified in writing, which may include mail, facsimile, email or other electronic means, by the Chair of the NCIMS Executive Board as to the status of their application and whether or not they have been selected to participate as a TPC in the NCIMS voluntary ICP.

d. If an applicant is not selected to participate as a TPC in the NCIMS voluntary ICP, included within the written NCIMS Executive Board notification, they shall be provided an opportunity to request a meeting with the NCIMS Executive Board and members of the ICP Committee to appeal the decision and present any additional information. This meeting request shall be received by the Chair of the NCIMS Executive Board within fifteen (15) days of the date of receipt of their official written notification that the applicant has not been selected to participate as a TPC in the NCIMS voluntary ICP. If a meeting request is received within this fifteen (15) day time period, the meeting shall take place at a time, location and manner (in person or via teleconference) agreed upon by the Chair of the NCIMS Executive Board and the applicant. If an agreement cannot be reached, the meeting shall take place at a reasonable time, location and manner as determined by the Chair of the NCIMS Executive Board.

e. If the applicant is selected to participate as a TPC in the NCIMS voluntary ICP, they shall be provided a Letter of Understanding (LOU), signed and dated by the Chair of the NCIMS Executive Board, and the TPC shall be provided fifteen (15) days from the date of receipt of their official notification of selection as a TPC to sign, date and return the LOU to the Chair of the NCIMS Executive Board.

f. If the LOU is not signed and dated by the TPC and returned to the Chair of the NCIMS Executive Board within this fifteen (15) day time period, the TPC has been determined to decline their selection as a TPC in the NCIMS voluntary ICP. If they wish to seek selection as a TPC in the NCIMS voluntary ICP at a later date, they shall complete and submit a new official NCIMS voluntary ICP application form along with all of the appropriate documentation to the ICP Committee.

g. Once the signed and dated LOU has been received by the Chair of the NCIMS Executive Board, within the time period as cited in 3.e. above, a copy of the signed and dated LOU shall be provided to the ICP Committee Chair and PHS/FDA MST.

h. PHS/FDA MST upon receipt of the signed and dated LOU shall issue an M-I officially announcing the selection of the TPC to participate in the NCIMS voluntary ICP and include the TPC on the *IMS List*.

i. If a TPC has not IMS listed any milk shippers within two (2) years of the signed and dated LOU, the ICP Committee Chair shall request a meeting with the TPC to discuss why their LOU shall continue to remain valid. The meeting shall take place at

a time, location and manner (in person or via teleconference) agreed upon by the ICP Committee Chair and the TPC. If an agreement cannot be reached, the meeting shall take place at a reasonable time, location and manner as determined by the ICP Committee Chair.

Following the meeting, the ICP Committee Chair shall make a recommendation to the NCIMS Executive Board that the LOU remain valid or that the LOU shall be suspended. If the NCIMS Executive Board agrees with the recommendation from the ICP Committee Chair, then the Chair of the NCIMS Executive Board shall provide written notification to the TPC of their findings, with a copy to the ICP Committee Chair and to PHS/FDA MST.

If the agreed upon recommendation is for the suspension of the LOU, a TPC meeting request and the process as cited in 3.d. above shall be followed. Following this meeting, if the ICP Committee recommendation is still agreed to by the NCIMS Executive Board, then the Chair of the NCIMS Executive Board shall provide written notification to the TPC of their official LOU suspension, with a copy to the ICP Committee Chair and to PHS/FDA MST.

PHS/FDA MST, upon receipt of the written notification to officially suspend the TPC's LOU, shall issue an M-I officially announcing the suspension of the TPC to participate in the NCIMS voluntary ICP and immediately withdraw the TPC from the *IMS List*.

C. THIRD PARTY CERTIFER (TPC) RESPONSIBILITIES

1. Required Signed and Dated Agreements/Commitments

The following written agreements are required of TPCs with their MCs participating in the NCIMS voluntary ICP:

a. **Letter of Intent (LOI):** A TPC shall sign and date a formal written agreement with a MC that it intends to certify and IMS list under the NCIMS voluntary ICP. A copy of each agreement, signed and dated by the TPC and the MC selected to participate in the NCIMS voluntary ICP, shall be immediately submitted to the ICP Committee Chair and PHS/FDA MST. A copy of the official LOI for the NCIMS voluntary ICP may be obtained from the NCIMS Executive Secretary or the ICP Committee Chair. A copy is included in Appendix A. of this document.

b. **Memorandum of Agreement (MOA):** This formal written, signed and dated memorandum states the requirements and responsibilities of each party (TPC and MC) to participate and execute the NCIMS voluntary ICP. The MOA shall include, but is not limited to, the issues and concerns addressed in all documents involved in the NCIMS voluntary ICP and NCIMS documents. This agreement shall be considered the MC's permit to operate in the context of the NCIMS Grade "A" Milk Safety Program and shall be renewed (signed and dated) on an annual basis. A copy of the official MOA for the NCIMS voluntary ICP may be obtained from the NCIMS Executive Secretary or the ICP

Committee Chair. A copy is included in Appendix A. of this document.

A signed and dated MOA shall be submitted to the ICP Committee Chair and PHS/FDA MST prior to the initial rating/certification of any milk shipper, or official laboratory, or official designated laboratory, respectively. The MOA shall be reviewed by the ICP Committee and PHS/FDA MST and LPET to determine that it contains all the provisions set forth herein. PHS/FDA MST and LPET shall provide comments to the ICP Committee concerning the MOA. There shall not be any ratings/certifications conducted of any milk shipper, or official laboratory, or official designated laboratory, respectively, of the MC until the ICP Committee has indicated in writing, which may include mail, facsimile, email or other electronic means, to the TPC that the signed and dated MOA complies with the requirements herein stated.

All annual renewed (signed and dated) MOAs shall be immediately submitted to the ICP Committee Chair and PHS/FDA MST.

Either party (TPC or MC) may terminate an MOA upon the MOA's required specified number of days notice by registered or certified mail, return receipt requested, addressed to the other party. If either party (TPC or MC) terminates a MOA, both the TPC and the MC shall immediately notify the ICP Committee Chair and PHS/FDA MST. Upon the TPC ceasing to provide oversight of the MC, the MC shall be immediately withdrawn from the *IMS List* and removed from the NCIMS voluntary ICP. Within fifteen (15) days of the TPC ceasing to provide oversight, they shall forward all related records, including, but not limited to: sample results, equipment tests, plant inspection notes and reports, etc. to PHS/FDA MST in a manner acceptable to PHS/FDA MST. PHS/FDA MST shall retain such records until such time as a suitable replacement TPC, authorized under the NCIMS voluntary ICP, has been hired and a signed and dated LOI has been submitted to the ICP Committee Chair and PHS/FDA MST to fulfill the obligations of the NCIMS voluntary ICP.

2. Qualifications of TPC Personnel

a. Regulatory Personnel

The TPC's regulatory personnel performing the routine required inspections of dairy farms, milk plants, transfer/receiving stations, etc. and the required pasteurization equipment testing shall be adequately trained to perform these duties and shall have had previous work experience in the NCIMS Grade "A" Milk Safety Program.

NOTE: All regulated MCs shall provide an interpreter during all official inspections, ratings/listings, training, and accreditation/certification activities.

b. Milk Sanitation Rating Personnel

TPC personnel conducting rating/listing activities shall meet the qualification and

certification requirements set forth in Section V, D, and Section VIII, E. 4, if applicable, of this document. SROs cannot have direct responsibility for the routine inspection and enforcement or regulatory auditing of the milk shipper to be rated or listed.

c. Sampling Surveillance Personnel

TPC personnel conducting sampling surveillance activities shall meet the qualification and certification requirements set forth in Section V, F, and Section VIII, E.7, if applicable, of this document.

d. Milk Laboratory Evaluation Personnel

TPC personnel conducting milk laboratory evaluation activities shall meet the qualification and certification requirements set forth in Section V, G, and Section VIII, E. 8, if applicable, of this document and those of the *EML*.

e. NCIMS HACCP Program Personnel

Before a milk plant, receiving station or transfer station may be regulated under the requirements of the NCIMS voluntary HACCP Program, all relevant industry personnel and TPC regulatory and rating personnel shall complete all of the required NCIMS HACCP Program training as required in this document. Before a MC is allowed to begin the NCIMS voluntary HACCP Program there shall be a mutual agreement between the milk plant, receiving station or transfer station and the TPC. A TPC's NCIMS HACCP Program shall be evaluated as a part of the required triennial Regulatory/Rating Agency Program Evaluation completed by FDA.

f. NCIMS Aseptic Program Personnel

Before a milk plant may be regulated under the requirements of the NCIMS Aseptic Program, all relevant TPC regulatory and rating personnel shall successfully complete the mandatory NCIMS Aseptic Program training developed and offered by the NCIMS Aseptic Program Committee.

NOTE: Any change in TPC personnel shall be immediately reported to the ICP Committee Chair and PHS/FDA MST.

3. Code of Ethics

The TPC, its personnel and contractors, if any, are obligated to abide by the following Code of Ethics:

The TPC:

a. Shall not be owned, operated or controlled by a manufacturer, supplier or vendor of

milk and/or milk products regulated under the NCIMS;

b. Shall not be financially affiliated with a manufacturer, supplier or vendor of milk and/or milk products regulated under the NCIMS;

c. Shall not charge fees contingent or based upon results from the TPC inspection, rating and certification activities; and

d. Shall hold all personnel, including contractors, to the same conflict of interest standards.

The TPC and its personnel:

a. Shall act with honesty and integrity;

b. Shall act impartially and shall not give preferential treatment to any organization(s) or individual(s);

c. Shall not discriminate because of race, religion, national origin or gender;

d. Shall not hold financial interest(s) that conflict with the conscientious and impartial performance of their duties;

e. Shall not engage in financial transactions using Regulatory/Rating derived information or allow the improper use of such information to further any private interest;

f. Shall not disclose or use confidential or privileged information for personal benefit or for financial gain. The TPC and its personnel shall maintain strict confidentiality of proprietary information learned through their Regulatory/Rating oversight activities;

g. Shall avoid conflicts of interest or the appearance of a conflict of interest. The TPC and its personnel shall not participate in any matter in which they, or their spouse or dependents, have a private interest which may directly or indirectly affect or influence the performance of their duties.

h. Shall perform only the activities within the scope of their responsibilities, training and/or certification within the context of the NCIMS Grade "A" Milk Safety Program;

i. Shall endeavor to avoid any actions creating the appearance that they are violating the ethical tenets set forth in this Section. Whether particular circumstances create an appearance that these tenets have been violated shall be determined from the perspective of a reasonable person with the knowledge of the relevant facts; and

j. The TPC, TPC personnel, their spouses and dependants shall not solicit or accept any gift or other items of monetary value for their duties beyond the agreed upon

contract value from the regulated industry or entity seeking Regulatory/Rating activities whose interests may be substantially affected by the performance or nonperformance of their duties.

Violators of any of the Code of Ethics' tenets shall be subject to removal from participation in the NCIMS voluntary ICP.

4. Performance of Duties and Responsibilities

a. TPCs shall furnish all required services and activities as an independent contractor and not as an employee of the MC or of any company affiliated with the MC. The TPC does not have any power to or authority to act for, represent, or bind the MC or any company affiliated with the MC in any manner.

b. TPCs shall conduct all services and activities required under the signed and dated MOA with integrity and impartiality. The TPC shall avoid all conflicts of interest or the appearance of a conflict of interest. During the term of the signed and dated MOA, TPCs shall not enter into any activity, employment, or business arrangement that conflicts with the MC's interests or their own obligations to the MC under the signed and dated MOA, except that the TPC may sign an MOA with and provide Regulatory/Rating services to other MCs as allowed under the NCIMS voluntary ICP. The TPC shall advise the MC of any activity, employment or business arrangement contemplated by the TPC that may be relevant to this paragraph.

c. TPCs shall treat all proprietary or privileged information obtained during the course of their services with the MC with strict confidentiality.

d. TPCs shall submit all required rating/listing paperwork and forms to PHS/FDA MST upon the completion of all ratings/listings conducted by the TPC.

D. **MILK COMPANY (MC) RESPONSIBILITIES**

1. Required Signed and Dated Agreements/Commitments

The following agreements are required of a MC with their TPC for participating in the NCIMS voluntary ICP:

a. **Letter of Intent (LOI)**

b. **Memorandum of Agreement (MOA)**

A MC shall have the option of terminating a signed and dated MOA if, at any time, in the MC's sole judgment, a conflict of interest exists or is imminent. Termination shall be in accordance with the notification requirements addressed in Item 8 of the signed and dated MOA. The MC shall be aware and fully understand that if a signed and dated MOA is terminated after they have been listed on the *IMS List* they shall be

immediately withdrawn from the *IMS List* and removed from the NCIMS voluntary ICP.

2. The MC shall comply with the signed and dated MOA and all applicable requirements of the NCIMS Grade "A" Milk Safety Program and the NCIMS voluntary ICP.

3. The MC shall allow unannounced inspections, during reasonable working hours, of all facilities included in the NCIMS voluntary ICP.

4. The MC shall provide access to the TPC of all required records relating to the provisions and requirements of the NCIMS Grade "A" Milk Safety Program and the NCIMS voluntary ICP. They shall also provide access to the TPC for all required pasteurization equipment testing and the collection of all required milk and/or milk products and milk containers, if applicable, and the required sampling of all applicable water system(s), including recirculated water systems.

5. Along with all of the other requirements as cited in the NCIMS documents, a MC seeking listing on the *IMS List*, shall provide documentation, acceptable to the TPC, the ICP Committee, and PHS/FDA MST, that demonstrates their compliance with the provisions of Section 8. Animal Health and Appendix A. Animal Disease Control of the *Grade "A" PMO* and the relevant USDA/APHIS requirements for tuberculosis and brucellosis.

6. All documents that are utilized and exchanged within the NCIMS voluntary ICP shall be in English or translated into English by the MC. These documents include all forms, contracts and written communication between the TPC and the regulated MC. The MC shall provide an interpreter during all official inspections, ratings/listings, training, and accreditation/certification activities.

E. COMPLIANCE WITH THE NCIMS VOLUNTARY INTERNATIONAL CERTIFICATION PROGRAM (ICP)

1. Third Party Certifier (TPC)

Compliance with the requirements of the NCIMS voluntary ICP shall be determined by PHS/FDA MST and LPET. Failure to adequately comply with the regulatory and enforcement provisions of the NCIMS Grade "A" Milk Safety Program; the requirements of the NCIMS voluntary ICP; requirements for IMS listing; Code of Ethics; etc. can result in the removal of the TPC from the NCIMS voluntary ICP.
Reasons for the removal of a TPC from the NCIMS voluntary ICP and subsequent withdrawal of MCs and certified laboratories from the *IMS List* include, but are not limited to, the following:

a. If a TPC is found to be in non-compliance with the requirements set forth in the documents of the NCIMS Grade "A" Milk Safety Program by PHS/FDA MST and/or LPET, the TPC shall be subject to procedures addressing their removal from the NCIMS

voluntary ICP.

b. If a TPC ceases to provide oversight of all of their IMS listed MCs for purposes of the NCIMS voluntary ICP, both the TPC and the MCs shall immediately notify the ICP Committee Chair and PHS/FDA MST and/or LPET. Both the TPC and MCs shall immediately be removed from the NCIMS voluntary ICP and the MCs shall immediately be withdrawn from the *IMS List* by PHS/FDA MST and/or LPET. Within fifteen (15) days of a TPC ceasing to provide this required MC oversight, the TPC shall transfer all existing records to PHS/FDA MST in a manner acceptable to PHS/FDA MST.

c. When there is evidence, found during PHS/FDA check ratings or a triennial Regulatory/Rating Agency Program Evaluation, that the TPC is in non-compliance with the applicable requirements set forth in the documents of the NCIMS Grade "A" Milk Safety Program, the TPC shall be referred to the NCIMS Executive Board in accordance with Section IV, A. 3. b of this document. The TPC and MC(s) listed by the TPC can be subject to withdrawal by PHS/FDA MST and/or LPET from the *IMS List*.

d. Violators of any of the required Code of Ethics' tenets by a TPC or their personnel shall be subject to removal from participation in the NCIMS voluntary ICP by the Executive Board.

2. Milk Company (MC)

Compliance with the requirements of the NCIMS voluntary ICP shall be determined by PHS/FDA MST and LPET. Failure to adequately comply with the sanitation requirements and provisions of the NCIMS Grade "A" Milk Safety Program; the requirements of the NCIMS voluntary ICP; requirements for IMS listing; etc. can result in the removal of the MC from the NCIMS voluntary ICP.

Reasons for the removal of a MC from the NCIMS voluntary ICP and subsequent withdrawal of MCs and certified laboratories from the *IMS List* include, but are not limited to, the following:

a. If a MC's IMS listed milk shipper changes status due to non-compliance or a change in the Sanitation Compliance Rating to less than ninety percent (90%), the TPC shall immediately notify the PHS/FDA MST and all known receiving Member States and/or TPCs. The MC's IMS listed milk shipper shall immediately be withdrawn from the *IMS List* by PHS/FDA MST.

b. If a TPC ceases to provide the required oversight of an IMS listed MC for purposes of the NCIMS voluntary ICP, both the TPC and the MC shall immediately notify the ICP Committee Chair and PHS/FDA MST and/or LPET. The MC, including all associated facilities, shall immediately be removed from the NCIMS voluntary ICP and the MC shall also immediately be withdrawn from the *IMS List* by PHS/FDA MST and/or LPET. Within fifteen (15) days of a TPC ceasing to provide this required MC oversight, the TPC shall transfer all existing records to PHS/FDA MST in a manner acceptable to PHS/FDA

MST.

c. When there is evidence that the MC or it's servicing laboratory is not meeting the applicable requirements of the Grade "A" PMO and/or the EML, respectively, as determined by the TPC, or the ICP Committee, and/or PHS/FDA MST and/or LPET, the MC's IMS listing(s) is subject to withdrawal from the IMS List. The TPC or the ICP Committee shall immediately notify PHS/FDA MST and/or LPET, respectively. In the case that PHS/FDA MST and/or LPET makes this determination based upon the results of a check rating or a laboratory evaluation, the MC is subject to suspension and/or removal from the NCIMS voluntary ICP until compliance, as determined by PHS/FDA MST and/or LPET, is achieved. With this determination, PHS/FDA MST and/or LPET, respectively, shall notify all known receiving Member States.

F. **CONFIDENTIALITY**

The Member States of the NCIMS, the ICP Committee, and the PHS/FDA are obligated to operate under rules and regulations pursuant to the Freedom of Information Act that may require disclosure of information related to a TPC and the rating and certification of MCs and their related facilities.

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SECTION ~~I~~XX. APPLICATION OF CONFERENCE AGREEMENTS

A. **IMPLEMENTATION OF CHANGES** …

2. PHS/FDA ~~will~~ shall review the transcript and within ninety (90) days of receipt, notify the Conference Chair of those issues with which they do or do not concur. The changes involved, that have been concurred with shall be effective within one (1) year of the electronic publication of the affected documents or notification to the States and TPCs by IMS-a, following the Conference at which the changes were approved.

3. Those issues with which PHS/FDA does not concur ~~will~~ shall be referred to the NCIMS Executive Board for further discussion (within thirty (30) days if possible). If mutual concurrence is obtained, the changes shall be effective within one (1) year of the electronic publication of the affected documents or notification to the States and TPCs by IMS-a, following the Conference at which the changes were approved, unless otherwise mutually agreed upon by PHS/FDA and the NCIMS Executive Board.

4. If mutual concurrence cannot be reached, the matter ~~will~~ shall be referred to the next Conference for further discussion. In the interim period between the PHS/FDA-NCIMS Executive Board Meeting (referred to in 3. above) and the next NCIMS Conference, PHS/FDA ~~will~~ shall consider additional information that becomes available concerning Proposals for which there was not mutual concurrence. If following the review of this additional information causes PHS/FDA to reconsider its position, PHS/FDA may bring Proposals back to the NCIMS Executive Board for reconsideration and the establishment

of an alternative effective date. …

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APPENDIX A. OFFICIAL AGREEMENTS UTILIZED IN THE NCIMS VOLUNTARY INTERNATIONAL CERTIFICATION PROGRAM

LETTER OF INTENT (LOI):

LETTER OF INTENT TO PARTICIPATE IN THE NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS VOLUNTARY INTERNATIONAL CERTIFICATION PROGRAM

It is necessary to comply with all applicable requirements of the Grade "A" Pasteurized Milk Ordinance (PMO) in order to properly produce and/or process and label our Grade "A" milk and/or milk products for distribution in the United States of America. We hereby confirm our intent to review through inspection our milk production (dairy farms), transportation, bulk milk hauler/samplers, processing, industry plant samplers, laboratory facilities, etc. in order to prepare them for compliance with the Grade "A" PMO. We understand that our facilities shall also meet the rating and certification requirements of the National Conference on Interstate Milk Shipments (NCIMS) Grade "A" Milk Safety Program.

_____
Milk Company

_____ _____
Signature of Most Responsible Party Name

_____ _____
Title Date

We hereby confirm our intent to provide (Milk Company) with routine regulatory inspections, laboratory services and other obligations under the NCIMS voluntary International Certification Program to determine if your milk production (dairy farms), transportation, bulk milk hauler/samplers, processing, industry plant samplers, laboratory facilities, etc. comply with the Grade "A" PMO and the NCIMS Grade "A" Milk Safety Program. Once compliance is determined, your milk production (dairy farms), transportation, bulk milk hauler/samplers, processing, industry plant samplers, laboratory facilities, etc. shall be rated and potentially certified in accordance with the provisions of the NCIMS Grade "A" Milk Safety Program. Upon an acceptable rating and certification of your milk production (dairy farms), transportation, bulk milk hauler/samplers, processing, industry plant samplers, laboratory facilities, etc. and you having signed a "Permission to Publish" release form, you shall be granted a listing on the Interstate Milk Shipper's List of Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers (IMS List).

Third Party Certifier

Signature of Most Responsible Party

Name

Title

Date

{TPC and MC} hereby agree to indemnify and hold harmless all members of the National Conference on Interstate Milk Shipments (NCIMS), including, but not limited to, all members of the NCIMS International Certification Program Committee, all federal regulatory agencies including the U.S. Food and Drug Administration, all State Regulatory Agencies, all trade associations including the International Dairy Foods Association and the National Milk Producers Federation, and all private entities including companies and consultants, and their respective members, agents, officers, directors and employees, against any and all losses, liabilities, costs, actions, claims and other obligations and proceedings, including any reasonable attorney's fees incurred in connection with, or which may arise or result in any way from the operation of the NCIMS voluntary International Certification Program.

MEMORANDUM OF AGREEMENT (MOA)

NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS VOLUNTARY INTERNATIONAL CERTIFICATION PROGRAM MEMORANDUM OF AGREEMENT BETWEEN A THIRD PARTY CERTIFIER AND A MILK COMPANY

1.) **Introduction**: This Memorandum of Agreement (MOA) is entered into on {date} by and between {Third Party Certifier} with offices at {address} , and {Milk Company } with principal offices at {address}.

2.) **Retention and Description of Services**: During the term of this MOA, {Third Party Certifier} shall furnish regulatory, rating, laboratory, etc. services and activities related to the regulatory compliance of {Milk Company} with the National Conference on Interstate Milk Shipments (NCIMS) voluntary International Certification Program (ICP). These services and activities shall be within the area of their technical competence and shall include, but are not limited to, the following:

- All required regulatory inspections and related enforcement;
- All required pasteurization system equipment testing;
- All required sampling and analysis of Grade "A" raw, pasteurized, ultra-pasteurized

and/or aseptically processed milk and/or milk products, and milk containers, if applicable;
- All ratings/listings of shippers of Grade "A" milk and/or milk products; and
- Laboratory certification/approval program activities required for compliance with all applicable NCIMS Grade "A" Milk Safety Program requirements.

For purposes of this NCIMS voluntary ICP, the Third Party Certifier (TPC) shall have similar authority and responsibilities as State Regulatory Agencies, State Rating Agencies, State Laboratory Control Agencies and/or Officially Designated Laboratories, if applicable, as identified in the NCIMS Grade "A" Milk Safety Program. A detailed explanation of each service and activity can be found in the NCIMS documents (Grade "A" Pasteurized Milk Ordinance (PMO), Methods of Making Sanitation Ratings of Milk Shippers (MMSR), Procedures Governing the Cooperative State Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments (Procedures), and Evaluation of Milk Laboratories (EML)).

During the term of this MOA, {Milk Company} shall comply with all applicable requirements of the NCIMS Grade "A" Milk Safety Program and the NCIMS voluntary ICP. They shall allow unannounced inspections, during reasonable working hours, of all facilities identified in Item 4. below. They shall provide access to the TPC of all required records relating to the provisions and requirements of the NCIMS Grade "A" Milk Safety Program and the NCIMS voluntary ICP. They shall provide access to the TPC for all required pasteurization equipment testing and the collection of all required milk and/or milk products and milk containers, if applicable, and the required sampling of all applicable water system(s), including recirculated water systems.

The MC shall provide written evidence acceptable to the TPC, the ICP Committee, and the U.S. Food and Drug Administration Milk Safety Team and Laboratory Proficiency Evaluation Team (FDA MST and LPET) that the milk and/or milk products used to produce Grade "A" milk and/or milk products for importation into the U.S. are from sources that comply with the provisions of Section 8 and Appendix A of the PMO and U.S. Department of Agriculture (USDA) regulations for tuberculosis and brucellosis testing and control.

All documents that are utilized and exchanged within the NCIMS voluntary ICP shall be in English or translated into English by the MC. These documents include all forms, contracts and written communication between the TPC and the regulated MC. The MC shall provide an interpreter during all official inspections, ratings/listings, training and accreditation/certification activities.

3.) **Term of the Memorandum Of Agreement (MOA)**: This formal written, signed and dated memorandum states the requirements and responsibilities of each party (TPC and MC) to participate and execute the NCIMS voluntary ICP. The MOA shall include, but is not limited to, the issues and concerns addressed in all documents involved in the NCIMS voluntary ICP and NCIMS documents. This agreement shall be considered the MC's permit to operate in the context of the NCIMS Grade "A" Milk Safety Program and shall be renewed (signed and dated) on an annual basis.

This signed and dated MOA shall be submitted to the ICP Committee Chair and FDA MST and shall be reviewed by the NCIMS ICP Committee and FDA MST and LPET to determine that it contains all provisions set forth within the NCIMS voluntary ICP. There shall not be any ratings/listings/certifications conducted of any MC's milk shipper or official laboratory or official designated laboratory, respectively, until the ICP Committee has indicated in writing that this MOA complies with the requirements of the Grade "A" Milk Safety Program and the NCIMS voluntary ICP.

Compliance with the requirements of the NCIMS voluntary ICP shall be determined by the FDA MST and LPET. Failure to adequately comply with the regulatory and enforcement provisions of the Grade "A" Milk Safety Program; the requirements of the NCIMS voluntary ICP; requirements for IMS listing; the required Code of Ethics; etc. may result in the removal of {Third Party Certifier} from the NCIMS voluntary ICP.

Reasons for the removal of TPCs or MCs from the NCIMS voluntary ICP and withdrawal of MCs from the Interstate Milk Shippers (IMS) List include, but are not limited to, the following:

a. If a TPC is found to be in non-compliance with the requirements set forth in the documents of the NCIMS Grade "A" Milk Safety Program by PHS/FDA MST and/or LPET, the TPC shall be subject to procedures addressing their removal from the NCIMS voluntary ICP.

b. If a TPC ceases to provide the required oversight of an IMS listed MC for purposes of the NCIMS voluntary ICP, both the TPC and the MC shall immediately notify the ICP Committee Chair and PHS/FDA MST and/or LPET. The MC, including all associated facilities, shall immediately be removed from the NCIMS voluntary ICP and the MC shall also immediately be withdrawn from the IMS List by PHS/FDA MST and/or LPET. Within fifteen (15) days of a TPC ceasing to provide this required MC oversight, the TPC shall transfer all existing records to PHS/FDA MST in a manner acceptable to PHS/FDA MST.

c. If a TPC ceases to provide oversight of all of their IMS listed MCs for purposes of the NCIMS voluntary ICP, both the TPC and the MCs shall immediately notify the ICP Committee Chair and PHS/FDA MST and/or LPET. Both the TPC and MCs shall immediately be removed from the NCIMS voluntary ICP and the MCs shall immediately be withdrawn from the *IMS List* by PHS/FDA MST and/or LPET. Within fifteen (15) days of a TPC ceasing to provide this required MC oversight, the TPC shall transfer all existing records to PHS/FDA MST in a manner acceptable to PHS/FDA MST.

d. When there is evidence, found during PHS/FDA check ratings or a triennial Regulatory/Rating Agency Program Evaluation, that the TPC is in non-compliance with the applicable requirements set forth in the documents of the NCIMS Grade "A" Milk Safety Program, the TPC shall be referred to the NCIMS Executive Board in accordance with Section IV, A. 3. b of the Procdures. The TPC and MC(s) listed by

the TPC can be subject to withdrawal by PHS/FDA MST and/or LPET from the *IMS List*.

e. If a MC's IMS listed milk shipper changes status due to non-compliance or a change in the Sanitation Compliance Rating to less than ninety percent (90%), the TPC shall immediately notify the PHS/FDA MST and all known receiving Member States and/or TPCs. The MC's IMS listed milk shipper shall immediately be withdrawn from the IMS List by PHS/FDA MST.

f. When there is evidence that the MC or it's servicing laboratory is not meeting the applicable requirements of the Grade "A" PMO and/or the EML, respectively, as determined by the TPC, or the ICP Committee, and/or PHS/FDA MST and/or LPET, the MC's IMS listing(s) is subject to withdrawal from the IMS List. The TPC or the ICP Committee shall immediately notify PHS/FDA MST and/or LPET, respectively. In the case that PHS/FDA MST and/or LPET makes this determination based upon the results of a check rating or a laboratory evaluation, the MC is subject to suspension and/or removal from the NCIMS voluntary ICP until compliance, as determined by PHS/FDA MST and/or LPET, is achieved. With this determination, PHS/FDA MST and/or LPET, respectively, shall notify all known receiving Member States.

g. Violators of any of the required Code of Ethics' tenets by a TPC or their personnel shall be subject to removal from participation in the NCIMS voluntary ICP by the Executive Board.

4.) **Where Services Are To Be Performed**: {Third Party Certifiers} services and activities shall be performed at the {Milk Company's} facilities located at [address] and at such other locations that are appropriate and required to fulfill the requirements of the NCIMS voluntary ICP.

5.) **Third Party Certifier as an Independent Contractor**: {Third Party Certifier} shall furnish all required services and activities as an independent contractor and not as an employee of {Milk Company} or of any company affiliated with {Milk Company}. The TPC does not have any power to or authority to act for, represent, or bind the MC or any company affiliated with the MC in any manner.

6.) **Third Party Certifier is not to Engage in Conflicting Activities**: {Third Party Certifier} shall conduct all services and activities required under this MOA with integrity and impartiality. The TPC shall avoid all conflicts of interest or the appearance of a conflict of interest. During the term of this MOA, {Third Party Certifier} shall not enter into any activity, employment, or business arrangement that conflicts with the MC's interests or their own obligations to {Milk Company} under this MOA, except that the TPC may sign an MOA with and provide regulatory and rating services to another MC as allowed under the NCIMS voluntary ICP.

The MC shall have the option of terminating this MOA if, at any time, in the MC's sole judgment, a conflict of interest exists or is imminent. The TPC shall advise the MC of any

activity, employment or business arrangement contemplated by the TPC that may be relevant to this Paragraph. Termination shall be in accordance with the notification requirements in Item 8. of this Agreement. The MC understands that if this MOA is terminated after they have been listed on the IMS List that their IMS Listings shall be immediately withdrawn from the IMS List and the MC shall be immediately removed from the NCIMS voluntary ICP.

7.) **Confidentiality**: {Third Party Certifier} shall treat all proprietary or privileged information obtained during the course of their services with the MC with strict confidentiality.

8.) **Termination of MOA by Notice**: Either party may terminate this MOA upon [number] days notice by registered or certified mail, return receipt requested, addressed to the other party. If either party terminates this MOA, both the TPC and the MC shall immediately notify the ICP Committee Chair and FDA MST. Upon the TPC ceasing to provide oversight of the MC, the MC shall be immediately withdrawn from the IMS List and immediately removed from the NCIMS voluntary ICP. Within fifteen (15) days of the TPC ceasing to provide oversight, they shall forward all related records, including, but not limited to: sample results, equipment tests, plant inspection notes and reports to FDA MST in a manner acceptable to FDA MST. FDA MST shall retain such records until such time as a suitable replacement TPC, within the criteria of the NCIMS voluntary ICP, has been hired to fulfill the obligations of the NCIMS voluntary ICP.

9.) **Issuance of Grade A Permit/License**: Upon execution of this MOA by all involved parties, it is understood that it effectively constitutes the authority of the TPC and the MC to operate within the framework of the Grade "A" Milk Safety Program and the NCIMS voluntary ICP. As such, this signed and dated MOA shall be accepted as the Grade "A" Permit/License as long as the TPC and MC are in good standing with the NCIMS voluntary ICP and this MOA has not expired. This MOA shall be renewed (signed and dated) on an annual basis.

Effective Date: This signed and dated MOA shall become effective upon receipt and written acceptance by the ICP Committee and FDA MST and LPET and may be subject to termination at any time as subject to the requirements of the NCIMS voluntary ICP and as cited in this MOA.

{TPC and MC} hereby agree to indemnify and hold harmless all members of the NCIMS, including, but not limited to, all members of the ICP Committee, all federal regulatory agencies including FDA, all Member State Regulatory/Rating Agencies, all trade associations including the International Dairy Foods Association (IDFA) and the National Milk Producers Federation (NMPF), and all private entities including companies and consultants, and their respective members, agents, officers, directors and employees, against any, and all losses, liabilities, costs, actions, claims and other obligations and proceedings, including any reasonable attorney's fees incurred in connection with, or which may arise or result in any way from the operation of the NCIMS voluntary ICP.

For the TPC: (Name of TPC) For the MC: (Name of MC)

Most Responsible Person: **Most Responsible Person:**

Signature: _____ Signature: _____

Name: _____ Name: _____

Title: _____ Title: _____

Date: _____ Date: _____

Expiration Date: _____

Document: 2011 CONSTITUTION
Pages: 49-53

*Make the following changes to the **2011 CONSTITUTION OF THE NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS** on Pages 49-53:*

Page 49:

ARTICLE II ------ MISSION

The mission of the Conference shall be to "Assure the Safest Possible Milk Supply for all the People" by:

SECTION 1. Adopting sound, uniform procedures, which will be accepted by participating ~~State Milk~~ Rating and ~~State Milk~~ Regulatory Agencies.

SECTION 2. Promoting mutual respect and trust between ~~State Milk~~ Rating and ~~State Milk~~ Regulatory Agencies of producing and receiving States and Third Party Certifiers.

SECTION 3. Utilizing Public Health Service/Food and Drug Administration (PHS/FDA) personnel for training programs and using that Agency as a channel for the dissemination of information among ~~State Milk~~ Rating and ~~State Milk~~ Regulatory Agencies for the objective of promoting uniformity among the States and ~~regions~~ Third Party Certifiers.

SECTION 4. Acquainting producers, processors, and consumers with the purpose of the Conference through the media of meetings, conferences, workshops, press releases, publications, and by utilization of facilities and personnel of educational institutions, trade associations, ~~State Milk~~ Rating and ~~State Milk~~ Regulatory Agencies and other groups that are willing to assist in the dissemination of such information.

Page 50:

ARTICLE IV ------ VOTING DELEGATES, EXECUTIVE BOARD, OFFICERS, EXECUTIVE SECRETARY, COMMITTEES, COUNCILS, AND PROGRAM CHAIR

SECTION 1. The voting delegates, of the Conference, are representatives of the State ~~Milk~~ Rating Agencies, State ~~Milk~~ Regulatory Agencies, and like representatives from the District of Columbia, participating U.S. Trust Territories and each participating non-U.S. country or political subdivisions thereof, as identified in Article VII, Section 4., Subdivision 3. of the *Bylaws*.

SECTION 4. The Board shall be composed up to ~~twenty-five (25)~~ twenty-six (26) members as follows:

Four (4) members from Group I (Eastern States); Six (6) members from Group II (Central States) (two (2) at large); Four (4) members from Group III (Western States); all to be elected by the General Assembly by majority vote (General Assembly is defined as qualified voting delegates, assembled at a biennial or special meeting of the Conference); plus one (1) member at large from each of Groups I (PHS/FDA) and III (United States Department of Agriculture (USDA)), appointed as outlined in the following Section; plus one (1) non-voting member at large representing consumers, appointed by the Chair and confirmed by the Board; plus one (1) non-voting representative from the Third Party Certifiers, appointed by the Chair and confirmed by the Board; plus the immediate Past Chair, the Program Chair, Chair of the NCIMS Liaison Committee, and the three (3) Council Chairs who are appointed by the Chair and confirmed by the Board; and one (1) representative each from the International Dairy Foods Association (IDFA) and the National Milk Producers Federation (NMPF). The Program Chair, Chair of the NCIMS Liaison Committee, the three (3) Council Chairs, the immediate Past Chair and the representatives from IDFA and NMPF, except as otherwise provided, shall serve on the Board as non-voting members. Each elected member of the Board shall serve through three (3) biennial meetings of the Conference. Full term Board members may succeed themselves, unless re-election would extend the total terms of consecutive service to more than twelve (12)

years.

Page 51:

SECTION 5. The membership of the Board shall be selected as follows:

Subd. 1. Group I -- Eastern States

The Eastern States are Connecticut, Delaware, Florida, Georgia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, North Carolina, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, Vermont, Virginia, West Virginia and the District of Columbia. A total of four (4) members shall be selected for election from this area (one (1) member from a State ~~Milk~~ Rating Agency, one (1) member from industry, one (1) member from a State ~~Milk~~ Regulatory Agency, plus one (1) member from either a ~~Local Health Authority, a~~ State ~~Milk~~ Rating or State ~~Milk~~ Regulatory Agency), plus one (1) member (at large) from the PHS/FDA to be appointed by the Commissioner of FDA.

Subd. 2. Group II -- Central States

The Central States are Alabama, Arkansas, Illinois, Indiana, Iowa, Kentucky, Louisiana, Michigan, Minnesota, Mississippi, Missouri, Ohio, Tennessee, and Wisconsin. A total of four (4) members shall be selected for election from this area (one (1) member from a State ~~Milk~~ Rating Agency, one (1) member from industry, one (1) member from a State ~~Milk~~ Regulatory Agency, plus one (1) member from either a ~~Local Health Authority, a~~ State ~~Milk~~ Rating or State ~~Milk~~ Regulatory Agency), plus one (1) member (at-large) from an educational institution and one (1) member (at-large) from a laboratory. The at-large members need not live or be employed in Group II.

Page 52:

Subd. 3. Group III -- Western States

The Western States are Alaska, Arizona, California, Colorado, Hawaii, Idaho, Kansas, Montana, Nebraska, Nevada, New Mexico, North Dakota, Oklahoma, Oregon, South Dakota, Texas, Utah, Washington and Wyoming. A total of four (4) members shall be selected for election from this area (one (1) member from a State ~~Milk~~ Rating Agency, one (1) member from industry, one (1) member from a State ~~Milk~~ Regulatory Agency, plus one (1) member from either a ~~Local Health Authority, a~~ State ~~Milk~~ Rating Agency or State ~~Milk~~ Regulatory Agency), plus one (1) member (at-large) from USDA to be appointed by

the Secretary of Agriculture. …

Page 53:

SECTION 6. The Board shall elect a Chair and a Vice Chair from its membership after each biennial meeting of the Conference and they may retain their position at the pleasure of the Board as long as they are officially members of the Board. If the Chair cannot perform the duties, the Board shall again elect a Chair. The Board shall retain the services of an Executive Secretary. The Executive Secretary shall be bonded, shall not have ~~no~~ a vote on the Board~~, shall have no vote~~ and in biennial or special meetings of the Conference; but shall perform all duties required in Article IV of the *Bylaws*. The compensation of the Executive Secretary shall be set by the Board. …

SECTION 10. Each Council shall have a voting membership of twenty (20) members to be appointed by the Chair with the approval of the Board.

Subd. 1. Each Council shall have ten (10) representatives from ~~State Milk~~ Rating and/or ~~State Milk~~ Regulatory Agencies and ten (10) representatives from industry. …

SECTION 11. Each Council shall have a Council Chair and a Vice Chair …

Subd. 2. If the Council Chair represents a ~~State Milk~~ Rating and/or ~~State Milk~~ Regulatory Agency, the Vice Chair shall represent industry. If the Council Chair represents industry, the Vice Chair shall represent a ~~State Milk~~ Rating and/or ~~State Milk~~ Regulatory Agency.

Document: 2011 BYLAWS
Pages: 55-62

*Make the following changes to the **2011 BYLAWS OF THE NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS** on Pages 55-62:*

Page 55:

ARTICLE I ------ DUTIES OF THE BOARD …

SECTION 5. The Board shall have the right of approval of the Nominating Committee appointed by the Chair at each Conference for the purpose of nominating registrants to be elected to the Board by the voting delegates. The Nominating Committee shall be composed of six (6) members, one (1) each from State ~~Milk~~ Rating and State ~~Milk~~ Regulatory Agencies in each of the three (3) geographical groups of States. …

Page 56:

SECTION 14. The Board shall, after written notification of PHS/FDA recommendations, within 120 days, rule on the matter of non-compliance with ~~State~~ Regulatory/Rating Agency Program Evaluations, including Regulatory, Rating and Laboratory as required by Section IV., A. 3.b. and VII., B. of the *Procedures*. …

ARTICLE II ------ DUTIES OF THE CHAIR …

Page 57:

SECTION 3. The Chair, with the approval of the Board, shall appoint qualified Conference registrants to Standing Committees, including the Constitution and Bylaws, Documents Review Committee, HACCP Implementation Committee, Laboratory, Methods of Making Sanitation Ratings, Liaison, Single-Service Container and Closure, Technical Engineering Review, Scientific Advisory, Hauling Procedures, ~~and~~ Other Species and International Certification Program Committees, and Councils as is necessary to carry out the mission of the Conference.

SECTION 5. The Chair shall assure that at least one half (1/2) the voting membership of Standing Committees, Ad hoc Committees and Study Committees as set forth in Article II, Sections 3. and 4. of the *Bylaws*, shall be composed of ~~State Milk~~ Rating and ~~State Milk~~ Regulatory Agencies, provided the membership of the Nominating Committee, Resolutions Committee and Constitution and Bylaws Committee shall consist in whole from State ~~Milk~~ Rating and State ~~Milk~~ Regulatory Agencies. The Nominating Committee shall be composed as set forth in Article I, Section 5. of the *Bylaws*. …

Page 58:

ARTICLE IV ------ DUTIES OF THE EXECUTIVE SECRETARY …

SECTION 3. At least sixty (60) days prior to a biennial meeting, or as soon as possible for a special meeting of the Conference, the Executive Secretary shall notify the office or offices of the ~~State Milk~~ Rating and/or ~~State Milk~~ Regulatory Agency or Agencies in each participating State and Third Party Certifier, or a like representative from the District of Columbia, participating U.S. Trust Territories and each participating non-U.S. country or political subdivision thereof, of the time and place of the next Conference, and the issues which are to be voted on in the General Assembly of the Conference under the heading of unfinished business. …

Page 59:

ARTICLE VI ------ DUTIES AND RESPONSIBILITIES OF COUNCILS …

SECTION 3. Council III shall deal with Proposals submitted to the Conference regarding Sections 11, 17, and 18 and Appendix K of the *Grade "A" Pasteurized Milk Ordinance*; the *Constitution* and *Bylaws*; the *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments*; issues of reciprocity; Proposals addressing the International Certification Program; and Proposals assigned from the Program Committee. …

Page 60:

SECTION 5. The Chair of each Council shall appoint four (4) alternate Council members representing a dairy processor, a dairy producer, a ~~State Milk~~ Regulatory Agency and a ~~State Milk~~ Rating Agency for review and approval by the NCIMS Executive Board prior to each Conference. Alternate Council members shall be seated to cast votes during periods of temporary absence of Council members and shall be designated to replace Council members for the entire Conference if they cannot attend. …

ARTICLE VII ------ RULES OF THE CONFERENCE …

Page 61:

SECTION 4. Rules of the delegate business meeting. …

Subd. 3. Only a registrant at the Conference, who is a representative of a State ~~Milk~~ Rating Agency or a State ~~Milk~~ Regulatory Agency responsible for the enforcement of sanitation laws for Grade "A" milk and milk products, Grade "A" condensed and dry milk products and Grade "A" whey and whey products, or a like representative from the District of Columbia, or a participating U.S. Trust Territory, or a participating non-U.S. country or political subdivision thereof, is entitled to be a voting delegate. When any State is represented by both ~~Milk~~ Rating and ~~Milk~~ Regulatory Agencies, the vote may be cast together as one (1) vote or separately as one-half (1/2) vote each, provided that any State represented by both ~~Milk~~ Rating and ~~Milk~~ Regulatory delegates certified in compliance with the provisions of Subdivision 4. of this Section may during any delegate business meeting, reassign its one-half (1/2) vote privilege to the other duly certified State delegate by giving written notice of such action to the Chair. …

Page 62:

Subd. 4. Ninety (90) days prior to the biennial meeting of the Conference, or as soon as possible for a special meeting of the Conference, the Executive Secretary shall send to the office, or offices, of the State ~~Milk~~ Rating or State ~~Milk~~ Regulatory Agency or Agencies in each participating State, the District of Columbia, participating U.S. Trust Territories and each participating non-U.S. country or political subdivision thereof, notice of the forthcoming meeting. Each notice shall include a copy of Article VII, Section 4., Subdivisions 3. and 4. of the *Bylaws* that outlines the designation of voting delegates and their privileges.

Each Agency shall report to the Executive Secretary, in writing on forms provided, within thirty (30) days of the Conference, or a date determined by the Chair for a special meeting, the following:

a. Its officially designated responsibility whether as State ~~Milk~~ Rating Agency only, or as State ~~Milk~~ Regulatory Agency only, or both as identified in Article VII, Section 4., Subdivision 3. of the *Bylaws*. …

Document: 2011 MMSR (Entire Document)
Pages: Entire Document

*Make the following changes to the **2011 MMSR**:*

Cover:

~~2011~~ 2013 Revision

Page 1:

PREFACE

The objective of a rating is to provide an assessment of ~~State and Local~~ the Regulatory Agency's sanitation activities regarding public health protection and milk quality control. This is accomplished by evaluating sanitation compliance and enforcement standards of the current edition of the *Grade "A" Pasteurized Milk Ordinance* (*Grade "A" PMO)* and Related Documents as listed in the *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments* (*Procedures*). Rating results are used for the purpose of evaluating the sanitation compliance and enforcement requirements of shippers to determine the degree of compliance with public health standards as expressed in the *Grade "A" PMO.* Rating results are further utilized as a means of uniform education and interpretation, in addition to providing a basis for the acceptance/rejection of shippers by Regulatory ~~Officials~~ Agencies beyond the limits of routine inspection. Rating results are intended to establish uniform reciprocity between ~~States~~

Regulatory Agencies to prevent unnecessary restrictions of the interstate flow of milk and/or milk products, yet assure public health protection.

The rating method for evaluating the sanitary quality of milk and/or milk products measures the extent to which a shipper complies with the standards contained in the *Grade "A" PMO*. These nationally recognized standards, rather than local requirements, are used as a yardstick in order that ratings of individual Bulk Tank Units (BTUs) or attached shippers and milk plants, receiving stations and/or transfer stations may be comparable to each other, both interstate and intrastate. Ratings are expressed in terms of percentage compliance. For example, if the milk plant, receiving station, transfer station and/or dairy farms comply with all of the requirements of the *Grade "A" PMO*, the Sanitation Compliance Rating of the pasteurized milk supply and/or raw milk supply, respectively would be one hundred percent (100%); whereas, if the milk plant, receiving station, transfer station or some of the dairy farms fail to satisfy one (1) or more of these requirements, the Sanitation Compliance Rating would be reduced in proportion to the amount of milk and/or milk products involved in the violation and to the relative public health significance of the violated Item(s). Procedures for the collection of data, the computation of Sanitation Compliance Ratings for raw milk for pasteurization and pasteurized milk, and the computation of the Enforcement Rating of the Regulatory Agency, responsible for administering milk sanitation regulations, are described in the following Sections. …

Page ii:

A. DEFINITIONS

Page 2:

7. **CERTIFIED MILK LABORATORY EVALUATION OFFICER (LEO):** A Regulatory Agency or Milk Laboratory Control Agency employee who has been certified by the Public Health Service/Food and Drug Administration (PHS/FDA) Laboratory Proficiency Evaluation team (LPET) using the Evaluation of Milk Laboratories (EML) to evaluate milk laboratories for the purpose of accrediting or approving laboratories that conduct official NCIMS milk testing and has a valid certificate of qualification.

~~7~~8. **CERTIFIED MILK SANITATION RATING OFFICER (SRO):** A ~~State~~ Regulatory Agency employee who has been ~~standardized~~ certified by the Public Health Service/Food and Drug Administration (PHS/FDA), has a valid certificate of qualification and does not have direct responsibility for the routine regulatory inspection and enforcement or regulatory auditing of the shipper to be rated or listed. Directors, administrators, supervisors, etc. may be certified as Milk Sanitation Rating Officers (SROs). A Milk Sanitation Rating Officer (SRO) may be certified to make HACCP milk plant, receiving station or transfer station listings.

9. **CERTIFIED SAMPLING SURVEILLANCE OFFICER (SSO):** A Regulatory Agency employee who has been certified by the Public Health Service/Food and Drug Administration (PHS/FDA) and has a valid certificate of qualification. Directors, administrators, supervisors, etc., Milk Sanitation Rating Officers (SROs), Laboratory Evaluation Officers (LEOs), etc. may

be certified as Sampling Surveillance Officers (SSOs).

~~8~~10. **CRITICAL LISTING ELEMENT (CLE):** An item on FORM FDA 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT identified with a double star (**). The marking of a CLE by a Milk Sanitation Rating Officer (SRO) or FDA auditor, indicates a condition that constitutes a major dysfunction likely to result in a potential compromise to milk and/or milk product safety, or that violates NCIMS requirements regarding drug residue testing and trace back and/or raw milk sources, whereby a listing may be denied or withdrawn.

Renumber remaining DEFINITIONS accordingly.

~~12~~14. **HACCP LISTING:** An inclusion ~~in~~ on the *IMS List–Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers* (*IMS List*) based on a ~~SROs~~ Milk Sanitation Rating Officer's (SRO's) evaluation of a milk plant's, receiving station's or transfer station's NCIMS voluntary HACCP Program and other applicable NCIMS requirements.

~~13~~15. **INDIVIDUAL RATING:** …

Page 3:

16. **INTERNATIONAL CERTIFICATION PROGRAM (ICP):** The International Certification Program (ICP) means the NCIMS voluntary program designed to utilize Third Party Certifiers (TPCs) authorized by the NCIMS Executive Board in applying the requirements of the NCIMS Grade "A" Milk Safety Program for Milk Companies (MCs) located outside the geographic boundaries of NCIMS Member States that desire to produce and process Grade "A" milk and/or milk products for importation into the United States.

17. **LETTER OF INTENT (LOI):** A formal written signed agreement between a Third Party Certifier (TPC), authorized under the NCIMS voluntary International Certification Program (ICP), and a Milk Company (MC) that intends to be certified and IMS Listed under the NCIMS voluntary International Certification Program (ICP). A copy of each written signed agreement shall be immediately submitted to the International Certification Program (ICP) Committee following the signing by the Third Party Certifier (TPC) and Milk Company (MC).

18. **LETTER OF UNDERSTANDING (LOU):** A formal written signed agreement between a Third Party Certifier (TPC) and the NCIMS Executive Board that acknowledges the NCIMS' authorization of the Third Party Certifier (TPC) to operate under the NCIMS voluntary International Certification Program (ICP). It also states the Third Party Certifier's (TPC's) responsibilities under the NCIMS voluntary International Certification Program (ICP); their agreement to execute them accordingly; and their understanding of the consequences for failing to do so. The Letter of Understanding (LOU) shall include, but is not limited to, the issues and concerns addressed in all documents involved in the NCIMS voluntary International Certification Program (ICP).

~~14~~19. **LISTING AUDIT:** …

20. **MEMORANDUM OF AGREEMENT (MOA):** A formal written signed memorandum that states the requirements and responsibilities of each party (Third Party Certifier (TPC) and Milk Company (MC)) to participate and execute the NCIMS voluntary International Certification Program (ICP). The Memorandum of Agreement (MOA) shall include, but is not limited to, the issues and concerns addressed in all documents involved in the NCIMS voluntary International Certification Program (ICP). This agreement shall be considered the Milk Company's (MC's) permit to operate in the context of the NCIMS Grade "A" Milk Safety Program and shall be renewed (signed and dated) on an annual basis.

21. **MILK COMPANY (MC):** A Milk Company (MC) is a private entity that is listed on the IMS List by a Third Party Certifier (TPC) including all associated dairy farms, bulk milk haulers/samplers, milk tank trucks, milk transportation companies, milk plants, receiving stations, transfer stations, dairy plant samplers, industry plant samplers, milk distributors, etc. and their servicing milk and/or water laboratories, as defined in the *Grade "A" PMO*, located outside the geographic boundaries of NCIMS Member States.

~~15~~22. **MILK PLANT** ….

23. **RATING AGENCY:** A Rating Agency shall mean a State Agency, which certifies interstate milk shippers (BTUs, receiving stations, transfer stations, and milk plants) as having attained the Sanitation Compliance and Enforcement Ratings necessary for inclusion on the *IMS List*. The ratings are based on compliance with the requirements of the *Grade "A" PMO* and were conducted in accordance with the procedures set forth in the *Methods of Making Sanitation Ratings of Milk Shippers (MMSR)*. Ratings are conducted by FDA certified Milk Sanitation Rating Officers (SROs). They also certify single-service containers and closures for milk and/or milk products manufacturers for inclusion on the *IMS List*. The certifications are based on compliance with the requirements of the *Grade "A" PMO* and were conducted in accordance with the procedures set forth in the *Methods of Making Sanitation Ratings of Milk Shippers (MMSR)*. The definition of a Rating Agency also includes a Third Party Certifier (TPC) that conducts ratings and certifications of Milk Companies (MCs) located outside the geographic boundaries of NCIMS Member States that desire to produce and process Grade "A" milk and/or milk products for importation into the United States. …

~~16~~24. **RECEIVING STATION:** …

~~17~~25. **RECIPROCITY:** For the purposes of the *National Conference on Interstate Milk Shipments* (NCIMS) agreements, reciprocity shall mean ~~no~~ any action or requirements on the part of any Regulatory Agency will not cause or require any action in excess of the requirements of the current edition of the *Grade "A" PMO* and Related Documents of the NCIMS agreements.

~~18~~26. **REGULATORY AGENCY:** A Regulatory Agency shall mean an agency which has adopted an ordinance, rule or regulation in substantial compliance with the current edition of the *Grade "A" PMO* ~~or two (2) agencies which have mutually agreed to share the~~ and is ~~responsibilities~~ responsible for the enforcement of ~~an~~ such ordinance, rule or regulation, which is in substantial compliance with the *Grade "A" PMO* for a listed interstate milk

shipper. ~~The mutual agreement shall specify the details of how the rating will be made so long as the details do not conflict with the basic intent of this document.~~ The term, "Regulatory Agency", whenever it appears in the *MMSR* shall also mean the appropriate Third Party Certifier (TPC) having jurisdiction and control over the matters cited within this *MMSR*.

27. **THIRD PARTY CERTIFER (TPC):** A Third Party Certifier (TPC) is a non-governmental individual(s) or organization authorized under the NCIMS voluntary International Certification Program (ICP) that is qualified to conduct the routine regulatory functions and enforcement requirements of the *Grade "A" PMO* in relationship to milk plants, receiving stations, transfer stations, associated dairy farms, bulk milk hauler/samplers, milk tank trucks, milk transportation companies, dairy plant samplers, industry plant samplers, milk distributors, etc. participating in the NCIMS voluntary International Certification Program (ICP). The Third Party Certifier (TPC) provides the means for the rating and listing of milk plants, receiving stations, transfer stations and their related raw milk sources. They also conduct the certification and IMS listing of related milk and/or water laboratories and related single-service container and closure manufacturers on the *Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers (IMS) List*. To be authorized under the NCIMS voluntary International Certification Program (ICP), a valid Letter of Understanding (LOU) shall be signed between the NCIMS Executive Board and the Third Party Certifier (TPC).

~~19~~28. **TRANSFER STATION:** …

B. RATING METHODS FOR RAW MILK FOR PASTEURIZATION …

2. COLLECTION OF DATA …

Page 6:

c. Number of Bulk Milk Hauler/Samplers to be Evaluated

At each ~~producer~~ dairy farm, during the rating or check rating of a BTU, determine the identification of the bulk milk hauler/sampler(s), from at least the previous thirty (30) days, to be used when computing FORM FDA 2359j-MILK SANITATION RATING REPORT, SECTION C. EVALUATION OF SAMPLING PROCEDURES (PAGE 3). Obtaining records on bulk milk hauler/samplers from other ~~States~~ Regulatory Agencies may be necessary, depending on the Regulatory Agency, which issued the permit(s). …

Page 7:

e. Recording of Laboratory and Other Test Data

1.) Regulatory Agency records are used in determining compliance with bacterial, drug residue, somatic cell, and cooling temperature requirements. The acceptance of data from official and/or officially designated laboratories is contingent upon the utilization of standard procedures by the laboratories concerned. Accordingly, it is necessary for

the SRO to determine from the official ~~State~~ Milk Laboratory ~~Certifying~~ Control Agency that both sampling and laboratory procedures have been approved in accordance with the methods of the current edition of the *Evaluation of Milk Laboratories* (*EML*). Ratings shall not be conducted when an approved laboratory is not utilized by the Regulatory Agency for the necessary tests. …

3.) The SRO ~~may~~ shall utilize the Regulatory Agency's records in determining compliance with those Items of sanitation which require laboratory tests to complete the evaluation. …

Page 8:

NOTE: Item 8-Water Supply on FORM FDA 2359a-DAIRY FARM INSPECTION REPORT has been divided into two (2) point and five (5) point violations/debits. The maximum point value for the entire Item 8r cannot exceed five (5) points on FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION. (Refer to Appendix B. TABLE OF FARM WATER SUPPLY VIOLATIONS, which provides guidance, which may be used to differentiate between two (2) point (minor) and five (5) point (major) violations of Section 7, Item 8r of the *Grade "A" PMO* during ~~State~~ Ratings and FDA Check Ratings.) …

C. RATING METHODS FOR MILK PLANTS, RECEIVING STATIONS AND TRANSFER STATIONS …

2. COLLECTION OF DATA …

Page 11:

b. Recording of Laboratory and Other Test Data

1.) Regulatory Agency records are used in determining compliance with bacterial, coliform, phosphatase, drug residue, and cooling temperature requirements. The acceptance of data from official and/or officially designated laboratories is contingent upon the utilization of standard procedures by the laboratories concerned. Accordingly, it is necessary for the SRO to determine from the official ~~State~~ Milk Laboratory ~~Certifying~~ Control Agency that both sampling and laboratory procedures have been approved in accordance with the methods of the current edition of the *EML*. Ratings and HACCP listing audits shall not be conducted when an approved laboratory has not been utilized by the Regulatory Agency for the necessary tests. …

3.) The SRO ~~may~~ shall utilize Regulatory Agency's records in determining compliance with those Items of sanitation, which require laboratory tests to complete the evaluation. Official records of Equipment Tests may also be used in lieu of performing such Equipment Tests during the rating. Provided, that the SRO is satisfied as to the competency of the Regulatory Agency's personnel to perform these Equipment Tests as described in Appendix I. of the *Grade "A" PMO*. …

Page 14:

d. Recording of Data from Milk Plants and receiving Stations being Listed Under the NCIMS Aseptic Processing and Packaging Program and/or the NCIMS Retort Processed after Packaging Program

1.) Inspection Criteria …

(B.) ~~State~~ Regulatory Agency inspections of a milk plant or portion of a milk plant that is listed to produce aseptically processed and packaged Grade "A" milk and/or milk products shall be conducted in accordance with the *Grade "A" PMO* at least once every six (6) months. The milk plant's APPS, as defined by the *Grade "A" PMO,* shall be inspected by FDA, or ~~the State~~ a Regulatory Agency ~~when~~ designated by FDA under the FDA LACF, in accordance with the applicable requirements of 21 CFR Parts 108, 110 and 113 at a frequency determined by FDA. …

4. MILK PLANTS …

Page 20:

b. Milk Plant with an Unattached Supply of Raw Milk …

3.) The utilization of milk from a separately rated source, which has a ~~Milk~~ Sanitation Compliance Rating, which is not equal to ninety percent (90%) or greater, or is from an unlisted source, would initiate an immediate withdrawal of the shipper from the *IMS List*. …

Page 21:

c. Milk Plant with an Attached Supply of Raw Milk …

3.) The utilization of milk from a separately rated source, which has a ~~Milk~~ Sanitation Compliance Rating, which is not equal to ninety percent (90%) or greater, or is from an unlisted source, would initiate an immediate withdrawal of the shipper from the *IMS List*. …

Page 23:

F. PUBLICATION OF THE "INTERSTATE MILK SHIPPER's REPORT"

1. PURPOSE

a. The *IMS List-Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers* (*IMS List*) is an electronic publication of CFSAN's Milk Safety ~~Branch~~ Team (HFS-316), Food and Drug Administration, 5100 Paint Branch Parkway, College Park,

MD 20740-3835. This is a part of the activities of the PHS/FDA in cooperation with the ~~States~~ Regulatory Agencies in the cooperative program for the certification of interstate milk shippers. …

b. Triplicate copies or PHS/FDA's electronic version (transmitted via computer) of FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT shall be submitted by the ~~State Rating Officer~~ SRO to the appropriate PHS/FDA Regional Office ~~of the PHS/FDA~~ or PHS/FDA MST for TPCs for shippers who desire to be listed ~~in~~ on the *IMS List*. (Refer to Section G, #s 8 and 9 for a copy of the Form.)

A signed copy of a written FORM FDA 2359o-PERMISSION FOR PUBLICATION - INTERSTATE MILK SHIPPER's LISTING shall accompany each triplicate set of FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT, submitted to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs for publication ~~in~~ on the *IMS List*. For the submission of PHS/FDA's electronic version, a signed copy of the written FORM FDA 2359o-PERMISSION FOR PUBLICATION - INTERSTATE MILK SHIPPER'S LISTING shall be maintained on file by the Rating Agency for publication ~~in~~ on the *IMS List* and ~~will~~ shall be reviewed as part of the check rating and/or ~~State~~ Regulatory/Rating Agency Program Evaluation. Once a shipper has been listed, all new ratings shall be submitted to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs even though the shipper has refused to sign a written FORM FDA 2359o-PERMISSION FOR PUBLICATION - INTERSTATE MILK SHIPPER's LISTING. Supporting sampling and laboratory certification reports, as specified in the *Procedures,* are also necessary for inclusion and retention of the shipper on the list. (Refer to Section G, #12 for a copy of the Form.)

Page 24:

The Sanitation Compliance Rating of a shipper is not published unless the written and signed FORM FDA 2359o-"PERMISSION FOR PUBLICATION - INTERSTATE MILK SHIPPER's LISTING" of the shipper concerned has been obtained by the ~~State Milk Sanitation~~ Rating Agency. Milk plants, receiving stations and transfer stations shall achieve a Sanitation Compliance Rating of ninety percent (90%) or greater in order to be eligible for a listing ~~in~~ on the *IMS List*. The Sanitation Compliance Rating ~~score~~ for milk plants, receiving stations and transfer stations will not be printed ~~in~~ on the *IMS List*.

2. PREPARATION OF THE "INTERSTATE MILK SHIPPER's REPORT" …

Page 25:

c. Milk Plant

1.) Attached Supply Only: A milk plant with a single source of raw milk, both under the jurisdiction of the same Regulatory Agency. …

Following the computation of the Sanitation Compliance Rating on FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, FORM FDA 2359L-STATUS OF MILK PLANTS, and Parts I, II and III of FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), the resultant data ~~will~~ shall be transferred to FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT. The earliest rating date shall be the date of the first day of the rating of the dairy farms (BTU) or milk plant, whichever is earliest in time. …

2.) Attached Supply and Unattached Supplies: A milk plant with a source of raw milk ~~for pasteurization~~ under the jurisdiction of the same Regulatory Agency as the milk plant and one (1) or more sources of raw milk ~~for pasteurization~~ from other separate rated and listed sources.

Following the computation of the Sanitation Compliance Rating on FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, FORM FDA 2359L-STATUS OF MILK PLANTS, and Parts I, II and III of FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), the resultant data ~~will~~ shall be transferred to FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT. The earliest rating date and the Raw Milk Sanitation Compliance Rating shall be computed by the following methods:

All unattached supplies shall have a Sanitation Compliance Rating of ninety percent (90%) or greater. The Sanitation Compliance Rating of the attached supply shall be reported as the Raw Milk Sanitation Compliance Rating for the milk plant. The earliest rating date shall be reported on FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT. In addition, the name of each unattached shipper, during the thirty (30) days preceding the rating, along with the Sanitation Compliance Rating and Date of Rating of each shipper shall be listed on the reverse side of FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT. If milk is received from an unlisted source or from a source having a Raw Milk Sanitation Compliance Rating of less than ninety percent (90%), the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs shall be notified and the milk plant shall be immediately withdrawn from the *IMS List.*…

Page 26:

3.) Unattached Supplies Only: A milk plant with one (1) or more sources of raw milk received from other rated and listed sources.

Following the computation of the Sanitation Compliance Rating on FORM FDA 2359L-STATUS OF MILK PLANTS and Parts II and III of FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), the resultant data ~~will~~ shall be transferred to FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT. The earliest rating date and the ~~Milk~~ Sanitation Compliance Rating shall be computed by one (1) of the following two (2) options: …

A.) **Option 1:** If all raw milk sources have a published, or submitted for publication, Sanitation Compliance Rating of ninety percent (90%) or greater and the milk plant desires to be listed with the milk plant rating date, the raw milk ~~will~~ shall be reported as ninety percent (90%) or listed with an asterisk (*), which denotes all supplies are ninety percent (90%) or greater. This ~~will~~ shall eliminate the need for frequent updating of FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT by the ~~State Milk Sanitation~~ Rating Agency. Certain precautions shall be taken to ensure that the raw supply remains at or above the required listed ninety percent (90%) Sanitation Compliance Rating. The name of each shipper of raw milk for the thirty (30) days preceding the rating shall be listed on the reverse side of FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT, along with their Sanitation Compliance Rating and the Expiration Rating Date ~~of Rating~~. The milk plant shall be immediately withdrawn from the *IMS List* when milk is received from an unlisted source or from a source having a Raw Milk Sanitation Compliance Rating of less than ninety percent (90%). The appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs shall be immediately notified ~~should~~ shall either of the above events occur.

B.) **Option 2:** If the milk plant desires to be listed with the actual Sanitation Compliance Rating of the raw milk, a weighted average of all raw milk sources, the requirements of the preceding **Option** shall also apply except that:

(i) The earliest rating date of any of the raw milk sources or the milk plant, whichever is earliest in time, ~~will~~ shall be shown as the earliest rating date on FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT.

(ii) The Raw Milk Sanitation Compliance Rating ~~will~~ shall be prorated on a weighted basis as follows: …

Page 27:

The SRO shall re-compute the Raw Milk Sanitation Compliance Rating whenever any of the raw milk sources is re-rated and a new FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT shall be submitted to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs.

NOTE: The acceptance of milk, which has a Sanitation Compliance Rating ~~score~~ of less than ninety percent (90%), or is from an unlisted source, is a violation of the agreed upon provisions of **Options 1** and **2** and ~~would~~ shall initiate an immediate withdrawal of the shipper from the *IMS List*.

The utilization of milk from a separately rated source which has an Enforcement Rating of less than ninety percent (90%) for longer than six (6) months, or which has been re-rated and received an Enforcement Rating of less than ninety percent (90%), following a rating with an Enforcement Rating of less than ninety percent (90%), is considered a violation of Section 11 of the *Grade "A" PMO* and ~~would~~ shall initiate an immediate withdrawal of the shipper from the ~~IMS list~~ *IMS List*.

3. PREPARATION OF THE "INTERSTATE MILK SHIPPER's REPORT" FOR HACCP LISTINGS …

a. A statement regarding the acceptability, or unacceptability of the HACCP System ~~will~~ shall be substituted on FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT for the Sanitation Compliance and Enforcement ~~Rating Scores~~ Ratings; and

b. FORM FDA 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT and FORM FDA 2359n-NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT shall be submitted to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs for quality assurance reviews with all FORM FDA 2359i's.

G. **EXAMPLES OF RATING, NCIMS HACCP LISTING, AND ASEPTIC PROCESSING AND PACKAGING PROGRAM LISTING FORMS** …

Page 38:

FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT

FRONT

STATE/COUNTRY

(10/~~11~~13)

Page 39:

BACK

CITY AND STATE/COUNTRY

(10/~~11~~13)

Page 41:

FORM FDA 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT

PAGE 1

TYPE OF AUDIT

☐ ~~STATE~~ REGULATORY* ☐ ~~STATE~~ REGULATORY FOLLOW-UP ☐ ~~STATE~~ LISTING ☐ FDA AUDIT OF LISTING

STATE/COUNTRY

(10/~~11~~13)

Page 42:

PAGE 2

(10/~~11~~13)

Page 43:

PAGE 3

(10/~~11~~13)

Page 44:

FORM FDA 2359n-NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT

2. Milk plant, receiving station or transfer station audited by a HACCP trained ~~State~~ Regulatory Agency auditor at the minimum required frequency and follow-ups conducted as required.

(10/~~11~~13)

Page 45:

FORM FDA 2359o-PERMISSION FOR PUBLICATION-*Interstate Milk Shipper's Listing*

Publication Permission Section

Permission is hereby granted to release and publish the above-stated Rating or HACCP Listing for use by ~~State and Territorial Milk Control Authorities~~ Regulatory Agencies and prospective purchasers. …

(10/~~10~~13)

G. EXAMPLES OF HOW TO PROPERLY COMPLETE RATING, NCIMS HACCP LISTING, AND ASEPTIC PROCESSING AND PACKAGING PROGRAM LISTING FORMS

Pages 65 and 72:

FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT

FRONT
STATE/COUNTRY

(10/~~11~~13)

Pages 66 and 73:

BACK
CITY AND STATE/COUNTRY

Page 66:

ABC BTU	Bulls Role, State/Country
Udderly Delightful BTU	Tootle Town, State/Country
GMI Good Dairy	Paradise, State/Country

(10/~~11~~13)

Page 73:

Cows BTU #1	Midtown, State/Country
Udderly Delightful BTU #2	Tootle Town, State/Country
Moosville BTU	Cow Palace, State/Country

Page 68:

FORM FDA 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT

PAGE 1

TYPE OF AUDIT
☐ ~~STATE~~ REGULATORY* ☐ ~~STATE~~ REGULATORY FOLLOW-UP ☐ ~~STATE~~ LISTING ☐ FDA AUDIT OF LISTING

STATE/COUNTRY
(10/~~11~~13)

Page 69:

PAGE 2

(10/~~11~~13)

Page 70:

PAGE 3

(10/~~11~~13)

Page 71:

FORM FDA 2359n-NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT

2. Milk plant, receiving station or transfer station audited by a HACCP trained ~~State~~ Regulatory Agency auditor at the minimum required frequency and follow-ups conducted as required.

(10/~~10~~13)

Pages 74 and 75:

FORM FDA 2359o-PERMISSION FOR PUBLICATION-*Interstate Milk Shipper's Listing*

Publication Permission Section

Permission is hereby granted to release and publish the above-stated Rating or HACCP Listing for use by ~~State and Territorial Milk Control Authorities~~ Regulatory Agencies and prospective purchasers. …

(10/~~10~~13)

Page 79:

APPENDIX A.

GUIDELINES FOR COMPUTING ENFORCEMENT RATINGS
(FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2))

PART I. DAIRY FARMS

~~NOTE:~~ Enforcement evaluation is based on NCIMS requirements, not on individual State's and/or Country's laws or regulations.

The term "permit", whenever it appears in this document shall also mean a MC operating under the ICP possessing a valid MOA with a TPC.

1. All dairy ~~farms~~ farm operators hold valid permits (*Grade "A" PMO*, Section 3 - PERMITS). Prorate by the number of dairy farms in compliance.

Page 80:

5. Tuberculosis and Brucellosis Certification on file as required (*Grade "A" PMO*, Section 8 - ANIMAL HEALTH and APPENDIX A. - ANIMAL DISEASE CONTROL). All or nothing Item based on record verification.

a. Located in a Certified Brucellosis - Free Area as defined by USDA and enrolled in the testing program for such areas; or

1.) Meet USDA requirements for an individually certified herd; or
2.) Participate in an approved milk ring testing program; or
3.) Have individual blood agglutination testing done annually; or
4.) For goat, sheep, water buffalo, or any other hooved mammal herds/flocks, excluding cattle and bison, they are included in an official annual written certification from the State Veterinarian documenting their brucellosis-free status.

b. Located in an Area, which has a Modified Accredited Advanced Tuberculosis status or greater as determined by USDA. Other Areas or herds shall have passed an annual tuberculosis test or the Area has established a tuberculosis testing protocol that assures tuberculosis protection and surveillance of the dairy industry and is approved by FDA, USDA and the ~~State~~ Regulatory Agency….

e. Milk from Brucellosis reactor animals withheld as required.

NOTE: For the ICP, references to USDA and/or State within 5 above, shall mean the Government Agency responsible for animal disease control in the Country or region of that Country. The term "State Veterinarian" shall mean an individual veterinarian authorized for those activities in said Country or region of that Country.

6. Water samples tested and reports on file as required (*Grade "A" PMO*, Section 7 - STANDARDS FOR MILK AND MILK PRODUCTS, APPENDIX D. - STANDARDS FOR WATER SOURCES and APPENDIX G. - CHEMICAL AND BACTERIOLOGICAL TESTS). Prorate by number of dairy farms in compliance. A dairy farm missing one (1) water sample during a required time period ~~will~~ shall not receive any credit for this Item.

NOTE: A single dairy farm BTU ~~will~~ shall be prorated by the number of water samples tested during the required time period vs. the total number of water tests due per water system. …

Page 81:

f. ~~No sampling~~ Sampling is not required for public, community, or rural water system(s), which are under EPA/~~State~~ applicable Government Water Control Authority and in compliance with their requirements. …

NOTE: ~~State~~ Applicable Government Water Control Authority requirements, which are less stringent than the *Grade "A" PMO*, shall be superseded by the *Grade "A" PMO*. ~~State~~ Applicable Government Water Control Authority requirements, which are more strict than the *Grade "A" PMO*, shall not be considered in determining the acceptability of water supplies during ratings, check ratings, single-service listing evaluations and audits.

For Example: If the ~~State~~ applicable Government Water Control Authority's law required more frequent individual water supply samples to be taken, a SRO conducting a ~~sanitation~~

rating, which includes that dairy farm ~~or milk plant~~, ~~will now~~ shall give that dairy farm ~~or milk plant~~ full credit for water sample frequency, if the *Grade "A" PMO* minimum sampling frequency requirement is met, even though, the ~~State~~ applicable Government Water Control Authority's frequency is not met.

Supplies other than individual water supplies, which have been approved as safe by the ~~State~~ applicable Government Water Control Authority, shall be considered to be acceptable sources, as provided in Section 7 of the *Grade "A" PMO*, for Grade "A" inspections, as well as for all other IMS purposes, without further inspection of the spring, well or reservoir treatment facility(ies), testing records, etc. …

Page 82:

10. Permit issuance, suspension, revocation, reinstatement, hearings and/or court action taken as required (*Grade "A" PMO*, Section 3 - PERMITS, Section 5 - INSPECTION OF DAIRY FARMS, Section 6 - EXAMINATION OF MILK AND MILK PRODUCTS and Section 16 - PENALTY). The BTU ~~will~~ shall be prorated by enforcement action(s) in compliance per dairy farm. Five (5) Categories (a-e) ~~will~~ shall be utilized for determining compliance with this Item and each ~~will~~ shall possess a value of twenty percent (20%) compliance. The Categories are as follows: …

e. Category V: Hearing/Court Action

The Categories relate to the following Sanitation Requirements and Product Compliance. Compliance ~~will~~ shall be prorated based on **full** compliance with each of the five (5) Categories. …

SANITATION REQUIREMENTS …

Category II: Permit Suspension …

c. Milk produced during suspension or while a monetary penalty is imposed for repeated inspection violations is not eligible for sale as Grade "A".

Page 83:

NOTE: *Grade "A" PMO*, Section 3 states: "The Regulatory Agency may forego suspension of the permit, provided the milk and/or milk product in violation is not sold or offered for sale as a Grade "A" milk and/or milk product. A Regulatory Agency may allow the imposition of a monetary penalty in lieu of a permit suspension, provided the milk and/or milk product in violation is not sold or offered for sale as a Grade "A" milk and/or milk product. Except, that a milk producer may be assessed a monetary penalty in lieu of permit suspension for violative counts provided ….."

The option to issue a monetary penalty in lieu of a permit suspension as cited above, shall not be applicable to a TPC authorized under the ICP. …

PRODUCT COMPLIANCE …

Category II: Permit Suspension

a. All milk produced during a permit suspension or while a monetary penalty is imposed for bacterial, somatic cell, cooling temperature or drug residue violation is not eligible for sale as Grade "A". …

c. Permit suspension; stop sale; or imposition of a monetary penalty upon violation of:

1.) Section 3 for serious health hazard; or
2.) Section 6 for:
   i. Three (3) out of the last five (5) samples exceeding the bacterial, somatic cell, or cooling temperature standards; or
   ii. "Four (4) in six (6) months" positive antibiotic (not of Appendix N. origin); or
   iii. If pesticide contaminated milk is not withheld from sale.

NOTE: The option to issue a monetary penalty in lieu of a permit suspension as cited above, shall not be applicable to a TPC authorized under the ICP. …

Page 84:

11. Records systematically maintained and current (*Grade "A" PMO*, Section 3 - PERMITS, Section 5 - INSPECTION OF DAIRY FARMS, Section 6 - EXAMINATION OF MILK AND MILK PRODUCTS, and Section 7 - STANDARDS FOR MILK AND MILK PRODUCTS). Make use of both general record-keeping deficiencies and record keeping by dairy farm to determine the value. The BTU ~~will~~ shall be prorated by the number of identified record-keeping deficiencies per dairy farm. The four (4) Categories (a-d) listed below ~~will~~ shall be utilized for determining compliance with this Item and each ~~will~~ shall possess a value of twenty-five percent (25%) compliance. Compliance ~~will~~ shall be prorated based on **full** compliance with each of the four (4) Categories.

NOTE: Use FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 4). (Refer to Section G, #4 for an example of the Form.)

a. Category I: Permit records available, accurate and current, including permit suspension, impositions of a monetary penalty, notices, reinstatement, etc. The results shall be entered on appropriate ledger forms. The use of a computer or other information retrieval system may be used.

NOTE: The option to issue a monetary penalty in lieu of a permit suspension as cited above, shall not be applicable to a TPC authorized under the ICP. …

Page 85:

PART II. MILK PLANTS

~~**NOTE:**~~ Enforcement evaluation is based on NCIMS requirements, not on individual State's and/or Country's laws or regulations.

The term "permit", whenever it appears in this document shall also mean a MC operating under the ICP possessing a valid MOA with a TPC. …

Page 87:

6. Individual and cooling water samples tested and reports on file as required (*Grade "A" PMO*, …

c. ~~No sampling~~ Sampling is not required for public, community, or rural water system(s), which are under EPA/~~State~~ applicable Government Water Control Authority and in compliance with their requirements. …

Page 88:

j. Current records of sample results on file at the Regulatory Agency, back to the last rating.

NOTE: ~~State~~ Applicable Government Water Control Authority requirements, which are less stringent than the *Grade "A" PMO*, shall be superseded by the *Grade "A" PMO*. ~~State~~ Applicable Government Water Control Authority requirements, which are more strict than the *Grade "A" PMO*, shall not be considered in determining the acceptability of water supplies during ratings, check ratings, single-service listing evaluations and audits.

For Example: If the ~~State~~ applicable Government Water Control Authority's law required more frequent individual water supply samples to be taken, a SRO conducting a ~~sanitation~~ rating, which includes that ~~farm or~~ milk plant, ~~will now~~ shall give that ~~farm or~~ milk plant full credit for water sample frequency, if the *Grade "A" PMO* minimum sampling frequency requirement is met, even though, the ~~State~~ applicable Government Water Control Authority's frequency is not met.

Supplies other than individual water supplies, which have been approved as safe by the ~~State~~ applicable Government Water Control Authority, shall be considered to be acceptable sources, as provided in Section 7 of the *Grade "A" PMO*, for Grade "A" inspections, as well as for all other IMS purposes, without further inspection of the spring, well or reservoir treatment facility(ies), testing records, etc. …

Page 89:

9. Permit issuance, suspension, revocation, reinstatement, hearings and/or court action taken as required (*Grade "A" PMO*, Section 3 - PERMITS, Section 5 - INSPECTION OF MILK PLANTS, Section 6 - EXAMINATION OF MILK AND MILK PRODUCTS and Section 16 -

PENALTIES). Prorate by enforcement action(s) in compliance.

NOTE: A milk plant ~~will~~ shall be prorated by enforcement action(s) in compliance. Five (5) Categories ~~will~~ shall be utilized for determining compliance with this Item and each ~~will~~ shall possess a value of twenty percent (20%) compliance. The Categories are as follows: ...
The Categories relate to the following Sanitation Requirements and Product Compliance. Compliance ~~will~~ shall be prorated based on **full** compliance with each of the five (5) Categories. …

SANITATION REQUIREMENTS …

Category II: Permit Suspension …

Page 90:

c. Milk products processed during suspension or while a monetary penalty is imposed for repeated inspection violations is not eligible for sale as Grade "A".

NOTE: *Grade "A" PMO*, Section 3 states: "The Regulatory Agency may forego suspension of the permit, provided the milk and/or milk product in violation is not sold or offered for sale as a Grade "A" milk and/or milk product. A Regulatory Agency may allow the imposition of a monetary penalty in lieu of a permit suspension, provided the milk and/or milk product in violation is not sold or offered for sale as a Grade "A" milk and/or milk product. ~~Except, that a milk producer may be assessed a monetary penalty in lieu of permit suspension for violative counts provided~~ ….."

The option to issue a monetary penalty in lieu of a permit suspension as cited above, shall not be applicable to a TPC authorized under the ICP. …

PRODUCT COMPLIANCE

Category II: Permit Suspension

a. All milk and milk products produced during a permit suspension or while a monetary penalty is imposed for bacterial, somatic cell, cooling temperature or drug residue violation is not eligible for sale as Grade "A".

NOTE: The option to issue a monetary penalty in lieu of a permit suspension as cited above, shall not be applicable to a TPC authorized under the ICP. …

Page 91:

Category IV: Permit Reinstatement

a. All milk and/or milk product violations followed promptly by an inspection to determine the cause(s). …

10. Records systematically maintained and current (*Grade "A" PMO*, Section 3 - PERMITS, Section 4 - LABELING, Section 5 - INSPECTION OF MILK PLANTS, Section 6 - EXAMINATION OF MILK AND MILK PRODUCTS, and Section 7 - STANDARDS FOR MILK AND MILK PRODUCTS.) Make use of both general and specific record-keeping deficiencies to determine the value. The four (4) Categories (I-IV) listed below ~~will~~ shall be utilized for determining compliance with this Item and each ~~will~~ shall possess a value of twenty-five percent (25%) compliance. Compliance ~~will~~ shall be prorated based on **full** compliance with each of the four (4) Categories.

NOTE: Use FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION E. MILK PLANT ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 5). (Refer to Section G, #5 for an example of the Form.)

a. Category I: Permit records available, accurate and current, including permit suspension, imposition of a monetary penalty, notices, reinstatement, etc. The results shall be entered on appropriate ledger forms. The use of a computer or other information retrieval system may be used.

NOTE: The option to issue a monetary penalty in lieu of a permit suspension as cited above, shall not be applicable to a TPC authorized under the ICP. …

Page 92:

PART III. INDIVIDUAL SHIPPER RATING …

NOTE: All records shall be summarized in ledger form. Computer ledgers are acceptable. Records include:

a. Inspections of dairy farms, milk plants, receiving and transfer stations, samplers, ~~vehicles~~ milk tank trucks, etc.;
b. Laboratory information, i.e., raw milk, ~~heat-treated milk,~~ finished milk and/or milk products, vitamin assays, water, cooling media, etc.); and …

Page 93:

GUIDANCE FOR COMPUTING ENFORCEMENT CREDIT FOR PART I, ITEM 9 AND/OR PART II, ITEM 8 OF FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2)

FORM FDA 2359j-MILK SANITATION RATING REPORT- SECTION C. EVALUATION OF SAMPLING PROCEDURES (PAGE 3) ~~is~~ shall be used to determine enforcement credit for Part I, Item 9, FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2) (Dairy Farms), and Part II, Item 8, FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2) (Milk Plant). Items 4 and 7 on FORM FDA 2359j-

MILK SANITATION RATING REPORT- SECTION C. EVALUATION OF SAMPLING PROCEDURES (PAGE 3) do not apply when calculating Enforcement Ratings for milk plants, receiving and transfer stations for FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), Part II, Item 8.

Item 1. Sampling Surveillance Officers (SSOs) Properly Certified

a. All SSOs are certified by FDA.
b. Certification is currently valid (three years).
c. SSOs shall be a certified SRO, LEO or ~~State~~ Regulatory Supervisor per "*Procedures*" Section V., F. …

Item 3. Sampling Surveillance Authority Properly Delegated …

c. Initial Delegation: Comparison evaluations shall be performed on at least five (5) bulk milk hauler/samplers during a routine milk pick-up at a ~~producer~~ dairy farm; one (1) plant sampler that collects raw and finished milk and/or milk product samples and single-service container/closures at one (1) milk plant, if applicable; and one (1) industry plant sampler that collects a raw milk sample from a milk tank truck at one (1) milk plant, if applicable, with at least eighty percent (80%) agreement on each listed Item.
d. Re-delegation conducted at least each three (3) years. Comparison evaluations shall be performed on at least two (2) bulk milk hauler/samplers during a routine milk pick-up at a ~~producer~~ dairy farm; one (1) plant sampler that collects raw and finished milk and/or milk product samples and single-service containers/closures at one (1) milk plant, if applicable; and one (1) industry plant sampler that collects a raw milk sample from a milk tank truck at one (1) milk plant, if applicable, with at least eighty percent (80%) agreement on each listed Item.

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e. Proper certification of industry field ~~person~~ personnel when applicable.

Item 4. Permit Issuance (Applies to Part 1-DAIRY Farms only.) …

Item 5. Sampler (Including Dairy Plant and Industry Plant Samplers at the Receiving Site) **Evaluated Every Two (2) Years and Reports Properly Filed**

a. Samplers shall have their sampling collection procedures evaluated by a certified SSO or a properly delegated Sampling Surveillance Regulatory Agency Official (dSSO) every two (2) years. SSOs or ~~properly delegated Sampling Surveillance Regulatory Officials~~ dSSOs are not required to be evaluated for sampling collection procedures. …

Item 7. Permit Suspension, Revocation, Reinstatement, Hearings and/or Court Actions Ta as Required (Applies to Part 1-DAIRY FARMS only.) …

Item 8. Records Systematically Maintained and Current

a. Records of the delegation of sampling evaluation authority to other ~~State, Local,~~ Regulatory Agency or industry individuals on file and available for review with the ~~producer~~ dairy farm or milk plant records.
b. Records of each sampler evaluation on file and available for review with the ~~producer~~ dairy farm or milk plant records. …

APPENDIX B …

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Major (5 point)

2. **Permanent in-line high pressure pump (power washer): Without acceptable protection, such as:**
a. Properly functioning low-pressure cut-off switch with a properly located test valve; and
b. Other methods acceptable to the ~~State~~ applicable Government Water Control Authority.

Minor (2 point)

2. Portable high pressure water pump (power washer): Without acceptable protection, such as:
a. Separate water supply or reservoir;
b. Properly functioning low-pressure cut-off switch with a properly located test valve; and
c. Other methods acceptable to the ~~State~~ applicable Government Water Control Authority.

Document: 2011 EML (Entire Document)
Pages: Entire Document

*Make the following changes to the **2011 EML**:*

Cover:

~~2011~~ 2013 Revision

Page ii:

TABLE OF CONTENTS

Re-number the remaining SECTIONS within the TABLE OF CONTENTS accordingly.

Page 1:

EVALUATION OF MILK LABORATORIES
~~2011~~ 2013 Revision

INTRODUCTION

Official accreditation of milk laboratories and Certified Industry Supervisors (~~CIS~~ CISs) requires that ~~the appropriate Federal or State milk laboratory control agency~~ FDA/LPET or the appropriate Milk Laboratory Control Agency conduct an on-site survey to determine satisfactory performance of analysis in milk laboratories and performance of analysis by ~~CIS~~ CISs in facilities where the examinations, required by the *Grade ~~'A'~~ "A" Pasteurized Milk Ordinance* (*Grade "A" PMO*), are performed. In addition, satisfactory performance in the analysis of annual proficiency test samples ~~must~~ shall be demonstrated. An accredited milk laboratory may be an approved official or officially designated milk laboratory under the administrative control of a ~~federal, state or local~~ Regulatory ~~authority~~ Agency. Approval of Industry Supervisors (~~IS~~ ISs) and Industry Analysts (~~IA~~ IAs) requires verification of proficiency in performing drug residue analysis at least biennially, through on-site performance evaluation and/or analysis of split samples or by other means as noted in SECTION ~~1~~2 ~~below~~.

~~The State~~ A certified Laboratory Evaluation Officer (~~State~~ LEO) ~~will~~ shall use the appropriate FDA-2400 Series Forms when evaluating official laboratories, officially designated laboratories, ~~CIS, IS~~ CISs, ISs and ~~IA~~ IAs. The ~~Federal~~ FDA/LPET Laboratory Evaluation Officer (~~Federal~~ FDA/LPET LEO) ~~will~~ shall use the appropriate FDA-2400 Series Forms when evaluating State Central Milk Laboratories and ~~State~~ LEOs. Appropriate FDA-2400 Series Forms are those forms that have been approved by the NCIMS Laboratory Committee working cooperatively with the ~~Food and Drug Administration (~~FDA~~)~~ and the NCIMS Executive Board, and are effective 90 days after executive board approval. Approved forms shall be issued within 90 days of NCIMS Executive Board approval. If the FDA is unable to release the approved forms within the 90 day time frame, FDA/LPET shall issue a draft version of the 2400 series forms 90 days after NCIMS Executive Board approval.

~~Official Laboratory: An official laboratory is a biological, chemical or physical laboratory which is under direct supervision of the state or a local regulatory agency.~~

~~State Central Milk Laboratory: A State-owned and operated Official Laboratory with analysts employed by the State working in conjunction with the State Regulatory Agency designated as the primary State laboratory for the examination of producer samples of Grade 'A' raw and~~

~~commingled raw milk for pasteurization, pasteurized milk and milk products, and dairy waters, as necessary.~~

~~Officially Designated Laboratory: An officially designated laboratory is a commercial laboratory authorized to do official work by the regulatory agency, or a milk industry laboratory officially designated by the regulatory agency for the examination of producer samples of Grade 'A' raw milk for pasteurization and commingled milk tank truck samples of raw milk for drug residues.~~

~~Certified Industry Supervisor (CIS): An industry supervisor who is evaluated and listed by a State LEO as certified to conduct drug residue screening tests at industry drug residue screening sites for PMO, Appendix N regulatory actions (confirmation of tankers, producer trace back and/or permit actions).~~

Page 2:

~~Industry Supervisors (IS): An individual trained by the State LEO who is responsible for the supervision and training of industry analysts who test milk tank trucks for Appendix N drug residue requirements.~~

~~Industry Analyst (IA): A person under the supervision of the CIS or IS who is assigned to conduct screening of milk tank trucks for Appendix N drug residue requirements.~~

~~BactoScan Industry Operator (BIO): A person who operates a BactoScan FC under the supervision of a certified BactoScan analyst and analyzes samples for regulatory compliance.~~

~~Food and Drug Administration (~~FDA) laboratory accreditation procedures provide a ~~national~~ base for the uniform collection and examination of milk, in compliance with the sanitation standards of the *Grade "A" PMO*.

Uniform accreditation of milk laboratories is maintained by the following two (2) functions:

1. FDA accreditation of ~~state~~ State central milk laboratories and certification of analysts is based on:
   ~~(a)~~a. ~~satisfactory~~ Satisfactory triennial on-site evaluations of laboratory facilities, equipment, records, and analyst performance of techniques, and
   ~~(b)~~b. ~~satisfactory~~ Satisfactory annual proficiency testing (the examination of split milk samples) to continuously appraise analyst performance.

2. FDA certification of ~~State~~ LEOs who:
   ~~(1)~~a. ~~accredit~~ Accredit local laboratories and certify analysts and ~~CIS~~ CISs based on:
      (~~a~~1) ~~satisfactory~~ Satisfactory biennial on-site evaluations of laboratory facilities, equipment, records and analyses and
      (~~b~~2) ~~satisfactory~~ Satisfactory annual proficiency testing which meets established national standards ~~and~~.
   ~~(2)~~b. ~~approve IS and IA~~ Approve ISs and IAs (who only screen for drugs) based on:
      (~~a~~1) ~~verification~~ Verification that each IS has been trained (by conducting required

workshops for all industry supervisors) and has established a program that ensures the proficiency of the IA they supervise~~,~~ and

(~~b~~2) ~~verification~~ Verification that each IS and IA has demonstrated proficiency in performing drug residue analysis at least biennially. Verification of proficiency may include an analysis of split samples and/or an on-site performance evaluation or another proficiency determination that the ~~State~~ LEO and the FDA/LPET agree is appropriate. (*Grade "A" PMO*, Appendix N)

SECTION 1: DEFINITIONS

1. **BACTOSCAN INDUSTRY OPERATOR (BIO):** A person who operates a BactoScan FC under the supervision of a certified BactoScan analyst and analyzes samples for regulatory compliance.

2. **CERTIFIED INDUSTRY SUPERVISOR (CIS):** An industry supervisor who is evaluated and listed by a LEO as certified to conduct drug residue screening tests at industry drug residue screening sites for *Grade "A" PMO*, Appendix N regulatory actions (confirmation of ~~tankers~~ milk tank trucks, producer trace back and/or permit actions).

3. **CERTIFIED MILK LABORATORY EVALUATION OFFICER (LEO):** A Regulatory Agency or Milk Laboratory Control Agency employee who has been certified by the Food and Drug Administration (FDA) Laboratory Profiency Evaluation Team (LPET), using the Evaluation of Milk Laboratories (EML) to evaluate milk laboratories for the purpose of accrediting or approving laboratories that conduct official NCIMS milk testing has a valid certificate of qualification.

4. **FOOD AND DRUG ADMINISTRATION/LABORATORY PROFICIENCY EVALUATION TEAM LABORATORY EVALUATION OFFICER (FDA/LPET LEO):** A Food and Drug Administration (FDA) employee that has been internally standardized to evaluate State Central Milk Laboratories for the purpose of accreditation to conduct official NCIMS milk testing. They are standardized to evaluate and certify milk laboratory evaluation officers (LEOs) working for a Regulatory Agency or Milk Laboratory Control Agency for the purpose of accrediting other official and officially designated laboratories participating in the NCIMS Grade "A" Milk Safety Program.

5. **INDUSTRY ANALYST (IA):** A person under the supervision of ~~the~~ a CIS or IS who is assigned to conduct screening of milk tank trucks for Appendix N drug residue requirements.

6. **INDUSTRY SUPERVISORS (IS):** An individual trained by the LEO who is responsible for the supervision and training of industry analysts who test milk tank trucks for Appendix N drug residue requirements.

7. **INTERNATIONAL CERTIFICATION PROGRAM (ICP):** The International Certification Program (ICP) means the NCIMS voluntary program designed to utilize Third Party Certifiers (TPCs) authorized by the NCIMS Executive Board in applying the requirements of the NCIMS Grade "A" Milk Safety Program for Milk Companies (MCs)

located outside the geographic boundaries of NCIMS Member States that desire to produce and process Grade "A" milk and/or milk products for importation into the United States.

8. **MILK LABORATORY CONTROL AGENCY:** A Milk Laboratory Control Agency shall mean a governmental or other Regulatory Agency body which has adopted an ordinance, rule or regulation in substantial compliance with the current edition of the *Evaluation of Milk Laboratories (EML)* and is responsible for the enforcement of such ordinance, rule or regulation in substantial compliance with the Grade "A Milk Safety Program for a listed milk laboratory. The Milk Laboratory Control Agency has authority, recognized by the National Conference on Interstate Milk Shipments (NCIMS), to oversee and control the activities of milk laboratories and/or personnel involved with official NCIMS Grade "A" milk testing. The term, "Milk Laboratory Control Agency", whenever it appears in the *EML* shall also mean the appropriate Third Party Certifier (TPC) having jurisdiction and control over the matters cited within this *EML*.

9. **OFFICIAL LABORATORY:** An official laboratory is a biological, chemical or physical laboratory which is under the direct supervision of the Regulatory Agency or Milk Laboratory Control Agency.

10. **OFFICIALLY DESIGNATED LABORATORY:** An officially designated laboratory is a commercial laboratory authorized to do official work by the Regulatory Agency, or a milk industry laboratory officially designated by the Regulatory Agency or Milk Laboratory Control Agency for the examination of producer samples of Grade 'A' raw milk for pasteurization and commingled milk tank truck samples of raw milk for drug residues.

11. **RATING AGENCY:** A Rating Agency shall mean a State Agency, which certifies interstate milk shippers (BTUs, receiving stations, transfer stations, and milk plants) as having attained the Sanitation Compliance and Enforcement Ratings necessary for inclusion on the *IMS List*. The ratings are based on compliance with the requirements of the *Grade "A" PMO* and were conducted in accordance with the procedures set forth in the *Methods of Making Sanitation Ratings of Milk Shippers (MMSR)*. Ratings are conducted by FDA certified Milk Sanitation Rating Officers (SROs). They also certify single-service containers and closures for milk and/or milk products manufacturers for inclusion on the *IMS List*. The certifications are based on compliance with the requirements of the *Grade "A" PMO* and were conducted in accordance with the procedures set forth in the *Methods of Making Sanitation Ratings of Milk Shippers (MMSR)*. The definition of a Rating Agency also includes a Third Party Certifier (TPC) that conducts ratings and certifcations of Milk Companies (MCs) located outside the geographic boundaries of NCIMS member States that desire to produce and process Grade "A" milk and/or milk products for importation into the United States.

12**. REGULATORY AGENCY:** A Regulatory Agency shall mean an agency which has adopted an ordinance, rule or regulation in substantial compliance with the current edition of the *Grade "A" PMO* and is responsible for the enforcement of such ordinance, rule or regulation, which is in substantial compliance with the *Grade "A" PMO* for a listed interstate milk shipper and milk laboratory. The term "Regulatory Agency", whenever it appears in the *EML* shall also mean the appropriate Third Party Certifier (TPC) having jurisdiction and

control over the matters cited within this *EML*.

13. **STATE CENTRAL MILK LABORATORY:** A State owned and operated Official Laboratory with analysts employed by the State working in conjunction with the State Regulatory Agency designated as the primary State laboratory for the examination of producer samples of Grade 'A' raw and commingled raw milk for pasteurization, pasteurized milk and milk products, and dairy waters, as necessary.

14. **THIRD PARTY CERTIFER (TPC):** A Third Party Certifier (TPC) is a non-governmental individual(s) or organization authorized under the NCIMS voluntary International Certification Program (ICP) that is qualified to conduct the routine regulatory functions and enforcement requirements of the *Grade "A" PMO* in relationship to milk plants, receiving stations, transfer stations, associated dairy farms, bulk milk hauler/samplers, milk tank trucks, milk transportation companies, dairy plant samplers, industry plant samplers, milk distributors, etc. participating in the NCIMS voluntary International Certification Program (ICP). The Third Party Certifier (TPC) provides the means for the rating and listing of milk plants, receiving stations, transfer stations and their related raw milk sources. They also conduct the certification and IMS listing of related milk and/or water laboratories and related single-service container and closure manufacturers on the *Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers (IMS) List*. To be authorized under the NCIMS voluntary International Certification Program (ICP), a valid Letter of Understanding (LOU) shall be signed between the NCIMS Executive Board and the Third Party Certifier (TPC).

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SECTION ~~1~~2: LABORATORY EVALUATION PROGRAMS

An evaluation of a milk laboratory ~~must~~ shall include an on-site visit to the laboratory, a review of the records, including training records of IAs, records of split sample performance, facilities, equipment, materials and procedures. The evaluation shall be made using the most recent approved Official Milk Laboratory Evaluation Forms (FDA-2400 Series Forms). The ~~Federal or State~~ FDA/LPET LEO or LEO shall determine if the laboratory facilities, equipment, records and techniques of analysts are in compliance with the FDA-2400 Series Forms.

A copy of the "Grade ~~'A'~~ "A" Milk Laboratory Evaluation Request and Agreement Form" (see page 20) ~~must~~ shall be signed by a representative of the facility prior to the initiation of the survey. This document ~~must~~ shall be maintained on file by the ~~Federal or State~~ FDA/LPET LEO or LEO.

A set of completed evaluation forms may accompany the narrative report which describes the degree of suitability of the laboratory facilities, equipment, records, the analysts' procedures, and a statement as to whether the results of the analyst or CIS examinations are acceptable for use in rating milk for interstate shipments. The narrative report ~~must~~ shall be sufficiently detailed to allow readers to determine what is being cited without having to refer to the FDA-

2400 Series Forms.

Survey reports of on–site evaluations of Official Milk Laboratories and CISs shall be sent within sixty (60) days of the initial, biennial/triennial anniversary or supplemental date of the laboratory evaluation to the Official Milk Laboratory/CIS, the appropriate ~~Food and Drug Administration~~ FDA Regional Office and the FDA/LPET. Reports can be submitted by traditional fashion (mail, common courier) or electronically. Reports to the Official Milk Laboratories /CIS ~~must~~ shall include the narrative report and may include copies of the completed FDA-2400 Series Forms. Reports to the FDA Regional Office and FDA/LPET shall be sent electronically and shall include the narrative report and appropriate, completed FDA summary template only (see ~~page~~ pages 37 – 40). …

CERTIFICATION/APPROVAL OF MILK LABORATORY ANALYSTS

Certification of milk laboratory analysts by ~~the Federal or State~~ a FDA/LPET LEO or LEO shall be based on the following criteria:

1. Evaluations of State ~~central milk laboratories'~~ Central Milk Laboratory ~~evaluations~~ shall be scheduled and performed by their triennial expiration date. State central milk laboratories shall submit requests, in writing, for on-site evaluation of new analyst(s) performance of techniques, new methods and/or new facilities to the FDA/LPET. The ~~Federal~~ FDA/LPET LEO shall schedule a mutually agreeable date within thirty (30) days of the request for an evaluation.

2. Evaluations of other milk laboratories ~~within a state~~ shall be scheduled and performed by their biennial expiration date. Milk laboratories ~~within a state~~ shall submit requests, in writing, for on-site evaluation of new analyst(s) performance of techniques, new methods and/or new facilities to the ~~State~~ LEO. The ~~State~~ LEO shall schedule a mutually agreeable date within 30 days of the receipt of the request for an evaluation. …

Page 4:

5. Analysts meet the performance levels of the proficiency testing program (SECTION ~~2~~3). The ~~State~~ LEO may issue a certificate of approval to each laboratory analyst who meets the stated criteria in numbers 3 and 4 above.

6. Vitamin testing laboratories have submitted satisfactory quality control information, use methods acceptable to the FDA or other official methodologies which give statistically equivalent results to the FDA methods, have one or more certified analysts who have satisfactorily participated in the vitamin split sample program and have met performance levels of the proficiency testing program (SECTION ~~2~~3).

Analysts seeking certification or approval who are employed in laboratories not previously approved, or laboratories that have lost accreditation or approval and are seeking Recertification, may be approved to conduct official examinations only if criteria 3 and 4 above are met. When such analysts successfully complete the next official proficiency tests

administered by the ~~State~~ LEO, a certificate of approval may be issued to such analyst. If such analyst does not successfully meet the performance levels of the proficiency testing program, the approval to conduct official examinations shall be withdrawn. …

When a new analyst is assigned to an accredited laboratory between on-site evaluations, conditional approval status ~~will~~ shall be provided to the new analyst upon satisfactory completion of criteria 4 or 5 above. Full certification ~~will~~ shall follow after acceptable completion of both criteria 4 and 5 above. Conditionally approved analysts failing to meet the established applicable criteria of laboratory performance during an on-site laboratory evaluation ~~will~~ shall have their conditionally approved status revoked.

The ~~CIS~~ CISs and certified analysts ~~must~~ shall participate, at least annually, in proficiency testing (the examination of milk split samples) for those specific procedures for which they are certified. Failure without cause to participate in the annual split sample evaluation or failure to meet established satisfactory performance criteria ~~will~~ shall result in the ~~CIS~~ CISs or certified analyst(s) having their certification status downgraded from full to provisional. Failure of a provisionally certified analyst or ~~CIS~~ CISs to participate in the examination of or to meet established satisfactory performance levels on the next set of split samples ~~will~~ shall result in withdrawal of their certification.

A CIS or certified analyst that loses their certification for one (1) or more tests cannot examine official samples using a test for which their certification was withdrawn. Recertification procedures are shown in "SECTION ~~2~~3: PROFICIENCY TESTING PROGRAMS".

Page 5:

Copies of notices of changes of certification or revocation of certification shall be sent to the laboratory or facility involved, the ~~milk regulatory agency~~ Regulatory Agency, the ~~state milk sanitation rating agency~~ Rating Agency, the appropriate FDA Regional Office and the FDA/LPET. For FDA/LPET notification, changes in certification shall be indicated on the appropriate, completed FDA summary template and shall be submitted electronically.

Upon notice of revocation, the certificate, if issued, shall be returned to the issuing ~~State~~ LEO within ninety (90) days.

ACCREDITATION/APPROVAL OF MILK LABORATORIES

Accreditation or approval of milk laboratories by ~~Federal or State milk laboratory control agencies~~ FDA/LPET or Milk Laboratory Control Agencies shall be based on meeting the following requirements:

1. The laboratory facilities, equipment, procedures and records ~~must~~ shall meet the requirements stated on the appropriate FDA-2400 Series Forms and for ~~CIS~~ CISs, appropriate Appendix N 2400 Series Forms, as determined by an on-site evaluation.

2. All official examinations required by the *Grade "A" PMO* ~~must~~ shall only be performed by certified analysts or ~~CIS~~ CISs.

3. Vitamin testing laboratories have submitted satisfactory quality control information, use methods acceptable to the FDA or other official methodologies which give statistically equivalent results to the FDA methods, have one or more certified analysts who have satisfactorily participated in the vitamin split sample program and have met performance levels of the proficiency testing program (SECTION ~~2~~3).

The ~~State~~ LEO may issue a certificate of accreditation or approval to each official, commercial, and industry laboratory meeting criteria 1 and 2 above.

When an accredited laboratory changes location or undergoes substantial remodeling, an evaluation of the new laboratory or screening facility is required within three (3) months. ~~No~~ An evaluation of personnel or procedures is not required at this time. …

When a certified analyst or CIS leaves an accredited laboratory, the laboratory/facility manager ~~must~~ shall notify the ~~Federal or State~~ FDA/LPET LEO or LEO immediately since the loss of a certified analyst may result in the loss of certification for one or more procedures, or may result in the loss of the laboratory's accreditation. For example, a laboratory having only one certified analyst ~~will~~ shall lose accreditation. Official examinations cannot be conducted at non-accredited laboratories. When a laboratory or CIS facility loses its accreditation because of a lack of certified analysts, or for some other reason, the ~~Federal or State~~ FDA/LPET LEO or LEO shall immediately notify the milk laboratory involved, the ~~state milk regulatory agency, the state milk sanitation rating agency~~ respective Regulatory/Rating Agency, any ~~out-of-state milk regulatory agencies~~ other Regulatory/Rating Agency that oversees locations where known customers of that laboratory are located, the appropriate FDA Regional Office and the FDA/LPET, by a letter of notification to be dated within five (5) working days of the loss of accreditation. For any FDA/LPET notification, changes in accreditation shall be indicated on the appropriate, completed FDA summary template and shall be submitted electronically.

Page 6:

Laboratories requesting withdrawal of accreditation shall notify the ~~State~~ LEO in writing. Upon receipt of the written request, the ~~State~~ LEO shall immediately notify the ~~state milk regulatory agency, the state milk sanitation rating agency~~ respective Regulatory/Rating Agency, any ~~out-of-state milk regulatory agencies~~ other Regulatory/Rating Agency that oversees locations where known customers of that laboratory are located, the appropriate FDA Regional Office and the FDA/LPET by a letter of notification to be dated within five (5) working days of receipt of the written request. Upon notice of withdrawal of accreditation, the certificate, if issued, shall be returned to the issuing ~~State~~ LEO within ninety (90) days. …

Additionally, the laboratory shall notify its customers in writing, that it has withdrawn or been decertified and shall not represent itself as an official laboratory or officially designated laboratory, for those decertified or unapproved procedures under the agreements of the NCIMS. A copy of the generic notification ~~must~~ shall be sent to the ~~State~~ LEO. Decertification ~~will~~ shall remain in effect until measures are taken by the laboratory to attain compliance and another survey is completed successfully.

APPROVAL OF INDUSTRY ANALYSTS/INDUSTRY SUPERVISORS

Approval of Industry Supervisors (~~IS~~ ISs) and Industry Analysts (~~IA~~ IAs) by the ~~State~~ LEOs shall be based on meeting all of the following requirements: …

2. All screening tests required by the *Grade "A" PMO*, Appendix N ~~must~~ shall only be performed by approved ~~IS, IA~~ ISs, IAs or by a certified entity. …

Page 7:

5. Approval of ~~IS and IA~~ ISs and IAs require verification of proficiency in performing drug residue analyses at least biennially, through on site performance evaluation and/or analysis of split samples, or another proficiency determination that the ~~State~~ LEO and the FDA/LPET agree is appropriate. (~~PMO,~~ Refer to Appendix N of the *Grade "A" PMO*.)

6. The IS has attended and received training by the ~~State~~ LEO. This training ~~must~~ shall be documented.

The IS shall report to the ~~State~~ LEO the result of all competency evaluations performed by ~~IA~~ IAs. The name of each IS and IA (as well as their training and evaluation status) shall be maintained by the ~~State~~ LEO and updated as replacement, additions and/or removals occur. The ~~State~~ LEO shall verify (document) that each IS has established a program that ensures the proficiency of the ~~IA~~ IAs they supervise. The ~~State~~ LEO shall also verify that each IS and IA has demonstrated proficiency in performing drug residue analysis at least biennially. Verification may include an analysis of split samples and/or an on-site performance evaluation or another proficiency determination that the ~~State~~ LEO and the FDA/LPET agree is appropriate. …

Failure by the ~~IS~~ ISs or the ~~IA~~ IAs to demonstrate adequate proficiency to the ~~State~~ LEO shall lead to their removal from the ~~State~~ LEO list of ~~IS/IA~~ Approved ISs/IAs. Re-instatement of their testing status shall only be possible by completing retraining and/or successfully analyzing split samples and/or passing an on-site evaluation or otherwise demonstrating proficiency to the ~~State~~ LEO. Analysts not on the ~~State~~ LEO list of Approved ~~IS/IA~~ ISs/IAs are not approved to test bulk milk in the Appendix N program.

When a screening facility loses its approval because of a lack of approved ~~IS or IA~~ ISs or IAs, or for some other reason, the ~~State~~ LEO shall immediately notify the screening facility involved, the ~~state milk regulatory agency, the state milk sanitation rating agency~~ respective Regulatory/Rating Agency, any ~~out-of-state milk regulatory agencies~~ other Regulatory/Rating Agency that oversees locations where known customers of that laboratory are located, the appropriate FDA Regional Office and the FDA/LPET, by a letter of notification to be dated within five (5) working days of receipt of the loss of approval. For FDA/LPET notification, changes in approval shall be indicated on the appropriate, completed FDA summary template and shall be submitted by email.

Page 8:

Screening facilities requesting withdrawal of approval shall notify the ~~State~~ LEO in writing. Upon receipt of the written request, the ~~State~~ LEO shall immediately notify the ~~state milk regulatory agency, the state milk sanitation rating agency~~ respective Regulatory/Rating Agency, any ~~out-of-state milk regulatory agencies~~ other Regulatory/Rating Agency that oversees locations where known customers of that laboratory are located, the appropriate FDA Regional Office and the FDA/LPET by a letter of notification to be dated within five (5) working days of receipt of the written request. For FDA/LPET notification, changes in approval shall be indicated on the appropriate, completed FDA summary template and shall be submitted by email.

Additionally, the screening facility shall notify its customers in writing that it has been withdrawn or has lost its approval and shall not represent itself as an approved screening facility under the agreements of the NCIMS. A copy of the generic notification ~~must~~ shall be sent to the ~~State~~ LEO. Loss of approval ~~will~~ shall remain in effect until measures are taken by the screening facility to attain compliance and another survey is completed successfully.

APPROVAL OF BACTOSCAN INDUSTRY OPERATORS

Approval of BactoScan Industry Operators (BIO) shall be based on meeting the following requirements:

1. The industry operator ~~must~~ shall complete the BIO operating protocols, training and oversight specified in the training procedure document.

2. The laboratory ~~must~~ shall maintain one (1) certified BactoScan analyst (see current FDA 2400 series form) for training and ongoing oversight of the BIO. …

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SECTION ~~2~~3: PROFICIENCY TESTING PROGRAMS

The ~~Food and Drug Administration~~ FDA/LPET shall split samples annually with all ~~federally~~ FDA/LPET certified analysts of each ~~State/Territory (hereafter noted as State) central accredited milk laboratory~~ Milk Laboratory Control Agency's accredited Central Milk Laboratory. ~~State milk laboratory control agencies~~ Milk Laboratory Control Agencies shall split samples at least annually with all ~~state~~ certified analysts of each official, officially designated accredited milk laboratory, and all ~~CIS~~ CISs. ~~State milk laboratory control agencies~~ Milk Laboratory Control Agencies shall verify that each IS and IA has demonstrated proficiency in performing drug residue analysis at least biennially through on-site performance evaluation and/or analysis of split samples, or another proficiency determination that the ~~State~~ LEO and the FDA/LPET agree is appropriate.

~~State milk laboratory control agencies~~ Milk Laboratory Control Agencies having less than ten (10) analysts (total) in their milk laboratory program are to develop joint ~~state~~ proficiency testing programs with other ~~states~~ Milk Laboratory Control Agencies, which can meet the criteria for certification of analysts and accreditation of laboratories. In cases where a

minimum number of analysts (≥ ten (10)) are not available, evaluation of proficiency ~~will~~ shall be made by a determination that the ~~State~~ LEO and the FDA/LPET agree is appropriate.

An acceptable annual proficiency testing program shall meet the following applicable criteria: …

4. When a CIS examines bulk milk tanker milk or its equivalent for Appendix N purposes, a minimum of eight (8) samples shall be analyzed utilizing the test kit(s) for which that CIS is certified or approved, or for which the CIS is seeking certification. In general, the milk samples shall consist of the members of the beta-lactam family, at the safe/tolerance levels, which the test kit(s) is designed to detect as well as milk samples ~~containing no~~ that do not contain animal drug residues. The CIS may misidentify one (1) of the samples and maintain and/or gain certification. If more than one (1) sample is misidentified, the CIS falls one (1) level of certification. If this occurs twice consecutively, the CIS is no longer certified or approved (rules for Recertification of laboratories apply).

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5. When an IS or an IA examines bulk milk tanker milk or its equivalent for Appendix N purposes, a minimum of eight (8) samples shall be analyzed utilizing the test kits for which that IS or IA is approved or for which the IS or IA is seeking approval. In general, the milk samples shall consist of members of beta-lactam family, at the safe/tolerance levels, which the test kits are designed to detect as well as milk samples ~~containing no~~ that do not contain animal drug residues. The IS or IA may misidentify one (1) of the samples and maintain and/or gain approval. If more than one (1) sample is misidentified, the IS or IA falls one (1) level of approval. If this occurs twice consecutively, the IS or IA is no longer approved. Re-instatement of their testing status shall only be possible by completing retraining and/or successfully analyzing split samples and/or passing an on-site evaluation or otherwise demonstrating proficiency to the State LEO.

6. Each analyst certified to perform visual drug residue tests ~~will~~ shall participate in annual proficiency tests to demonstrate their ability to detect the beta-lactams at safe/tolerance level per kit label claim (Penicillin G, Cloxacillin, Ceftiofur, and Cephapirin) using blind samples with duplicate negatives. A minimum of six (6) samples may be used. However, with six (6) samples ALL results ~~must~~ shall be correct. If eight (8) samples are used, an analyst/CIS may miss one (1) and still pass the proficiency test. …

SPLIT SAMPLE ANALYSIS …

The Standard Plate Count (SPC), Petrifilm Aerobic Count (PAC), Plate Loop Count (PLC), BactoScan FC Count (BSC), Spiral Plate Count Method (SPLC), Direct Microscopic Somatic Cell Count (DMSCC), Electronic Somatic Cell Count (ESCC), Electronic Phosphatase Count and Vitamin A and D_3 result of each certified analyst shall fall within the limits shown in Table 2, page 28.

The steps for statistical analysis of split sample results are as follows: …

2. Calculate the logarithmic mean for the ~~Standard Plate Count~~ SPC, ~~Petrifilm Aerobic Count~~ PAC, ~~Plate Loop Count~~ PLC, ~~BactoScan FC Count (~~BSC~~)~~, ~~Spiral Plate Count Method (~~SPLC~~)~~, ~~Direct Microscopic Somatic Cell Count~~ DMSCC, ~~Electronic Somatic Cell Count~~ ESCC, Electronic Phosphatase Count and Vitamin A and D_3 results of each test sample; using a table of common logarithms, list the logarithms of all analyst counts for a given sample. Calculate the mean of the logarithms for the sample. …

Page 11:

ANALYST PERFORMANCE LEVEL

Analysts certified to perform the examinations required by the ~~"~~*Grade "A" PMO*~~"~~ shall meet the following performance levels on an annual basis.

1. Analysts certified to perform the ~~Standard Plate Count~~ SPC, ~~Petrifilm Aerobic Count~~ PAC, ~~Plate Loop Count~~ PLC, ~~BactoScan FC Count (~~BSC~~)~~, ~~Spiral Plate Count Method~~ (~~SPLC~~)~~, ~~Direct Microscopic Somatic Cell Count~~ DMSCC, ~~Electronic Somatic Cell Count~~ ESCC, Electronic Phosphatase Count and Vitamin A and D_3 analysis, and BIOs approved to operate a BactoScan FC shall meet the acceptance limits and performance levels shown in Tables 2 and 3, page 28.

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2. Analysts certified to perform inhibitor tests shall detect samples that contain beta-lactam or other animal drug residues detectable by the appropriate official test for the drug and product. If using a drug other than beta-lactam, samples ~~must~~ shall be spiked in duplicate. See Table 3, page 28. …

5. ~~Certified Industry Supervisors~~ CISs certified to perform Appendix N test(s) for beta-lactam drugs shall detect members of the beta-lactam family, at the safe/tolerance levels, which the test kit(s) is designed to detect. See Table 3, page 28.

Fully certified analysts not meeting the described performance levels shall be provisionally certified for the test procedure(s) in which they exceed the maximum number of unacceptable results on samples. Provisionally certified analysts can regain full certification status by meeting satisfactory performance levels on the next set of split samples. If a provisionally certified analyst does not meet satisfactory performance levels on the next set of split samples, certification to perform the specific test(s) ~~will~~ shall be withdrawn. An analyst who has lost certification may be required to participate in a training program acceptable to the ~~milk laboratory certifying authority~~ Milk Laboratory Control Agency before requesting recertification. Recertification after training shall be based on the analyst meeting the certification criteria described in SECTION ~~1~~2: LABORATORY EVALUATION PROGRAMS. A certified analyst may only become conditionally approved again by the route by which he/she lost certification, i.e. if the analyst lost certification due to failure on milk split samples then he/she can only become conditionally certified by passing the next set of milk split samples. If the analyst failed an on-site evaluation that leads to his/her loss of

certification then he/she ~~must~~ shall pass the next on-site certification to become conditionally certified.

~~BactoScan Industry Operators~~ BIOs performance levels shall follow the performance procedures indicated above for fully certified analysts. …

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SPLIT SAMPLES – CHEMISTRY

VITAMINS

The Grade "A" Vitamin Proficiency Test Program is operated by the FDA/LPET. In order to be accredited and be listed, laboratories ~~must~~ shall have analysts who have satisfactorily participated in at least two (2) consecutive split sample analyses and ~~must~~ shall have submitted satisfactory method validation and quality control/quality assurance (QC/QA) information. Participation in proficiency testing alone does not satisfy the criteria for analyst certification and laboratory accreditation.

The Grade ~~A~~ "A" Vitamin Proficiency Testing Program involves the analysis of sets of four (4) samples sent to participating laboratories every four (4) months, i.e., three (3) times a year with a total of twelve (12) samples. Certification status is based in part on the ability of analysts to analyze samples and have their results fall within limits (L_1=0.300 and L_2=0.200, based on the statistical parameters set at the 1995 NCIMS Conference in St. Louis, MO). Conditional certification is granted to an analyst (not to a laboratory) when the analyst has satisfactorily analyzed two (2) sets of samples (eight (8) samples in two (2) consecutive shipments). Analysts may have one (1) unsatisfactory result, i.e., miss (out of limits) one (1) sample, and still be considered as having satisfactory performance. After analyzing the next consecutive set of samples the analyst is considered fully certified if ~~no~~ not more than ~~2~~ two (2) samples have been missed over the course of a one (1) year period (twelve (12) consecutive samples analyzed).

Once fully certified, analysts maintain certification by satisfactorily analyzing all three (3) sets of split samples each year. During the course of the year full certification is maintained if ~~no~~ not more than two (2) samples (of twelve (12)) are missed. Failure without cause to analyze all twelve (12) samples during the course of the year ~~will~~ shall result in the down grading of an analyst's status. It is imperative that laboratory schedules be set up to allow for the analysis of these samples. If a fully certified analyst misses more than two (2) samples (of twelve (12)) then that analyst ~~will~~ shall be down graded to provisional certification. Full certification ~~will~~ shall be regained if that analyst misses ~~no~~ not more than one (1) sample of the next eight (8) that he/she analyzes. Provisionally or conditionally certified analysts that miss more than one (1) sample in the next eight (8) samples analyzed after receiving the respective status ~~will~~ shall have their certification/approval removed.

Once certification/approval is removed an analyst may only regain conditional certification by satisfactory performance on the next eight (8) samples, i.e., miss ~~no~~ not more than one (1)

sample. Full certification requires that the analyst meet the criteria described above.

For split sample purposes each analyst ~~must~~ shall independently analyze the samples. Routine analysis may be performed by multiple analysts working together or by partitioning duties. Certified analysts are responsible for conducting official analysis. Non-certified analysts may assist in analysis but may not solely perform official analyses or report official results.

Re-entry of laboratories that have voluntarily withdrawn or laboratories that have had their accreditation removed ~~is~~ are subject to meeting all of the requirements needed from a new laboratory, including all quality control (QC) information. It is the responsibility of the laboratory to inform the FDA/LPET when a certified analyst is no longer employed at that laboratory. A laboratory that loses all of their certified analysts is no longer accredited to do official work and ~~must~~ shall seek new laboratory entry prior to resuming official analysis. ..

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WATER MICROBIOLOGY

Laboratories using EPA or ~~State~~ other officially administrated programs for water analysis are not required to meet the intentions of this Section. ~~State-administered programs~~ Programs administered by ~~laboratory control agencies~~ Milk Laboratory Control Agencies include central, official, officially designated and other water testing laboratories sanctioned by the ~~state~~ Milk Laboratory Control Agencies and participation in a split sample program is voluntary.

Each State central accredited milk laboratory, and all ~~State~~ official, officially designated accredited milk laboratories not participating in an EPA or ~~State~~ other officially administered program for water analysis shall participate annually in a microbiological proficiency testing program for each water analysis methodology for which the laboratory is certified. The proficiency testing samples are to be provided by ~~State programs~~ Milk Laboratory Control Agencies or through private providers. …

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LABORATORY PERFORMANCE LEVEL …

Fully accredited laboratories not meeting the described performance levels shall be provisionally accredited for the test procedure(s) in which they exceed the maximum number of unacceptable results on samples. Provisionally accredited laboratories can regain full accreditation status by meeting satisfactory performance levels on the next set of split samples. If a provisionally accredited laboratory does not meet satisfactory performance levels on the next set of split samples, accreditation to perform the specific test(s) ~~will~~ shall be withdrawn. A laboratory that has lost their accreditation ~~must~~ shall participate in a training program acceptable to the ~~milk laboratory certifying authority~~ Milk Laboratory Control Agency before requesting ~~reaccreditation~~ re-accreditation. Re-accreditation after training shall be based on the laboratory meeting the accreditation criteria described in SECTION ~~1~~2: LABORATORY

EVALUATION PROGRAMS.

Copies of the proficiency testing report, including tabulation of laboratory results, shall be sent within four (4) months of the split sample examination date to the participating laboratory, the appropriate ~~Food and Drug Administration~~ FDA Regional Office~~,~~ and the FDA/LPET.

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SECTION ~~3~~4: CERTIFICATION OF MILK LABORATORY CONTROL AGENCY MILK LABORATORY EVALUATION OFFICERS

Initial certification of a ~~State~~ LEO shall be based on meeting the following criteria:

1. The individual ~~must~~ shall be ~~a State government~~ an employee of a Regulatory or a Milk Laboratory Control Agency and demonstrate competence in evaluating milk testing laboratories and analysts' performance of milk laboratory test methods or Appendix N procedures as stated on the FDA-2400 Series Forms when accompanied by a representative of the ~~FDA/ LPET~~ FDA/LPET on an initial check laboratory survey. The ~~Federal~~ FDA/LPET LEO shall accompany the ~~State~~ LEO to not more than two (2) laboratories/facilities during an initial check survey for initial certification purposes. Initial check surveys (for certification) should not be conducted at sites that have been evaluated within the past ninety (90) days.

2. The individual ~~must~~ shall submit an acceptable written report of the milk laboratory initial check survey to the FDA/LPET within sixty (60) days of the evaluation. Reports to the appropriate FDA Regional Office and FDA/LPET shall be sent by email and shall include the narrative report and appropriate, completed FDA summary template only (see ~~page~~ pages 37 – 40).

3. The individual ~~must~~ shall attend the Milk Laboratory Evaluation Officers Workshop (FDA Course FD373) conducted by the FDA/LPET ~~in conjunction with the Food and Drug Administration, State Training Team~~. If the individual does not have experience in the examination of dairy products, they ~~must~~ shall attend Course FD374 "Laboratory Examination of Dairy Products" prior to or within the year of attending the Milk Laboratory Evaluation Officers Workshop. …

Laboratory evaluations conducted by conditionally approved ~~State~~ LEOs ~~will~~ shall be considered official.

Conditional certification of a new ~~State~~ LEO can occur following the initial check survey described above. Full certification ~~will~~ shall be granted after the ~~State~~ LEO attends the next scheduled Milk Laboratory Evaluation Officers Workshop. Failure of a conditionally certified ~~State~~ LEO to attend the next scheduled Milk Laboratory Evaluation Officers Workshop, unless excused with cause by FDA/LPET, ~~will~~ shall require that the ~~State~~ LEO ~~must~~ restart the process. The ~~State~~ LEO candidate would then be required to participate in ~~another~~ a new check survey with a representative of the FDA/LPET, and then attend the next scheduled Milk

Laboratory Evaluation Officers Workshop.

Recertification of the ~~State~~ LEO ~~will~~ shall occur triennially, and ~~will~~ shall be based on satisfactorily meeting the following criteria:

1. The individual ~~must~~ shall be ~~a State government~~ an employee of a Regulatory Agency or a Milk Laboratory Control Agency and demonstrate continued competence in evaluating milk testing laboratories and analysts' performance of milk laboratory test methods or Appendix N procedures as stated on the FDA-2400 Series Forms when accompanied by a representative of the FDA/LPET on a check laboratory survey. The ~~Federal~~ FDA/LPET LEO shall accompany the ~~State~~ LEO to not more than two (2) laboratories/facilities during a check survey for recertification purposes.

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2. The individual ~~must~~ shall submit an acceptable written report of the milk laboratory check survey to the FDA/LPET within sixty (60) days of the evaluation. Reports to the appropriate FDA Regional Office and FDA/LPET shall be sent by email and shall include the narrative report and appropriate, completed FDA summary template only (see page 37 – 40).

3. The individual ~~must~~ shall have all laboratory evaluations, proficiency test examinations, and reports current (in particular, biennial surveys ~~must~~ shall be performed within the month of their anniversary date).

4. The individual ~~must~~ shall have prepared and transmitted, at least annually, a summary list of certified and approved analysts and procedures by laboratory to the ~~state milk sanitation rating agency~~ Regulatory Agency and/or Rating Agency and ~~the~~ FDA/LPET.

5. The individual has met the responsibilities for the training of ~~Industry Supervisors~~ ISs.

6. The individual ~~must~~ shall attend the Milk Laboratory Evaluation Officers Workshop once every three (3) years.

7. The individual ~~must~~ shall not fail, without cause, to attend an FDA Regional Milk Seminar. If a region holds a FDA Regional Milk Seminar, then ~~State~~ LEOs in that region are obligated to attend. If another region holds their regional milk seminar in the same year the ~~State~~ LEO may opt to attend that regional milk seminar in lieu of attending the regional milk seminar held in their region and still meet the requirement.

Once an individual has become a ~~State~~ LEO and is therefore considered fully certified, if he/she fails to submit acceptable written reports of milk laboratory evaluations within sixty (60) days to the FDA/LPET or fails to comply with item 2 above for Recertification (or continued certification), the ~~State~~ LEO ~~will~~ shall have ~~their~~ his/her certification status downgraded from full to provisional. In addition, an action plan ~~will~~ shall be established that is mutually agreeable to the FDA/LPET and the ~~state~~ Milk Laboratory Control Agency. The

~~State~~ LEO ~~would~~ shall ~~have to~~ meet the action plan criteria in addition to continuing to meet all the criteria specified in items 1-7 above, to maintain provisional certification status.

Laboratory evaluations conducted by provisionally approved ~~State~~ LEOs ~~will~~ shall be considered official.

Should a provisionally certified ~~State~~ LEO meet the criteria specified by their action plan and EML, SECTION ~~3~~4, their certification ~~will~~ shall be returned to full certification once they have successfully undergone their next LEO check evaluation with the FDA/LPET.

Should a provisionally certified ~~State~~ LEO fail to meet the criteria specified in the EML, SECTION ~~3~~4 and/or follow the action plan, then their certification ~~would~~ shall be revoked.

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The procedures for revocation ~~must~~ shall follow SECTION V. QUALIFICATIONS AND CERTIFICATIONS, Part H. of the *Procedures* Document.

~~State~~ LEOs who lose certification cannot be re-certified for a period of sixty (60) days from the date of the loss of their certification. Recertification ~~will~~ shall require meeting the requirements for initial certification.

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SECTION 4~~5~~: EQUIPMENT AND APPARATUS OF AID TO MILK LABORATORY EVALUATION OFFICERS

While conducting laboratory evaluations, the ~~Federal or~~ ~~State~~ FDA/LPET LEO or LEO may find it extremely useful to have in his/her possession different types of equipment which ~~will~~ shall enable them to examine the apparatus in use and judge the proficiency of laboratory procedures in use for the examination of milk products. Some ~~evaluation officers~~ LEOs currently use a large percentage of the equipment and apparatus listed below. Equipment should be maintained in proper working conditions to assure accuracy.

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SECTION ~~5~~6: GUIDELINES FOR CONDUCTING LABORATORY EVALUATIONS

The evaluations of laboratories by a ~~Federal or State~~ FDA/LPET LEO or LEO should be systematic. These guidelines are recommended to enable complete evaluation of the laboratory facilities, equipment and records and of analyst technique.

Upon initial evaluation and/or renewal, the laboratory, ~~must~~ shall make application for an evaluation upon a form provided by the ~~Federal or~~ ~~State~~ FDA/LPET LEO or LEO. The application ~~will~~ shall include the statement: …

In preparation for the laboratory evaluation, normally the laboratory director or supervisor should be notified in advance to insure the presence of analysts and the availability of samples for laboratory examination. In arranging for an initial evaluation, laboratory officials should be told that all tests ~~must~~ shall be set up and that during the evaluation the work of all analysts, who may perform any official methods ~~must~~ shall be observed. If laboratory evaluations are conducted on days when procedures, e.g. the SPC, are not normally performed, advance arrangements should be made to have samples on hand in order to observe the SPC procedure and the laboratory personnel should be requested to save countable plates from the previous day. Where the latter is not feasible, previously prepared and incubated plates may be brought to the laboratory by the ~~Federal or State~~ FDA/LPET LEO or LEO to permit observations of counting procedures. …

After entering the laboratory, the ~~Federal or State~~ FDA/LPET LEO or LEO should note the names of all analysts in the laboratory as/or after they are introduced and record the procedures performed by each.

Before beginning the survey, the ~~Federal or State~~ FDA/LPET LEO or LEO should discuss the "ground rules" for the survey. Rules should be established for procedural evaluations (e.g. whether an analyst can restart a procedure if the analyst notices that he/she make an error, how many times may an analyst restart...).

During an evaluation of a large laboratory, various analysts may be performing different examinations which may make a comprehensive evaluation difficult, particularly since all analysts are to be observed for each bacteriological and chemical procedure for which certification is requested. It is recommended that the ~~officer~~ FDA/LPET LEO or LEO establish a schedule so as to be in a position to evaluate apparatus and procedures used in the laboratory without disrupting, as far as possible, the routine examination of samples. Since it is expected that various portions of the evaluation forms ~~will~~ shall be used at separate times, it is advisable to note observed items of the various procedures on the left hand margins of the evaluation forms. By frequent referral to the noted items, the ~~Federal or State~~ FDA/LPET LEO or LEO ~~will~~ shall be reminded to observe all laboratory procedures in use and avoid misuse of the phrase "undetermined" (U) when procedures were actually in use but were not observed.

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While observations of procedures are being made and the evaluation forms completed, certain precautions should be taken by the ~~Federal or State~~ FDA/LPET LEO or LEO: …

During the laboratory evaluation it is probable that some items pertinent to receiving samples will not be observed. However, the ~~Federal or State~~ FDA/LPET LEO or LEO should determine from consultation with the laboratory supervisor the procedures used in receiving samples from the sample collectors: …

Deviations are to be discussed with the analysts at some time after it has been observed and properly recorded. This discussion should include the nature of the deviation, any effect on

the validity of the results, remedial action suggested and reasons justifying the change. All interested personnel should have an opportunity to look over the completed evaluation form and each major deviation should be discussed by the ~~officer~~ FDA/LPET LEO or LEO with interested staff. At that time comments should be invited from the staff concerning the evaluation. The ~~Federal or State~~ FDA/LPET LEO or LEO should make suggestions concerning any needed improvement of laboratory techniques. Following the discussion of procedures and competence of analysts, past split sample results of the laboratory should be discussed, suggestions made for improvement, and/or commendations made for superior performance.

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In addition to a regularly scheduled visit, some ~~Federal or State~~ FDA/LPET LEOs or LEOs find that an occasional unannounced visit to an accredited laboratory provides them with supporting information concerning laboratory practices. Information generated on all surveys (unannounced, scheduled, check surveys) ~~must~~ shall be evaluated by the ~~Federal or State~~ FDA/LPET LEO or LEO and used to determine compliance with the NCIMS Milk Laboratory Program.

If at any time during a survey there is interference with or willful refusal to permit the survey, the ~~Federal or State~~ FDA/LPET LEO or LEO ~~will~~ shall serve notice that the laboratory ~~will~~ shall not be certified or ~~will~~ shall be decertified until such time as the laboratory agrees to abide by the voluntary certification program. The laboratory may make reapplication by completing the application form and stipulating that future interference or refusals ~~will~~ shall result in non-certification or decertification for thirty days (30). Or, if at any time before or during any survey the ~~Federal or State~~ FDA/LPET LEO or LEO feels their safety is in jeopardy or determines extensive non-compliance, they may terminate the survey. The ~~Federal or State~~ FDA/LPET LEO or LEO ~~must~~ shall indicate to the laboratory management the reason why the survey was terminated and ~~must~~ shall indicate what steps ~~must~~ shall be taken before a resurvey will be scheduled. The laboratory may make ~~reapplication~~ re-application by addressing the concerns that led to the termination of the survey and by completing the application form stipulating that the safety concerns and/or non compliance issues have been addressed.

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SECTION ~~6~~7: LABORATORY EVALUATION REPORTS

EVALUATION FORMS …

Copies of the survey forms may be prepared for the laboratory evaluated. The ~~Federal or State~~ FDA/LPET LEO or LEO ~~must~~ shall maintain a complete copy of the survey report, including forms. The laboratory/facility and ~~Federal or State~~ FDA/LPET LEO or LEO ~~must~~ shall maintain, at a minimum, copies of the last two (2) biennial/triennial ~~surveys~~ survey reports, subject to verification by the ~~State~~ LEO and the FDA/LPET. In marking the official copies of the completed survey forms, leave items in compliance blank. When typing copies for

transmittal to others, do not include check marks in the margin which were made at the time of the actual survey for the convenience of the evaluating official.

NARRATIVE REPORT

The set of completed survey forms for the laboratory may accompany the narrative report which states the conclusions of the ~~Federal or State~~ FDA/LPET LEO or LEO as to whether or not the laboratory is doing acceptable work. If the completed evaluation forms do not accompany the narrative report, the report ~~must~~ shall be sufficiently detailed to allow readers to determine what is being cited without having to refer to the FDA-2400 Series Forms. Each form used shall have the revision date noted. Additional narrative reports, without FDA-2400 Series Forms, are to be sent to others that need to be informed as to the outcome of the laboratory survey. The copy of the narrative report submitted by email to FDA/LPET ~~must~~ shall be accompanied by the appropriate, completed FDA summary template, both attached to the same email. The ~~State~~ LEO ~~must~~ shall receive verification of receipt by return email and ~~must~~ shall maintain a copy of the verification in their records. The narrative report ~~must~~ shall identify the laboratory, give the laboratory number, show the date of the survey, who made the survey, list the prior status, list the date of the last on-site survey, indicate the present status, what recommendations were made to correct any deviations, what test(s) were approved, and who was certified to do them. …

A paragraph headed "Remarks" or "Recommendations" may be included if the ~~officer~~ FDA/LPET LEO or LEO wishes to comment on an item, e.g., one which could be improved by a change in procedure or by new equipment, or for any comment which is not appropriately covered in other Sections of the report.

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After "Personnel and Procedures Certified" list the full name of all laboratory personnel qualified to make each individual test for which certification or approval is given. Include information on the analysts' last split sample performance. Also include a statement requiring participation in the Proficiency Testing Program to maintain certification (e.g., "To maintain certification, analysts ~~must~~ shall successfully participate in the Annual Proficiency Testing Program for all procedures for which certification has been granted"). …

Under "Conclusion" give a descriptive statement of the degree of acceptability or rejection of the procedures used by the laboratory, including recommendations for approval or rejection of the results of the laboratory. Some typical conclusions are given in the following text, and except in special circumstances, one of the conclusions listed ~~must~~ shall be used to indicate whether the results are (or are not) acceptable to ~~State authorities~~ the Milk Laboratory Control Agency for use in rating milk for interstate shipment, where this is the purpose of the evaluation.

CONCLUSIONS …

2. Although the procedures, records, facilities and/or equipment in use at the time of the

evaluation were in substantial compliance with the requirements of the *Grade ~~'A'~~ "A" PMO* the analyst/facility/equipment/records deviations noted ~~must~~ shall be corrected. This laboratory is accredited/approved for thirty (30) – sixty (60) days pending correction of the deviations and receipt of a letter by the ~~evaluation officer~~ FDA/LPET LEO or LEO detailing the corrections made. Upon receipt of such letter, full accreditation/approval ~~will~~ shall be given.

Explanation: A qualified acceptance where the ~~Federal or State~~ FDA/LPET LEO or LEO believes that the deviations noted do not seriously affect the analytical results and that a letter explaining the corrective actions taken ~~will~~ shall be sufficient to ensure compliance.

3. Although the procedures, records, facilities and/or equipment in use at the time of the evaluation did not substantially comply with the requirements of the *Grade ~~'A'~~ "A" PMO*, the analyst/facility/equipment/records deviations noted are readily correctable. This laboratory is accredited/approved for (___) days pending correction of the deviations. Corrections ~~must~~ shall be made and detailed in writing to the ~~evaluation officer~~ FDA/LPET LEO or LEO during this period. A new survey ~~will~~ shall be scheduled upon receipt of the letter to assure full compliance.

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Explanation: A qualified acceptance where procedural or technical errors or facilities which could have an effect on analytical results are noted but which are readily correctable by the analysts or management. Depending on the judgment of the ~~State~~ LEO, a period of ~~no~~ not more than sixty (60) days usually is given to make the required adjustments before another survey is made or specified criteria are met, record, new equipment, etc. (some things may not require a return visit) to fully accredit (or approve) the laboratory.

4. This laboratory is not accredited/approved as the procedures, records, facilities and/or equipment in use at the time of the survey did not comply with the requirements of the *Grade ~~'A'~~ "A" PMO".*

Explanation: Severe deficiencies in facilities, records, staff and/or procedural techniques exist which would result in unacceptable results. A new on-site survey shall be made when the ~~Federal or State~~ FDA/LPET LEO or LEO has reason to believe that a rating would result in an acceptable rating. A new on-site survey would not be required for certified milk laboratories, CIS facility or screening facilities if the withdrawal was for facility deficiencies only. The laboratory, CIS facility or screening facility would be required to submit pictures, invoices, etc. to show compliance with the facility requirements noted in the last on-site evaluation.

FDA SUMMARY TEMPLATES

The narrative report sent to FDA/LPET ~~must~~ shall be accompanied by the appropriate, completed FDA summary template for the laboratory, specifically representing the information required for verifying and updating the IMS List of accredited laboratories and CISs along

with other useful information to be used by FDA/LPET. Only the current revision of the FDA summary templates, authored by FDA/LPET, ~~may~~ shall be used. There are two (2) FDA summary templates: one (1) for full service laboratories and one (1) for Appendix N Screening Only facilities (~~CIS and IS~~ CISs and ISs). The information captured on the FDA summary template ~~must~~ shall match the information provided in the narrative report (i.e., IMS number, facility identification, accreditation and certification status, dates, procedures, conclusion, etc.). The information captured may also lend itself to analyst/laboratory tracking and filing by the ~~State~~ LEO.

The appropriate FDA summary template form ~~must~~ shall also be used for the notification of changes in accreditation and certification status, and ~~must~~ shall be submitted by email to FDA/LPET.

Directions for completing the FDA summary template, authored by LPET, ~~will~~ shall be updated with each revision of the FDA summary template, as necessary, and provided to the LEOs by email. …

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REFERENCES

1. Copies of the FDA-2400 Series Forms can be obtained from ~~Federal or State~~ ~~Federal or State~~ FDA/LPET LEOs or LEO(s)-.

   A list of ~~Federal and State~~ FDA/LPET LEOs and LEOs can be found at the website: http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/MilkSafety/FederalStatePrograms/InterstateMilkShippersList/default.htm; and

   http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/MilkSafety/FederalStatePrograms/InterstateMilkShippersList/ucm114736.htm#TPC

   For ~~Federal~~ FDA/LPET LEOs click on the link FDA CFSAN Personnel and scroll down to the Laboratory Proficiency and Evaluation Team.

   For State LEOs click on the link State Grade A Milk Regulatory, Rating and Laboratory Personnel and then click on your ~~state~~ State. The table is organized by listing Regulatory personnel first, then Rating personnel, and finally Laboratory personnel. Scroll down to the laboratory section to find the contact information for your ~~state's~~ State's LEO(s).

   For TPC LEOs click on the link International Certification Program Third Party Certifiers. The table is organized by individual TPCs, listing Regulatory personnel first, then Rating personnel, and finally Laboratory personnel. Scroll down to the laboratory section to find the contact information for your TPC's LEO(s).

The following text is a part of the Proposal but will not be placed in an NCIMS document.

The ICPPC requests the NCIMS Chair to assign the following charge to the SSCC Committee and report back to the 2015 NCIMS Conference:

Develop qualifications, authorization, certification/recertification procedures, etc. for consultants that currently certify or wish to certify SSCC manufacturers located outside the geographical boundaries of NCIMS Member States. Consultants that currently have SSCC listings on the IMS List shall participate on this Committee.

This Proposal also authorizes FDA to make appropriate editorial changes to the NCIMS documents as needed, in accordance with NCIMS *Procedures*, resulting from Proposals that are passed at the 2013 NCIMS Conference, and concurred with by FDA, related to the wording addressing references to State, Regulatory Agency, Milk Laboratory Control Agency, etc. as cited throughout this Proposal.

NOTE: *This Proposal shall take immediate effect upon the issuance of the IMS-a, Actions from the 2013 National Conference on Interstate Milk Shipments, following FDA's concurrence with the NCIMS Executive Board.*

Proposal: 304
Documents: 2011 PMO (Entire Document)
Pages: Entire Document

*Make the following changes to the **2011 PMO**:*

Cover Page:

~~2011~~ 2013 Revision

Page iv:

PREFACE …

This edition of the *Ordinance* contains sanitary standards for ~~only~~ Grade "A" raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging and Grade "A" milk and/or milk products defined in Section 1. …

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GRADE "A" PASTEURIZED MILK ORDINANCE
(*GRADE "A" PMO*)--~~2011~~ 2013 REVISION

An *Ordinance* defining "milk" and certain "milk products", "milk producer", "pasteurization", etc.; prohibiting the sale of adulterated and misbranded milk and/or milk products; requiring permits for the sale of milk and/or milk products; regulating the inspection of dairy farms and milk plants; the examination, labeling, pasteurization, ultra-pasteurization, aseptic processing and packaging, retort processed after packaging and distribution and sale of milk and/or milk products; providing for the construction of future dairy farms and milk plants; the enforcement of this *Ordinance*; and the fixing of penalties.

Be it ordained by the ... of ...[1] as follows:

SECTION 1. DEFINITIONS …

B. **ASEPTIC PROCESSING AND PACKAGING:** The term "Aseptic Processing and Packaging", when used to describe a milk and/or milk product, means that the milk and/or milk product has been subjected to sufficient heat processing and packaged in a hermetically sealed container, to conform to the applicable requirements of 21 CFR Parts 108, 110 and 113 and to maintain the commercial sterility of the milk and/or milk product under normal non-refrigerated conditions.

C. **ASEPTIC PROCESSING AND PACKAGING SYSTEM (APPS):** For the purposes of this *Ordinance*, the Aseptic Processing and Packaging System (APPS) in a milk plant is comprised of the processes and equipment used to process and package aseptic Grade "A" low-acid milk and/or milk products. The Aseptic Processing and Packaging System (APPS) shall be regulated in accordance with the applicable requirements of 21 CFR Parts 108, 110 and 113. The Aseptic Processing and Packaging System (APPS) shall begin at the constant level tank and end at the discharge of the packaging machine, provided that the Process Authority may provide written documentation which will clearly define additional processes and/or equipment that are considered critical to the commercial sterility of the product. …

Page 2:

F. **BULK MILK PICKUP TANKER:** A bulk milk pickup tanker is a vehicle, including the truck, tank and those appurtenances necessary for its use, used by a bulk milk hauler/sampler to transport bulk raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging from a dairy farm to a milk plant, receiving station, or transfer station. …

Page 4:

S. **HACCP DEFINITIONS:** (For use in conjunction with Appendix K.)

S-1. **AUDIT:** An evaluation of the entire milk plant, receiving station, or transfer station facility, and NCIMS HACCP System to ensure compliance with the NCIMS HACCP

System and other NCIMS regulatory requirements, with the exception of the Aseptic Processing and Packaging System (APPS) for aseptic processing and packaging milk plants and Retort Processed after Packaging System (RPPS) for retort processed after packaging milk plants, respectively. …

Page 6:

V. **LOW-ACID ASEPTIC AND RETORT MILK AND/OR MILK PRODUCTS:** Milk and/or milk products having a water activity (a_w) greater than 0.85 and a finished equilibrium pH greater than 4.6 and are regulated under 21 CFR Parts 108, 110 and 113. Aseptically processed and packaged low-acid milk and/or milk products and retort processed after packaging low-acid milk and/or milk products are stored under normal non-refrigerated conditions. Excluded from this definition are low-acid milk and/or milk products that are labeled for storage under refrigerated conditions. …

X. **MILK PLANT:** A milk plant is any place, premises; or establishment where milk and/or milk products are collected, handled, processed, stored, pasteurized, ultra-pasteurized, aseptically processed and packaged, retort processed after packaged, condensed, dried, packaged, or prepared for distribution. …

Page 8:

GG. **OFFICIALLY DESIGNATED LABORATORY:** An officially designated laboratory is a commercial laboratory authorized to do official work by the Regulatory Agency, or a milk industry laboratory officially designated by the Regulatory Agency for the examination of producer samples of Grade "A" raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging and commingled milk tank truck samples of raw milk for drug residues and bacterial limits. …

Page 9:

MM. **RETORT PROCESSED AFTER PACKAGING:** The term "Retort Processed after Packaging", when used to describe a milk and/or milk product, means that the milk and/or milk product has been subjected to sufficient retort heat processing after packaged in a hermetically sealed container, to conform to the applicable requirements of 21 CFR Parts 108, 110 and 113 and to maintain the commercial sterility of the milk and/or milk product under normal non-refrigerated conditions.

NN. **RETORT PROCESSED AFTER PACKAGING SYSTEM (RPPS):** For the purposes of this *Ordinance*, the Retort Processed after Packaging System (RPPS) in a milk plant is comprised of the processes and equipment used to retort process after packaging low-acid Grade "A" milk and/or milk products. The Retort Processed after Packaging System (RPPS) shall be regulated in accordance with the applicable requirements of 21 CFR Parts 108, 110 and 113. The Retort Processed after Packaging System (RPPS) shall begin at the container filler and end at the palletizer, provided that the Process Authority may provide written

documentation which will clearly define additional processes and/or equipment that are considered critical to the commercial sterility of the milk and/or milk product.

~~MM~~OO. **SANITIZATION:** Is the application of any effective method or substance to properly cleaned surfaces for the destruction of pathogens, and other microorganisms, as far as is practicable. Such treatment shall not adversely affect the equipment, the milk and/or milk product, or the health of consumers, and shall be acceptable to the Regulatory Agency. …

Re-letter remaining DEFINITIONS accordingly.

~~OO~~QQ. **TIME/TEMPERATURE CONTROL FOR SAFETY OF MILK AND/OR MILK PRODUCTS:** Milk and/or milk products that require time/temperature control for safety (TCS) to limit pathogenic microorganism growth or toxin formation includes: …

Page 11:

~~QQ~~SS. **ULTRA-PASTEURIZATION (UP):** The term "Ultra-Pasteurization", when used to describe a ~~dairy~~ milk and/or milk product, means that such milk and/or milk product shall have been thermally processed at or above 138°C (280°F) for at least two (2) seconds, either before or after packaging, so as to produce a milk and/or milk product, which has an extended shelf-life under refrigerated conditions. (Refer to 21 CFR 131.3.) …

Re-letter remaining DEFINITIONS accordingly.

Page 11:

SECTION 2. ADULTERATION OR MISBRANDED MILK AND/OR MILK PRODUCTS …

Page 15:

SECTION 4. LABELING …

All bottles, containers and packages containing milk or milk products, except milk tank trucks, storage tanks and cans of raw milk from individual dairy farms, shall be conspicuously marked with:

1. The identity of the milk plant where pasteurized, ultra-pasteurized, aseptically processed and packaged, retort processed after packaging, condensed and/or dried.
2. The words "keep refrigerated after opening" in the case of aseptically processed and packaged low-acid milk and/or milk products and retort processed after packaging low-acid milk and/or milk products. …

Page 16:

IDENTITY LABELING: "Identity", as used in this Section, is defined as the name and address or permit number of the milk plant at which the pasteurization, ultra-pasteurization, aseptic processing and packaging, retort processed after packaging, condensing and/or drying takes place. It is recommended that the voluntary national uniform coding system for the identification of milk plants, at which milk and/or milk products are packaged, be adopted in order to provide a uniform system of codes throughout the country.
In cases where several milk plants are operated by one (1) firm, the common firm name may be utilized on milk bottles, containers and packages. Provided, that the location of the milk plant at which the contents were pasteurized, ultra-pasteurized, aseptically processed and packaged, retort processed after packaged, condensed and/or dried is also shown, either directly or by a code. This requirement is necessary in order to enable the Regulatory Agency to identify the source of the pasteurized, ultra-pasteurized, aseptically processed and packaged, retort processed after packaged, condensed and/or dried milk and/or milk products. The street address of the milk plant ~~need~~ does not need to be shown when only one (1) milk plant of a given name is located within the municipality.

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The identity labeling requirement may be interpreted as permitting milk plants and persons to purchase and distribute, under their own label, milk and/or milk products processed and packaged at another milk plant, provided, that the label reads, "Processed at ... (name and address)", or that the processing and packaging milk plant is identified by a proper code.

MISLEADING LABELS: The Regulatory Agency shall not permit the use of any misleading marks, words or endorsements upon the label. They may permit the use of registered trade designs or similar terms on the bottle cap or label, when in their opinion, they are not misleading and are not so used as to obscure the labeling required by this *Ordinance*. For dry milk products, the outer bag ~~must~~ shall be preprinted "Grade "A" before filling. The use of super grade designations shall not be permitted. However, this should not be construed as prohibiting the use of official grade designations awarded to dry milk products by the United States Department of Agriculture (USDA). Grade designations such as “Grade "AA" Pasteurized”, “Selected Grade "A" Pasteurized”, “Special Grade "A" Pasteurized”, etc., give the consumer the impression that such a grade is significantly safer than Grade “A”. Such an implication is false, because the *Ordinance* requirements for Grade “A” pasteurized, ultra-pasteurized, ~~or~~ aseptically processed and packaged low-acid milk and/or milk products, or retort processed after packaged low-acid milk and/or milk products when properly enforced, will ensure that this grade of milk and/or milk products will be as safe as they can practically be made. Descriptive labeling terms ~~must~~ shall not be used in conjunction with the Grade “A” designation or name of the milk and/or milk product and ~~must~~ shall not be false or misleading.

SECTION 5. INSPECTION OF DAIRY FARMS AND MILK PLANTS

Each dairy farm, milk plant, receiving station, transfer station, milk tank truck cleaning facility whose milk and/or milk products are intended for consumption within ...of...[1] or it's jurisdic-

tion, and each bulk milk hauler/sampler who collects samples of raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging, for bacterial, chemical or temperature standards and hauls milk from a dairy farm to a milk plant, receiving station or transfer station and each milk tank truck and its appurtenances shall be inspected/audited by the Regulatory Agency prior to the issuance of a permit. Following the issuance of a permit, the Regulatory Agency shall: …

1. Inspect each milk tank truck and its appurtenances used by a bulk milk hauler/sampler who collects samples of raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging for bacterial, chemical or temperature standards and hauls milk from a dairy farm to a milk plant, receiving station or transfer station, at least once every twelve (12) months. …

3. Inspect each milk plant and receiving station at least once every three (3) months, provided that, for those milk plants and receiving stations that have HACCP Systems, which are regulated under the NCIMS voluntary HACCP Program, regulatory audits shall replace the regulatory inspections described in this Section. The requirements and minimum frequencies for these regulatory audits are specified in Appendix K. Provided further, that regulatory inspections of a milk plant or portion of a milk plant that is IMS listed to produce aseptically processed and packaged low-acid milk and/or milk products and/or retort processed after packaged low-acid milk and/or milk products shall be conducted by the State Regulatory Agency in accordance with this *Ordinance* at least once every six (6) months. (Refer to Appendix S.) The milk plant's APPS and RPPS, respectively, shall be inspected by FDA, or the State Regulatory Agency when designated by FDA, in accordance with the applicable requirements of 21 CFR Parts 108, 110 and 113 at a frequency determined by FDA. …

Page 19:

ADMINISTRATIVE PROCEDURES

INSPECTION FREQUENCY: For the purposes of determining the inspection frequency for dairy farms, transfer stations and milk plants or the portion of a milk plant that is IMS listed to produce aseptically processed and packaged low-acid milk and/or milk products and/or retort processed after packaged low-acid milk and/or milk products, the interval shall include the designated six (6) month period plus the remaining days of the month in which the inspection is due. …

One (1) milk tank truck inspection every twelve (12) months; or bulk milk hauler/sampler's or industry plant sampler's pickup and sampling procedures inspection each twenty-four (24) months; or one (1) ~~producer~~ dairy farm, transfer station, milk plants or the portion of a milk plant that is IMS listed to produce aseptically processed and packaged low-acid milk and/or milk products and/or retort processed after packaged low-acid milk and/or milk products, or milk tank truck cleaning facility inspection every six (6) months; or one (1) milk plant producing pasteurized, ultra-pasteurized, condensed or dried milk and/or milk products or receiving station inspection every three (3) months is not a desirable frequency, it is instead a legal minimum. Bulk milk hauler/samplers, industry plant samplers, milk tank trucks, milk

tank truck cleaning facilities, dairy farms, milk plants, receiving stations and transfer stations experiencing difficulty meeting requirements should be visited more frequently. Milk plants that condense and/or dry milk and/or milk products and which operate for a short duration of time or intermittent periods of time should also be inspected more frequently. Inspections of dairy farms shall be made at milking time as often as possible and of milk plants at different times of the day in order to ascertain if the processes of equipment assembly, sanitizing, pasteurization, ultra-pasteurization, cleaning and other procedures comply with the requirements of this *Ordinance*. …

Page 20:

ENFORCEMENT PROCEDURES - ASEPTIC PROCESSING AND PACKAGING MILK PLANTS AND/OR RETORT PROCESSED AFTER PACKAGING MILK PLANTS: The State Regulatory Agency shall take appropriate regulatory action, in coordination with FDA when applicable, to assure that the Grade "A" aseptic milk plant and/or Grade "A" retort milk plant and the ~~Grade "A"~~ aseptic Grade "A" low-acid milk and/or milk products and/or the retort processed Grade "A" low-acid milk and/or milk products, respectively, meet the applicable requirements of this *Ordinance*.

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SECTION 6. THE EXAMINATION OF MILK AND/OR MILK PRODUCTS …

1. During any consecutive six (6) months, at least four (4) samples of raw milk for pasteurization, ultra-pasteurization, ~~or~~ aseptic processing and packaging, or retort processed after packaging, shall be collected from each producer, in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days. These samples shall be obtained under the direction of the Regulatory Agency or shall be taken from each producer under the direction of the Regulatory Agency and delivered in accordance with this Section.
2. During any consecutive six (6) months, at least four (4) samples of raw milk for pasteurization, ultra-pasteurization, ~~or~~ aseptic processing and packaging, or retort processed after packaging, shall be collected in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days. These samples shall be obtained by the Regulatory Agency, from each milk plant after receipt of the milk by the milk plant and prior to pasteurization, ultra-pasteurization, ~~or~~ aseptic processing and packaging, or retort processed after packaging.
3. During any consecutive six (6) months, at least four (4) samples of pasteurized milk, ultra-pasteurized milk, flavored milk, flavored reduced fat or low fat milk, flavored nonfat (skim) milk, each fat level of reduced fat or low fat milk and each milk product defined in this *Ordinance*, shall be collected by the Regulatory Agency in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days from every milk plant. All pasteurized and ultra-pasteurized milk and/or milk products required sampling and testing is to be done only when there are test methods available that are validated by FDA and accepted by the NCIMS. Products ~~with no~~ that do not have validated and accepted methods are not required to be tested. Aseptically processed and

packaged low-acid milk and/or milk products and retort processed after packaged low-acid milk and/or milk products shall be exempt from the sampling and testing requirements of this Item. …

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Required bacterial counts, somatic cell counts and cooling temperature checks shall be performed on raw milk for pasteurization, ultra-pasteurized, ~~or~~ aseptic processing and packaging, or retort processed after packaging. In addition, drug tests on each producer's milk shall be conducted at least four (4) times during any consecutive six (6) months.
All pasteurized and ultra-pasteurized milk and/or milk products required sampling and testing to be done only when there are test methods available that are validated by FDA and accepted by the NCIMS, otherwise there would ~~be no~~ not be a requirement for sampling. Required bacterial counts, coliform counts, drug tests, phosphatase and cooling temperature determinations shall be performed on Grade "A" pasteurized and ultra-pasteurized milk and/or milk products defined in this *Ordinance* only when there are validated and accepted test methodology.

NOTE: When multiple samples of the same milk and/or milk products, except for aseptically processed and packaged low-acid milk and/or milk products and retort processed after packaged low-acid milk and/or milk products, are collected from the same producer or processor from multiple tanks or silos on the same day, the laboratory results are averaged arithmetically by the Regulatory Agency and recorded as the official results for that day. This is applicable for bacterial (standard plate count and coliform), somatic cell count and temperature determinations only. …

Page 25:

Assays of milk and/or milk products as defined in this *Ordinance*, including aseptically processed and packaged low-acid milk and/or milk products and retort processed after packaged low-acid milk and/or milk products, to which vitamin(s) A and/or D have been added for fortification purposes, shall be made at least annually in a laboratory, which has been accredited by FDA and which is acceptable to the Regulatory Agency, using test methods acceptable to FDA or other official methodologies, which gives statistically equivalent results to the FDA methods. Vitamin testing laboratories are accredited if they have one (1) or more certified analysts and meet the quality control requirements of the program established by FDA. Laboratory accreditation and analyst certification parameters are specified in the Evaluation of Milk Laboratories (EML) manual. …

Page 27:

SAMPLING PROCEDURES: *SMEDP* contains guidance for sampling of milk and milk products. Optionally, sample collection time may be identified in military time (24 hour clock). (Refer to Appendix G. for a reference to drug residues in milk and the conditions under which a positive phosphatase reaction may be encountered in properly pasteurized milk or cream.

Refer to Appendix B. for reference to farm bulk milk hauling programs regarding training, licensing/permitting, routine inspection and the evaluation of sampling procedures.)
When samples of raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging are taken at a milk plant prior to pasteurization, they shall be drawn following adequate agitation from randomly selected storage tanks. All counts and temperatures ~~should~~ shall be recorded on a milk-ledger form as soon as reported by the laboratory. A computer or other information retrieval system may be used. …

SECTION 7. STANDARDS FOR GRADE "A" MILK AND/OR MILK PRODUCTS

All Grade "A" raw milk and/or milk products for pasteurization, ~~or~~ ultra-pasteurization, ~~or~~ aseptic processing and packaging, or retort processed after packaging and all Grade "A" pasteurized, ultra-pasteurized, ~~or~~ aseptically processed and packaged low-acid milk and/or milk products, or retort processed after packaged low-acid milk and/or milk products, shall be produced, processed**,** manufactured and pasteurized, ultra-pasteurized, ~~or~~ aseptically processed and packaged, or retort processed after packaged to conform to the following chemical, physical, bacteriological and temperature standards and the sanitation requirements of this Section.
No process or manipulation other than pasteurization, ultra-pasteurization, ~~or~~ aseptic processing and packaging, or retort processed after packaging; processing methods integral therewith; and appropriate refrigeration shall be applied to milk and milk products for the purpose of removing or deactivating microorganisms, provided that filtration and/or bactofugation processes are performed in the milk plant in which the milk and/or milk product is pasteurized, ultra-pasteurized, ~~or~~ aseptically processed and packaged, or retort processed after packaged. Provided, that in the bulk shipment of cream, nonfat (skim) milk, ~~or~~ reduced fat or lowfat milk, the heating of the raw milk, one (1) time, to temperatures greater than 52ºC (125ºF) but less than 72ºC (161ºF), for separation purposes, is permitted when the resulting bulk shipment(s) of cream, nonfat (skim) milk, ~~or~~ reduced fat or lowfat milk are labeled heat-treated. In the case of heat-treated cream, the cream may be further heated to less than 75ºC (166ºF) in a continuing heating process and immediately cooled to 7ºC (45ºF) or less when necessary for enzyme deactivation (such as lipase reduction) for a functional reason. …

Page 28:

Whey shall be from cheese made from Grade "A" raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging as provided in this *Ordinance*. …

Page 29:

Table 1. Chemical, Physical, Bacteriological, and Temperature Standards

GRADE "A" RAW MILK AND MILK PRODUCTS FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ~~OR~~ ASEPTIC PROCESSING AND ~~PACKGING~~ PACKAGING, OR RETORT PROCESSED AFTER PACKAGING

Page 31:

STANDARDS FOR GRADE "A" RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ~~OR~~ ASEPTIC PROCESSING AND ~~PACKGING~~ PACKAGING OR RETORT PROCESSED AFTER PACKAGING …

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ITEM 18r. RAW MILK COOLING

Raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging shall be cooled to 10ºC (50ºF) or less within four (4) hours or less, of the commencement of the first milking, and to 7ºC (45ºF) or less, within two (2) hours after the completion of milking. Provided, that the blend temperature after the first milking and subsequent milkings does not exceed 10ºC (50ºF). …

Page 55:

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. Raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging shall be cooled to 10ºC (50ºF) or less within four (4) hours or less, of the commencement of the first milking, and to 7ºC (45ºF) or less, within two (2) hours after the completion of milking. Provided, that the blend temperature after the first milking and subsequent milkings does not exceed 10ºC (50ºF). …

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STANDARDS FOR GRADE "A" PASTEURIZED, ULTRA-PASTEURIZED, ~~AND~~ ASEPTICALLY PROCESSED AND PACKAGED LOW-ACID MILK AND/OR MILK PRODUCTS, AND RETORT PROCESSED AFTER PACKAGED LOW-ACID MILK AND/OR MILK PRODUCTS

Milk plants shall comply with all Items of this Section. Provided, in the case of milk plants or portions of milk plants that are IMS Listed to produce aseptically processed and packaged low-acid milk and/or milk products and/or retort processed after packaging low-acid milk and/or milk products, the APPS or RPPS, respectively, as defined by this *Ordinance,* shall be exempt from Items 7p, 10p, 11p, 12p, 13p, 15p, 16p, 17p, 18p, and 19p of this *Ordinance* and shall comply with the applicable portions of 21 CFR Parts 108, 110 and 113. Those Items, contained within the APPS and RPPS, shall be inspected by FDA or a State Regulatory Agency, when designated by FDA. …

Milk plants that have HACCP Systems, which are regulated under the NCIMS HACCP Program, shall comply with all of the requirements of Item 16p. Pasteurization, ~~and~~ Aseptic Processing and Packaging, and Retort Processed after Packaging of this *Ordinance*, and

pasteurization shall be managed as a CCP as described in Appendix H., VIII-MILK AND MILK PRODUCT CONTINUOUS-FLOW (HTST AND HHST) PASTEURIZATION---CCP MODEL HACCP PLAN SUMMARY; and MILK AND MILK PRODUCT VAT (BATCH) PASTEURIZATION---CCP MODEL HACCP PLAN SUMMARY. …

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ITEM 1p. FLOORS – CONSTRUCTION …

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when: …

3. The floors are provided with trapped drains. Cold-storage rooms used for storing milk and/or milk products need not be provided with floor drains when the floors are sloped to drain to one (1) or more exits. Storage rooms for dry ingredients, dry packaged milk and/or milk products, ~~and~~ aseptically processed and packaged low-acid milk and/or milk products and/or packaging materials; and retort processed after packaged low-acid milk and/or milk products and/or packaging materials ~~need~~ are not ~~be~~ required to be provided with drains. …

ITEM 2p. WALLS AND CEILINGS – CONSTRUCTION …

Page 57:

ADMINISTRATIVE PROCEDURES …

This Item is deemed to be satisfied when: …

NOTE: Refer to Item 11p for requirements for walls for drying chambers. Storage rooms used for the storage of packaged dry milk and/or milk products, ~~and~~ aseptically processed and packaged low-acid milk and/or milk products, and retort processed after packaged low-acid milk and/or milk products are exempt from the ceiling requirements of this Item. …

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ITEM 5p. SEPARATE ROOMS

There shall be separate rooms for: …

4. The fabrication of containers and closures for milk and/or milk products, except for aseptically processed and packaged low-acid milk and/or milk products and/or retort processed after packaged low-acid milk and/or milk products in which the containers and closures are fabricated within the APPS or RPPS, respectively. …

ITEM 11p. CONSTRUCTION AND REPAIR OF CONTAINERS AND EQUIPMENT

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when: …

Page 67:

12. Provided that all paper, plastics, foil, adhesives, and other components of containers and closures used in the packaging of milk and/or milk products that have been aseptically processed and packaged or retort processed after packaged are governed under the applicable provisions of 21 CFR Parts 110 and 113 and shall not be subject to this ~~Section~~ Item. …

Page 82:

ITEM 16p. PASTEURIZATION, ~~AND~~ ASEPTIC PROCESSING AND PACKAGING, AND RETORT PROCESSED AFTER PACKAGING

Pasteurization shall be performed as defined in Section 1, Definition HH and Item 16p of this *Ordinance*. Aseptic processing and packaging and retort processed after packaging shall be performed in accordance with the applicable requirements of 21 CFR Parts 108, 110 and 113. (Refer to Appendix L.) …

PUBLIC HEALTH REASON …

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A note of caution is in order. Although pasteurization destroys the organisms, it does not destroy the toxins that may be formed in milk and/or milk products when certain staphylococci are present, as from udder infections, and when the milk and/or milk product is not properly refrigerated before pasteurization. Such toxins may cause severe illness. Aseptic processing and packaging and retort processed after packaging ~~has~~ have also been conclusively demonstrated to be effective in preventing outbreaks from milkborne pathogens. Numerous studies and observations clearly prove that the food value of milk is not significantly impaired by pasteurization. ..

ITEM 17p. COOLING OF MILK AND/OR MILK PRODUCTS …

Page 106:

Aseptically processed and packaged low-acid milk and/or milk products and retort processed after packaged low-acid milk and/or milk products to be packaged in hermetically sealed containers shall be exempt from the cooling requirements of this Item. …

Page 116:

SECTION 8. ANIMAL HEALTH

1. All milk for pasteurization, ultra-pasteurization, ~~or~~ aseptic processing and packaging or retort processed after packaging shall be from herds under a tuberculosis eradication program, which meets one (1) of the following conditions: …

2. All milk for pasteurization, ultra-pasteurization, ~~or~~ aseptic processing and packaging or retort processed after packaging shall be from herds under a brucellosis eradication program, which meets one (1) of the following conditions: …

Page 117:

3. Goat, sheep, water buffalo, or any other hooved mammal milk for pasteurization, ultra-pasteurization, ~~or~~ aseptic processing and packaging or retort processed after packaging, defined under this *Ordinance*, shall be from a herd or flock that: …

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SECTION 9. MILK AND/OR MILK PRODUCTS WHICH MAY BE SOLD

From and after twelve (12) months from the date on which this *Ordinance* is adopted, only Grade "A" pasteurized, ultra-pasteurized, ~~or~~ aseptically processed and packaged low-acid milk and/or milk products or retort processed after packaged low-acid milk and/or milk products shall be sold to the final consumer, to restaurants, soda fountains, grocery stores or similar establishments. Provided, only Grade "A" milk and/or milk products shall be sold to milk plants for use in the commercial preparation of Grade "A' milk and/or milk products. Provided further, that in an emergency, the sale of pasteurized, ultra-pasteurized, ~~or~~ aseptically processed and packaged low-acid milk and/or milk products or retort processed after packaged low-acid milk and/or milk products, which have not been graded, or the grade of which is unknown, may be authorized by the Regulatory Agency, in which case, such milk and/or milk products shall be labeled "ungraded". …

SECTION 11. MILK AND/OR MILK PRODUCTS FROM POINTS BEYOND THE LIMITS OF ROUTINE INSPECTION

ADMINISTRATIVE PROCEDURES

Page 122:

11. Aseptically processed and packaged low-acid milk and/or milk products in Definition Z of this *Ordinance* shall be considered to be Grade "A" milk and/or milk products. The sources(s) of the milk and/or milk products used to produce aseptically processed and packaged low-acid milk and/or milk products shall be IMS listed. Aseptically processed and packaged low-acid milk and/or milk products shall be labeled "Grade "A"" and meet Section 4 labeling requirements of the PMO. The milk plant or portion of the milk plant that is producing aseptically processed and packaged low-acid milk and/or milk products shall be awarded a

Milk Sanitation Compliance Rating of at least ninety percent (90%) and an Enforcement Rating equal to the local supply, or equal to ninety percent (90%) or higher, or if the Enforcement Rating is below ninety percent (90%) on a rating, a re-rating ~~must~~ shall occur within (6) months of this rating. Both the Milk Sanitation Compliance and Enforcement Ratings ~~must~~ shall be equal to ninety percent (90%) or higher on the re-rating or the supply is considered in violation of this Section. In the case of HACCP/Aseptic listings, an acceptable HACCP listing by a SRO is required. For milk plants that produce aseptically processed and packaged Grade "A" milk and/or milk products, prior to the milk plant participating in the NCIMS Aseptic Processing and Packaging Program~~,~~ or the Aseptic Pilot Program, the State's regulatory and rating personnel shall have completed a training course that is acceptable to the NCIMS and FDA addressing the procedures for conducting regulatory inspections and ratings under the NCIMS Aseptic Processing and Packaging Program or Aseptic Pilot Program. The NCIMS Aseptic Pilot Program addressing aseptically processed and packaged acidified and fermented high-acid milk and/or milk products regulated under 21 CFR Parts 108, 110, and/or 114 ~~will~~ shall expire on December 31, ~~2013~~ 2015, unless extended by future conference action.

12. Retort processed after packaging low-acid milk and/or milk products as addressed in Definition Z of this *Ordinance* shall be considered to be Grade "A" milk and/or milk products if they are used as an ingredient to produce any milk and/or milk product defined in Definition Z of this *Ordinance*; or if they are labeled as Grade "A" as described in Section 4 of this *Ordinance*. Retort processed after packaging low-acid milk and/or milk products shall be labeled "Grade "A"" and meet Section 4 labeling requirements of this *Ordinance* whenever they meet the provisions cited within Definition Z of this *Ordinance*. The source(s) of the milk and/or milk products used to produce retort processed after packaging Grade "A" low-acid milk and/or milk products shall be IMS listed. The milk plant or portion of the milk plant that is producing retort processed after packaging Grade "A" low-acid milk and/or milk products shall be awarded a Milk Sanitation Compliance Rating of at least ninety percent (90%) and an Enforcement Rating equal to the local supply, or equal to ninety percent (90%) or higher; or if the Enforcement Rating is below ninety percent (90%) on a rating, a re-rating ~~must~~ shall occur within (6) months of this rating. Both the Milk Sanitation Compliance and Enforcement Ratings ~~must~~ shall be equal to ninety percent (90%) or higher on the re-rating; or the supply is considered in violation of this Section. In the case of HACCP/Retort listings, an acceptable HACCP listing by a SRO is required. For milk plants that produce retort processed after packaging Grade "A" low-acid milk and/or milk products and prior to the milk plant participating in the NCIMS Retort ~~Pilot~~ Processed after Packaging Program, the State's regulatory and rating personnel shall have completed a training course that is acceptable to the NCIMS and FDA addressing the procedures for conducting regulatory inspections and ratings under the NCIMS Retort ~~Pilot~~ Processed after Packaging Program. ~~The NCIMS Retort Pilot Program addressing retort processed after packaging Grade "A" milk and milk products regulated under 21 CFR Parts 108, 110, and 113 will expire on December 31, 2013, unless extended by future conference action.~~ …

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SECTION 13. PERSONNEL HEALTH

~~No persons~~ Persons affected with any disease capable of being transmitted to others through the contamination of food shall not work at a milk plant in any capacity which brings them into direct contact with pasteurized, ultra-pasteurized, ~~or~~ aseptically processed and packaged low-acid milk and/or milk products or retort processed after packaged low-acid milk and/or milk products or which brings them into direct contact with associated ~~pasteurized, ultra-pasteurized, or aseptically processed and packaged~~ milk and/or milk product-contact surfaces. …

ADMINSTRATIVE PROCEDURES

Milk plant operators who have received reports, under this Section, from employees who have handled pasteurized, ultra-pasteurized, aseptically processed and packaged low-acid milk and/or milk products or retort processed after packaged low-acid milk and/or milk products or associated milk and/or milk product-contact surfaces shall immediately report these facts to the appropriate ~~Milk~~ Regulatory Agency. …

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SECTION 14. PROCEDURE WHEN INFECTION OR HIGH RISK OF INFECTION IS DISCOVERED

When a person who may have handled pasteurized, ultra-pasteurized, ~~or~~ aseptically processed and packaged low-acid milk and/or milk products or retort processed after packaged low-acid milk and/or milk products or ~~pasteurized, ultra-pasteurized aseptically processed and packaged~~ associated milk and/or milk product-contact surfaces meets one (1) or more of the conditions specified in the **ADMINISTRATIVE PROCEDURES** of Section 13, the Milk Regulatory Agency is authorized to require any or all of the following measures: …

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NOTE: Persons at risk who decline to be examined may be reassigned to duties where they will not be required to handle pasteurized, ultra-pasteurized, ~~or~~ aseptically processed and packaged low-acid milk and/or milk products, or retort processed after packaged low-acid milk and/or milk products and associated milk and/or milk product-contact surfaces. …

APPENDIX K. HACCP PROGRAM …

II. IMPLEMENTATION OF A HACCP SYSTEM …

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VERIFICATION AND VALIDATION:

1. **Verification:** Every milk plant, receiving station or transfer station shall verify that the HACCP System is being implemented according to design, except that the milk plant's APPS or RPPS, respectively, as defined by this *Ordinance*, shall be managed separately from the

NCIMS HACCP System, even if identified as a CCP in the hazard analysis. The milk plant's APPS or RPPS, respectively, shall be inspected by FDA, or the State Regulatory Agency when designated by FDA, in accordance with the applicable requirements of 21 CFR Parts 108, 110 and 113 at a frequency determined by FDA. …

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APPENDIX Q. OPERATION OF AUTOMATIC MILKING INSTALLATIONS FOR THE PRODUCTION OF GRADE "A" RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ~~OR~~ ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING

This Appendix is intended to clarify how AMIs are to perform to be considered in compliance with the *Grade "A" PMO*. It is formatted to follow the Items as outlined in Section 7. STANDARDS FOR GRADE "A" RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ~~OR~~ ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING. Both requirements and recommendations are discussed. …

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ITEM 18r. RAW MILK COOLING

For AMIs the raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging shall be cooled to 10ºC (50ºF) within four (4) hours or less after starting the milking operation and the milk shall be cooled within two (2) more hours to 7ºC (45ºF). The bulk milk storage tank temperature ~~should~~ shall not exceed 7ºC (45ºF) after that point. Bulk milk tank recording thermometers are recommended. …

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APPENDIX R. DETERMINATION OF TIME/TEMPERATURE CONTROL FOR SAFETY MILK AND/OR MILK PRODUCTS …

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Before using Tables A and B, which are included in Definition ~~OO~~QQ. TIME/TEMPERATURE CONTROL FOR SAFETY MILK AND/OR MILK PRODUCTS of this *Ordinance*, in determining whether a milk or milk product requires TCS, answers to the following questions should be considered: …

5. Is the milk and/or milk product processed and packaged so that it ~~no longer~~ does not requires TCS; such as, ~~Grade "A"~~ aseptically processed and packaged Grade "A" low-acid milk and/or milk products and/or retort processed after packaged Grade "A" low-acid milk and/or milk products? …

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APPENDIX S. ASEPTIC PROCESSING AND PACKAGING PROGRAM AND RETORT PROCESSED AFTER PACKAGING PROGRAM

The Aseptic Processing and Packaging Program is designed to include all Grade "A" low-acid (21 CFR Part 113) ~~Grade "A" aseptic~~ aseptically processed and packaged milk and/or milk products.

The Retort Processed after Packaging Program is designed to include all Grade "A" low-acid (21 CFR Part 113) retort processed after packaged milk and/or milk products.

NOTE: Retort processed after packaging low-acid milk and/or milk products as addressed in Definition Z of the *Grade "A" PMO* shall be considered to be Grade "A" milk and/or milk products if they are used as an ingredient to produce any milk and/or milk product defined in Definition Z of this *Ordinance*; or if they are labeled as Grade "A" as described in Section 4 of this *Ordinance*.

Inspections of a milk plant or portion of a milk plant that is IMS listed to produce aseptically processed and packaged low-acid milk and/or milk products and/or retort processed after packaged low-acid milk and/or milk products shall be conducted by the Regulatory Agency in accordance with this *Ordinance* and the information provided below at least once every six (6) months. The milk plant's APPS or RPPS, respectively, as defined by this *Ordinance,* shall be exempt from Items 7p, 10p, 11p, 12p, 13p, 15p, 16p, 17p, 18p, and 19p of this *Ordinance* and shall comply with the applicable portions of 21 CFR Parts 108, 110 and 113. The milk plant's APPS and/or RPPS, respectively, shall be inspected by FDA, or the State Regulatory Agency when designated by FDA, in accordance with the applicable requirements of 21 CFR Parts 108, 110 and 113 at a frequency determined by FDA.

When the APPS, as defined by this *Ordinance*, is utilized to produce aseptically processed and packaged low-acid milk and/or milk products and pasteurized and/or ultra-pasteurized milk and/or milk products, the APPS shall be inspected and tested by the Regulatory Agency in accordance with the requirements cited in Section 7 of this *Ordinance*.

ASEPTIC PROCESSING AND PACKAGING PROGRAM AND RETORT PROCESSED AFTER PACKAGING PROGRAM CFR/PMO COMPARISON SUMMARY REFERENCE

PMO, Section 7 Items	Aseptic Program/Retort Program	Authority
1p. Floors – Construction	Floor drains are not required in storage rooms for aseptic processed and packaged low-acid milk and/or milk products and retort processed after packaged low-acid milk and/or milk products.	PMO

PMO, Section 7 Items	Aseptic Program/Retort Program	Authority
2p. Walls and Ceiling – Construction	Ceiling requirements are exempt in aseptically processed and packaged low-acid milk and/or milk products and retort processed after packaged low-acid milk and/or milk products dry storage rooms. (Same as for dry milk and/or milk products.)	PMO
3p. Doors and Windows	None	PMO
4p. Lighting and Ventilation	None	PMO
5p. Separate Rooms	Fabrication of containers and closures for aseptic processed and packaged low-acid milk and/or milk products and retort processed after packaged low-acid milk and/or milk products within the APPS and/or RPPS, respectively, is exempt.	PMO
6p. Toilet – Sewage Disposal Facilities	None	PMO
7p. Water Supply*	The APPS and/or RPPS, respectively, is exempt, but shall comply with the CFR.	PMO/CFR
8p. Handwashing Facilities	None	PMO
9p. Milk Plant Cleanliness	None	PMO
10p. Sanitary Piping*	The APPS and/or RPPS, respectively, is exempt, but shall comply with the CFR.	PMO/CFR
11p. Construction and Repair of Containers and Equipment*	The APPS and/or RPPS, respectively, is exempt, but shall comply with the CFR. Paper, plastics, foil, adhesives and other components of containers and closures used in the packaging of milk and/or milk products that have been aseptically processed and packaged or retort processed after packaged are not required to comply with Appendix J of the PMO; are not required to originate from an IMS Listed Source; and are subject to the requirements of the CFR.	PMO/CFR
12p. Cleaning and Sanitizing of Containers and Equipment*	The APPS and/or RPPS, respectively, is exempt, but shall comply with the CFR.	PMO/CFR
13p. Storage of Cleaned Containers and Equipment*	The APPS and/or RPPS, respectively, is exempt, but shall comply with the	PMO/CFR

PMO, Section 7 Items	Aseptic Program/Retort Program	Authority
	CFR.	
14p. Storage of Single- Service Containers, Utensils and Materials	None	PMO
15p.(A) Protection from Contamination*	The APPS and/or RPPS, respectively, is exempt, but shall comply with the CFR.	PMO/CFR
15p.(B) Protection from Contamination - Cross Connections*	The APPS and/or RPPS, respectively, is exempt, but shall comply with the CFR. APPS and/or RPPS equipment is exempt from the separation requirements of the PMO in relationship to instrumented steam blocks between milk and milk products and cleaning and/or chemical sanitizing solutions.	PMO/CFR
16p. Pasteurization and Aseptic Processing and Packaging (A) through (D)*	The APPS and/or RPPS, respectively, is exempt, but shall comply with the CFR. The State Regulatory Agency is not required to conduct the quarterly equipment testing and sealing of aseptic and retort processing equipment. Records and recording charts are not required to be reviewed during routine inspections, State ratings or check ratings.	CFR
17p. Cooling of Milk and Milk Products*	The APPS and/or RPPS, respectively; ~~and~~ aseptic processed and packaged low-acid milk and/or milk product storage; and retort processed after packed low-acid milk and/or milk product storage is exempt, but shall comply with the CFR.	PMO/CFR
18p. Bottling, Packaging and Container Filling*	The APPS and/or RPPS, respectively, is exempt, but shall comply with the CFR.	CFR
19p. Capping, Container Closure and Sealing and Dry Milk Product Storage*	The APPS and/or RPPS, respectively, is exempt, but shall comply with the CFR.	CFR
20p. Personnel -Cleanliness	None	PMO
21p. Vehicles	None	PMO
22p. Surroundings	None	PMO

*** NOTE:** In areas of the milk plant where these Items are dedicated only to the APPS and/or RPPS, respectively, as defined by this *Ordinance*, these Items shall be inspected and regulated in accordance with the applicable FDA regulations (21 CFR Parts 108, 110 and 113).

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Document: 2011 PROCEDURES (Entire Document)
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*Make the following changes to the **2011 PROCEDURES**:*

Cover Page:

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SECTION II. SCOPE

A. **PRODUCTS COVERED**

Agreements adopted by the NCIMS shall apply to Grade "A" raw milk and milk products for pasteurization, heat-treated products, pasteurized, ultra-pasteurized, ~~and~~ aseptically processed and packaged low-acid milk and/or milk products, and retort processed after packaged low-acid milk and/or milk products, condensed and dry milk products, and whey and whey products produced under the NCIMS program. …

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SECTION III. DEFINITIONS

B. **AREA RATING:** An area rating, if used, shall apply to raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging and retort processed after packaging ~~only~~. An area rating consists of more than one (1) producer group operating under the supervision of a single Regulatory Agency and which is rated as a single entity. An individual dairy farm shall only be included in one (1) IMS Listing.

C. **ASEPTIC PROCESSING AND PACKAGING SYSTEM (APPS):** For the purposes of this document, the Aseptic Processing and Packaging System (APPS) in a milk plant is comprised of the processes and equipment used to process and package aseptic Grade "A" low-acid milk and/or milk products. The Aseptic Processing and Packaging System (APPS) shall be regulated in accordance with the applicable requirements of 21 CFR Parts 108, 110 and 113. The Aseptic Processing and Packaging System (APPS) shall begin at the constant level tank and end at the discharge of the packaging machine, provided that the Process Authority may provide written documentation which will clearly define additional processes and/or equipment that are considered critical to the commercial sterility of the product. …

D. **BULK TANK UNIT (BTU):** A dairy farm or group of dairy farms from which raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging is collected under the routine supervision of one (1) Regulatory Agency and rated as a single entity and given a Sanitation Compliance and Enforcement Rating. An individual dairy farm shall only be included in one (1) IMS Listing.

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J. **IMS LISTED SHIPPER:** An interstate milk shipper (BTU, receiving station, transfer station, or milk plant, which has been certified by the State Rating Agency as having attained the Sanitation Compliance and Enforcement Ratings necessary for inclusion in the *IMS List*. The ratings are based on compliance with the requirements of the *Grade "A" PMO* and were made in accordance with the procedures set forth in the *Methods of Making Sanitation Ratings of Milk Shippers (MMSR)*. For milk plants that produce aseptically processed and packaged Grade "A" low-acid milk and/or milk products and/or retort processed after packaged Grade "A" low-acid milk and/or milk products, prior to the milk plant participating in the NCIMS Aseptic Processing and Packaging Program and/or Retort

Processed after Packaging Program, respectively, the State's regulatory and rating personnel shall have completed a training course that is acceptable to the NCIMS and PHS/FDA addressing the procedures for conducting regulatory inspections and ratings under the NCIMS Aseptic Processing and Packaging Program and/or the Retort Processed after Packaging Program**.**

K. **INDIVIDUAL RATING:** An individual rating is the rating of a single producer group, milk plant, receiving station, and/or transfer station under the supervision of a single Regulatory Agency. Milk plants producing Grade "A" condensed and/or dried milk and milk products and/or Grade "A" condensed or dry whey and whey products may be rated separately from the same milk plant producing other Grade "A" milk and/or milk products, provided each listing holds a separate permit. Milk plants that produce ~~both~~ aseptically processed and packaged Grade "A" low-acid milk and/or milk products, and/or retort processed after packaged Grade "A" low-acid milk and/or milk products. and pasteurized and/or ultra-pasteurized Grade "A" milk and/or milk products shall be rated separately. Provided that an NCIMS HACCP milk plant listing that produces aseptically processed and packaged Grade "A" low-acid milk and/or milk products and/or retort processed after packaged Grade "A" low-acid milk and/or milk products shall have only an NCIMS HACCP listing. An individual dairy farm shall only be included in one (1) IMS Listing. …

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P. **MILK PLANT:** A milk plant is any place, premises, or establishment where milk and/or milk products are collected, handled, processed, stored, pasteurized, ultra-pasteurized, aseptically processed and packaged, retort processed after packaged, condensed, dried, packaged, or prepared for distribution. …

T. **RETORT PROCESSED AFTER PACKAGING SYSTEM (RPPS):** For the purposes of this document, the Retort Processed after Packaging System (RPPS) in a milk plant is comprised of the processes and equipment used to retort process after packaging low-acid Grade "A" milk and/or milk products. The Retort Processed after Packaging System (RPPS) shall be regulated in accordance with the applicable requirements of 21 CFR Parts 108, 110 and 113. The Retort Processed after Packaging System (RPPS) shall begin at the container filler and end at the palletizer, provided that the Process Authority may provide written documentation which will clearly define additional processes and/or equipment that are considered critical to the commercial sterility of the milk and/or milk product.

~~T~~U.**STATE PROGRAM EVALUATION:** An evaluation of a State program by PHS/FDA. This shall include check ratings of IMS Listed Shippers, an assessment of State administrative procedures and records, adoption of the *Grade "A" PMO* (or equivalent laws and regulations), and compliance with NCIMS *Procedures*.

~~U~~V.**TRANSFER STATION:** A transfer station is any place, premises, or establishment where milk or milk products are transferred directly from one (1) milk tank truck to another. …

SECTION IV. OVERSIGHT AND RESPONSIBILITIES

A. **PHS/FDA RESPONSIBILITIES** …

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8. Check Ratings of the Sanitation Compliance Status of Listed Interstate Shippers

a. PHS/FDA shall conduct, each year, check ratings of the Sanitation Compliance status of listed interstate milk shippers. To conduct check ratings of aseptic or retort milk plants, the PHS/FDA Regional Milk Specialist shall have completed a training course that is acceptable to the NCIMS and PHS/FDA addressing the procedures for conducting check ratings under the NCIMS Aseptic Processing and Packaging Program or the NCIMS Retort Processed after Packaging Program, respectively. Within a State, check ratings ~~will~~ shall be ~~made~~ conducted of a representative number of IMS Listed shippers. The selection of shippers ~~for~~ to be check ~~rating~~ rated in a given State ~~will~~ shall be made randomly. …

B. **STATE RESPONSIBILITIES** …

7. Challenges and Remedies …

2.) Milk Plants, Receiving Stations and/or Transfer Stations …

c. Action to be Taken if the PHS/FDA Check Rating Indicates the Listed Rating is Not Justified: …

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C.) Withdrawal of Certification

When check rating data indicates that the Sanitation Compliance Rating of a milk plant, receiving station and/or transfer station requires a withdrawal of certification, the State Rating Agency, upon written recommendation of PHS/FDA, shall immediately withdraw the current certification of the shipper and notify such shipper, PHS/FDA, and all known receiving States thereof, in accordance with Section IV., B., 1.d. In case of withdrawal, a new rating shall be made in not less than thirty (30) days and not to exceed sixty (60) days, unless the State Rating Agency has reason to believe a new rating within a lesser time period would result in an acceptable rating. The effective date for action shall be determined from the date of the letter of notification by the State Rating Agency. Such letter shall be dated within five (5) working days following the date of the official notification. A withdrawal of certification is also required if an aseptic or retort milk plant has any Aseptic Critical Listing Element (ACLE) identified as not being in compliance on FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND

RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS ~~for~~ (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products) following the procedures cited above. …

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D. **MILK SANITATION RATING PERSONNEL** …

2. Have been ~~standardized~~ certified by PHS/FDA as a SRO and hold a valid certificate of qualification in one (1) or any combination of the following categories: milk pasteurization plants, including HACCP, and/or aseptic processing and packaging, and/or retort processed after packaging, if appropriate, dairy farms and transfer/receiving stations, including HACCP if appropriate. The PHS/FDA ~~will~~ shall issue a certificate, valid for three (3) years, to each individual who meets the criteria listed below, as applicable. Certification of a SRO shall qualify that SRO to perform ratings or HACCP listings, if applicable, in any State, upon the request of that State's Regulatory/Rating Agency as long as the ~~Officer's~~ SRO's certification is valid.

3. A SRO applicant for initial ~~standardization~~ certification shall be evaluated by PHS/FDA personnel in an independent side-by-side comparison of dairy facilities using the items listed on the appropriate inspection or evaluation report form. The applicant and PHS/FDA personnel shall be in agreement at least eighty percent (80%) of the time on each listed item. Comparison evaluations shall be performed on at least the following number of dairy facilities: …

b. Five (5) pasteurization milk plants. Milk plants of varying sizes using, vat, HTST~~,~~ and HHST pasteurization; ultra-pasteurization; ~~and/or~~ aseptic processing and packaging; and/or retort processed after packaging, if applicable, should be included in these evaluations. One (1) transfer or receiving station may also be included as one (1) of the required five (5) pasteurization milk plants. …

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6. To conduct ratings of aseptic processing and packaging milk plants and/or retort processed after packaging milk plants, the applicant shall have completed a training course that is acceptable to the NCIMS and PHS/FDA addressing the procedures for conducting the rating and the implementation of the NCIMS Aseptic Processing and Packaging Program or the NCIMS Retort Processed after Packaging Program, respectively. …

8. A certified SRO shall be ~~re-standardized~~ re-certified once each three (3) years by PHS/FDA personnel in an independent side-by-side comparison of dairy facilities using the items listed on the appropriate inspection or evaluation report form. The applicant and PHS/FDA personnel shall be in agreement at least eighty percent (80%) of the time on each listed item. Comparison evaluations shall be performed on at least the following number of dairy facilities: …

b. Three (3) pasteurization milk plants. Milk plants of varying sizes using, vat, HTST, and HHST pasteurization; ultra-pasteurization; ~~and/or~~ aseptic processing and packaging; and/or retort processed after packaging, if applicable, should be included in these evaluations. …

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5. The SSO may delegate the inspection of bulk milk hauler/samplers, who collect samples of raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging from individual producers, to other qualified State, Regional or Local Regulatory Agency personnel or certified industry personnel as outlined in Section 5 of the *Grade "A" PMO*. …

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J. **INDIVIDUAL RATINGS** …

3. If an aseptic or retort milk plant has any ACLE identified by a SRO or PHS/FDA Regional Milk Specialist as not being in compliance on FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS ~~for~~ (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products), the listing shall be immediately denied or withdrawn. …

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SECTION VIII. PROCEDURES GOVERNING THE CERTIFICATION OF MILK PLANT, RECEIVING STATION AND TRANSFER STATION NCIMS HACCP SYSTEMS FOR IMS LISTED SHIPPERS

A. **PURPOSE AND SCOPE** …

2. Products Covered Under HACCP Listings

Agreements adopted by the NCIMS shall apply to Grade "A" raw milk and milk products for pasteurization, heat-treated products, pasteurized, ultra-pasteurized, ~~and~~ aseptically processed and packaged low-acid milk and/or milk products, and retort processed after packaging low-acid milk and/or milk products, condensed and dry milk products, and whey and whey products produced under the NCIMS program. Listings made under the NCIMS voluntary HACCP listing system described in this Section, may be made for milk plants, receiving stations and transfer stations. …

B. **HACCP DEFINITIONS:** …

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1. **AUDIT:** An evaluation of the entire milk plant, receiving station, or transfer station facility, and NCIMS HACCP System to ensure compliance with the NCIMS HACCP System and other NCIMS regulatory requirements, with the exception of the Aseptic Processing and Packaging System (APPS) for aseptic processing and packaging milk plants and Retort Processed after Packaging System (RPPS) for retort processed after packaging milk plants, respectively. …

4. **PHS/FDA AUDIT:** An evaluation conducted by PHS/FDA of the entire milk plant, receiving station, or transfer station facility to ensure compliance with the NCIMS HACCP System and other NCIMS regulatory requirements, with the exception of the Aseptic Processing and Packaging System (APPS) for aseptic processing and packaging milk plants and Retort Processed after Packaging System (RPPS) for retort processed after packaging milk plants, respectively.. …

7. **LISTING AUDIT:** An evaluation conducted by a Milk Sanitation Rating Officer (SRO) of the entire milk plant, receiving station or transfer station facility to ensure compliance with the NCIMS voluntary HACCP Program and other NCIMS regulatory requirements, with the exception of the Aseptic Processing and Packaging System (APPS) for aseptic processing and packaging milk plants and Retort Processed after Packaging System (RPPS) for retort processed after packaging milk plants, respectively. …

C. **PHS/FDA HACCP RESPONSIBILITIES**

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8. PHS/FDA Audits of HACCP Listings

   a. PHS/FDA shall conduct, each year, PHS/FDA audits of HACCP listed shippers. To conduct audits of HACCP~~/~~ aseptic processing and packaging milk plants and/or retort processed after packaging milk plants, the PHS/FDA Regional Milk Specialist shall have completed a training course that is acceptable to the NCIMS and PHS/FDA addressing the procedures for conducting the audit and the implementation of the NCIMS Aseptic Processing and Packaging Program and/or the NCIMS Retort Processed after Packaging Program, respectively. Within a State conducting the NCIMS HACCP Program, PHS/FDA audits ~~will~~ shall be ~~made~~ conducted of a representative number of IMS HACCP listed shippers. The selection of shippers ~~for auditing~~ to be audited in a given State ~~will~~ shall be made randomly. …

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   h. PHS/FDA shall conduct on-site milk plant, receiving station and transfer station audits of the HACCP compliance status of listed interstate milk shippers. These PHS/FDA HACCP audits shall be conducted using the procedures for State HACCP listing audits as described in the *MMSR*. These audits ~~will~~ shall be used in the overall State Program Evaluation. Provided, that for NCIMS HACCP listed milk plants

producing aseptically processed and packaged Grade "A" low-acid milk and/or milk products and/or retort processed after packaged Grade "A" low-acid milk and/or milk products, PHS/FDA HACCP audits shall be conducted using the procedures identified in the NCIMS Aseptic Processing and Packaging Program or the NCIMS Retort Processed after Packaging Program, respectively, related to the inspection/auditing and regulation of the APPS and RPPS, respectively, as described in the *Grade "A" PMO* and *MMSR*, along with the completion of FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS ~~for~~ (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products). …

D. **STATE HACCP RESPONSIBILITIES**

7. State HACCP Listings for Milk Plants, Receiving Stations and Transfer Stations Section IV., B. 1.) shall apply as written, except that for purposes of this Section: …

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c. When the Sanitation Compliance status of a listed shipper's supply changes as a result of a new listing made within the twenty-four (24) month eligibility period, the most recent listing and FORM FDA 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT and FORM FDA 2359n-NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT, shall apply and shall be submitted to PHS/FDA. Provided that for NCIMS HACCP listed milk plants producing aseptically processed and packaged Grade "A" low-acid milk and/or milk products and/or retort processed after packaged Grade "A" low-acid milk and/or milk products, FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS ~~for~~ (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products) shall also be completed and submitted to PHS/FDA. …

7. Challenges and Remedies …

c. Action to be Taken if the PHS/FDA HACCP Audit Indicates the Listing is Not Justified: …

2.) Milk Plants, Receiving Stations and/or Transfer Stations …

C.) Withdrawal of Certification …

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3.) A HACCP~~/~~ aseptic listing that includes an aseptically processed and packaged Grade "A" low-acid milk and/or milk products ~~plants~~ plant and/or a HACCP retort listing that includes a retort processed after packaged Grade

"A" low-acid milk and/or milk products plant, shall be requested to be withdrawn when any ACLE is identified as not being in compliance on FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS ~~for~~ (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products). …

E. **QUALIFICATIONS AND CERTIFICATIONS**

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3. HACCP Listing

a. An acceptable HACCP listing shall be substituted for an acceptable Sanitation Compliance and Enforcement Rating for a milk plant, receiving station or transfer station participating in the NCIMS HACCP Program. FORM FDA 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT and FORM FDA 2359n-NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT shall be completed as a part of all milk plant, receiving station or transfer station HACCP listing audits. Provided that for NCIMS HACCP listed milk plants producing aseptically processed and packaged Grade "A" low-acid milk and/or milk products and/or retort processed after packaged Grade "A" low-acid milk and/or milk products, FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS ~~for~~ (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products) shall be completed as a part of all HACCP~~/~~ aseptic and/or HACCP retort listing audits. …

6. Certification Procedure for SROs Who Will Conduct HACCP Listing Audits …

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d. Paperwork Review

FORM FDA 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT, with attachments, FORM FDA 2359n-NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT, and FORM FDA 2359o-PERMISSION FOR PUBLICATION (*Interstate Milk Shipper's Listing*) shall be submitted with FORM FDA 2359i for each NCIMS HACCP Listing Audit to the PHS/FDA Regional Office for quality assurance review. Provided that for NCIMS HACCP listed milk plants producing aseptically processed and packaged Grade "A" low-acid milk and/or milk products and/or retort processed after packaged Grade "A" low-acid milk and/or milk products, FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS

~~for~~ (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products) shall also be completed and submitted for quality assurance review.

Document: 2011 BYLAWS
Page: 59

*Make the following changes to the **2011 BYLAWS OF THE NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS** on Page 59:*

ARTICLE VI ------ DUTIES OF THE PROGRAM OF COUNCILS …

SECTION 3. Council III shall deal with Proposals submitted to the Conference regarding Sections 11, 17, and 18 and ~~Appendix~~ Appendices K and S of the *Grade "A" Pasteurized Milk Ordinance*; the *Constitution* and *Bylaws*; the *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments*; issues of reciprocity; and Proposals assigned from the Program Committee.

Document: 2011 MMSR (Entire Document)
Pages: Entire Document

*Make the following changes to the **2011 MMSR**:*

Cover Page:

~~2011~~ 2013 Revision

Page i:

PREFACE …

The rating method for evaluating the sanitary quality of milk measures the extent to which a shipper complies with the standards contained in the *Grade "A" PMO*. These nationally recognized standards, rather than local requirements, are used as a yardstick in order that ratings of individual Bulk Tank Units (BTUs) or attached shippers and milk plants may be comparable to each other, both interstate and intrastate. Ratings are expressed in terms of percentage compliance. For example, if the milk plant and dairy farms comply with all of the requirements of the *Grade "A" PMO*, the Sanitation Compliance Rating of the pasteurized milk supply would be one hundred percent (100%); whereas, if the plant or some of the dairy farms fail to satisfy one (1) or more of these requirements, the Sanitation Compliance Rating would be reduced in proportion to the amount of milk and milk products involved in the violation and to the relative public health significance of the violated Item(s). Procedures for collection of data, computation of Sanitation Compliance Ratings for raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging and pasteurized milk, and computation of the Enforcement Rating of the Regulatory

Agency, responsible for administering milk sanitation regulations, are described in the following Sections. …

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6. FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING……

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13. FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ~~ELEMETNS~~ ELEMENTS ~~for~~ (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products).....

H. EXAMPLES OF HOW TO PROPERLY COMPLETE RATING, NCIMS HACCP LISTING, ~~AND~~ ASEPTIC PROCESSING AND PACKAGING PROGRAM, AND RETORT PROCESSED AFTER PACKAGING PROGRAM LISTING FORMS

13. FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING……

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23. FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS ~~for~~ (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products) …… ……...
24. FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2) (*EXAMPLE: ASEPTIC AND/OR RETORT MILK PLANT*) …….

Page 1:

A. DEFINITIONS

1. **AREA RATING:** An area rating, if used, shall apply to raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging and retort processed after packaging ~~only~~. An area rating consists of more than one (1) producer group operating under the supervision of a single Regulatory Agency and which is rated as a single entity. An individual dairy farm shall only be included in one (1) IMS Listing.

2. **ASEPTIC CRITICAL LISTING ELEMENT (ACLE):** An ~~item~~ Item on FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS ~~for~~ (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products). The identification of any Aseptic Critical Listing Element (ACLE) element by a Milk Sanitation Rating Officer (SRO) or FDA Regional Milk Specialist as not being in compliance, whereby a listing shall be immediately denied or withdrawn.

3. **ASEPTIC OR RETORT MILK PLANT RATING:** A rating of a milk plant or portion of a milk plant that produces aseptically processed and packaged Grade "A" low-acid milk and/or milk products and/or retort processed after packaged Grade "A" low-acid milk and/or milk products that is rated separately from the rating of pasteurized and/or ultra-pasteurized Grade "A" milk and/or milk products produced in the milk plant. This rating shall be made for all milk plants producing aseptically processed and packaged Grade "A" low-acid milk and/or milk products and/or retort processed after packaged Grade "A" low-acid milk and/or milk products as defined in the *Grade "A" PMO*. An NCIMS HACCP milk plant listing that produces aseptically processed and packaged Grade "A" low-acid milk and/or milk products and/or retort processed after packaged Grade "A" low-acid milk and/or milk products shall have only an NCIMS HACCP listing.

NOTE: The raw milk receiving area may be rated with the aseptic or retort milk plant, or with a separately-listed pasteurization and/or ultra-pasteurized milk plant, or separately as a receiving station. …

4. **ASEPTIC PROCESSING AND PACKAGING SYSTEM (APPS):** For the purposes of this document, the Aseptic Processing and Packaging System (APPS) in a milk plant is comprised of the processes and equipment used to process and package aseptic Grade "A" low-acid milk and/or milk products. The Aseptic Processing and Packaging System (APPS) shall be regulated in accordance with the applicable requirements of 21 CFR Parts 108, 110 and 113. The Aseptic Processing and Packaging System (APPS) shall begin at the constant level tank and end at the discharge of the packaging machine, provided that the Process Authority may provide written documentation which will clearly define additional processes and/or equipment that are considered critical to the commercial sterility of the product.

5. **AUDIT:** An evaluation of the entire milk plant, receiving station, or transfer station facility, and NCIMS HACCP System to ensure compliance with the NCIMS HACCP System and other NCIMS regulatory requirements, with the exception of the Aseptic Processing and Packaging System (APPS) for aseptic processing and packaging milk plants and Retort Processed after Packaging System (RPPS) for retort processed after packaging milk plants, respectively.

Page 2:

6. **BULK TANK UNIT (BTU):** A dairy farm or group of dairy farms from which raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging is collected under the routine supervision of one (1) Regulatory Agency and rated as a single entity and given a Sanitation Compliance and Enforcement Rating. An individual dairy farm shall only be included in one (1) IMS Listing. …

11. **FDA AUDIT:** An evaluation conducted by FDA of the entire milk plant, receiving station, or transfer station facility to ensure compliance with the NCIMS HACCP System and other NCIMS regulatory requirements, with the exception of the Aseptic Processing and Packaging System (APPS) for aseptic processing and packaging milk plants and Retort Processed after Packaging System (RPPS) for retort processed after packaging milk plants, respectively. …

13. **INDIVIDUAL RATING:** An individual rating is the rating of a single producer group, milk plant, receiving station, and/or transfer station under the supervision of a single Regulatory Agency. Milk plants producing Grade "A" condensed and/or dried milk and milk products and/or Grade "A" condensed or dry whey and whey products may be rated separately from the same milk plant producing other Grade "A" milk and/or milk products, provided each listing holds a separate permit. Milk plants that produce ~~both~~ aseptically processed and packaged Grade "A" low-acid milk and/or milk products, and/or retort processed after packaged Grade "A" low-acid milk and/or milk products, and pasteurized and/or ultra-pasteurized Grade "A" milk and/or milk products shall be rated separately. Provided that an NCIMS HACCP milk plant listing that produces aseptically processed and packaged Grade "A" low-acid milk and/or milk products and/or retort processed after packaged Grade "A" low-acid milk and/or milk products shall have only an NCIMS HACCP listing. An individual dairy farm shall only be included in one (1) IMS Listing. …

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14. **LISTING AUDIT:** An evaluation conducted by a Milk Sanitation Rating Officer (SRO) of the entire milk plant, receiving station or transfer station facility to ensure compliance with the NCIMS voluntary HACCP Program and other NCIMS regulatory requirements, with the exception of the Aseptic Processing and Packaging System (APPS) for aseptic processing and packaging milk plants and the Retort Processed after Packaging System (RPPS) for retort processed after packaging milk plants, respectively.

15. **MILK PLANT:** A milk plant is any place, premises, or establishment where milk and/or milk products are collected, handled, processed, stored, pasteurized, ultra-pasteurized, aseptically processed and packaged, retort processed after packaged, condensed, dried, packaged, or prepared for distribution. …

19. **RETORT PROCESSED AFTER PACKAGING SYSTEM (RPPS):** For the purposes of this document, the Retort Processed after Packaging System (RPPS) in a milk plant is comprised of the processes and equipment used to retort process after packaging low-acid Grade "A" milk and/or milk products. The Retort Processed after Packaging System (RPPS) shall be regulated in accordance with the applicable requirements of 21 CFR Parts 108, 110 and 113. The Retort Processed after Packaging System (RPPS) shall begin at the container filler and end at the palletizer, provided that the Process Authority may provide written documentation which will clearly define additional processes and/or equipment that are considered critical to the commercial sterility of the milk and/or milk product.

~~19~~ 20.**TRANSFER STATION:** A transfer station is any place, premises, or establishment where milk or milk products are transferred directly from one (1) milk tank truck to another.

B. RATING METHODS FOR RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING …

Page 7:

3. COMPUTATION OF SANITATION COMPLIANCE RATINGS

a. Rating results are transferred to FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING. This Form may be obtained from the Regional Offices of the PHS/FDA or at the following FDA website: http://www.fda.gov/aboutfda/reportsmanualsforms/forms/default.htm. The Form is sufficiently flexible to permit various combinations of pages to be used for reporting ratings of area or individual shippers.

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b. The identity of each dairy farm, included in the rating, and the total pounds of milk sold daily, expressed to the nearest 100 pound unit (cwt.), are entered in the first, "Name of Dairy Farm", and second, "Pounds Sold Daily (100# Units)", columns, respectively, of FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING …

NOTE: Item 8-Water Supply on FORM FDA 2359a-DAIRY FARM INSPECTION REPORT has been divided into two (2) point and five (5) point violations/debits. The maximum point value for the entire Item 8r cannot exceed five (5) points on FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING. (Refer to Appendix B. TABLE OF FARM WATER SUPPLY VIOLATIONS, which provides guidance, which may be used to differentiate between two (2) point (minor) and five (5) point (major) violations of Section 7, Item 8r of the *Grade "A" PMO* during State Ratings and FDA Check Ratings.)

Non-compliance with Item 15r-DRUG AND CHEMICAL CONTROL, Administrative Procedures #s 5, 6 and 7 of the *Grade "A" PMO* (debited under Item 15r(d) and (e) on FORM FDA 2359a-DAIRY FARM INSPECTION REPORT), would constitute a five (5) point debit, not to exceed a total of seven (7) points for the entire Item 15-Drugs on FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING.

Non-compliance with Item 18r-RAW MILK COOLING, Administrative Procedure #3 of the *Grade "A" PMO*, would constitute a one (1) point debit, not to exceed a total of five (5) points for the entire Item 18-Cooling on FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING.

c. The Sanitation Compliance Rating is Derived from the Following Formula: …

This rating figure is entered in the appropriate space in the upper right hand corner of FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING. It is also entered on FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION A. REPORT OF THE MILK SANITATION RATING (PAGE 1), in the appropriate location.

C. RATING METHODS FOR MILK PLANTS, RECEIVING STATIONS AND TRANSFER STATIONS …

2. COLLECTION OF DATA …

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b. Recording of Laboratory and Other Test Data …

2.) Compliance with bacterial, coliform and cooling temperature requirements is based on whether, at the time of the rating, a milk plant's Grade "A" milk and/or milk products meet the standards of Section 7 of the *Grade "A" PMO.* Each milk and/or milk product, including commingled raw milk prior to pasteurization, ultra-pasteurization, aseptic processing and packaging and retort processed after packaging for each of the above applicable requirements, shall be debited if two (2) of the last four (4) sample results exceed the limit(s), and the last sample result is in violation. A debit shall be given when less than the required number of samples has been examined during the preceding six (6) months. For rating purposes, the preceding six (6) months is considered to be the elapsed period for the month in which the rating is made and the preceding six (6) months. Milk plants which have had a permit for less than six (6) months at the time of the rating or which do not operate on a year round basis and for which the Regulatory Agency has not yet examined the required number of samples shall not be debited. Provided, that the last sample result is within the limit(s).

3.) The SRO may utilize Regulatory Agency's records in determining …

NOTE: The sampling and testing of aseptically processed and packaged Grade "A" milk and/or milk products and retort processed after packaged Grade "A" low-acid milk and/or milk products is not required, with the exception of the annual vitamin assay analysis to which vitamin(s) A and/or D have been added for fortification purposes. The sampling and testing requirements of Section 6 of the *Grade "A" PMO* for raw milk for aseptic processing and packaging and retort processed after packaging is required.

c. Recording of Data for Milk Plants, Receiving Stations and Transfer Stations Being Listed Under the NCIMS HACCP Listing Procedure …

4.) Criteria and Procedures for Denial or Withdrawal of a Listing …

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(viii) **HACCP SYSTEM AUDIT FOLLOW-UP ACTION:** A series of observations that lead to a finding of a potential HACCP System failure that is likely to result in a compromise to milk or milk product safety. …

NOTE: In the case of a HACCP~~/~~ aseptic listed milk plant and/or HACCP retort listed milk plant, the identification of any ACLE element on FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS ~~for~~ (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products) by a SRO or FDA Regional Milk Specialist as not being in compliance shall also constitute an ACLE deficiency under the NCIMS HACCP System, whereby a listing shall be immediately denied or withdrawn.

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d. Recording of Data for Milk Plants and Receiving Stations Being Listed Under the NCIMS Aseptic Processing and Packaging Program and/or the NCIMS Retort Processed after Packaging Program

1.) Inspection Criteria

(A.) The NCIMS Aseptic Processing and Packaging Program includes all low-acid aseptically processed and packaged Grade "A" milk and/or milk products as defined in the *Grade "A" PMO*.

(B.) The NCIMS Retort Processed after Packaging Program includes all low-acid retort processed after packaging Grade "A" milk and/or milk products as defined in the *Grade "A" PMO*.

NOTE: Retort processed after packaging low-acid milk and/or milk products as addressed in Definition Z of the *Grade "A" PMO* shall be considered to be Grade "A" milk and/or milk products if they are used as an ingredient to produce any milk and/or milk product defined in Definition Z of the *Grade "A" PMO*; or if they are labeled as Grade "A" as described in Section 4 of this *Ordinance*.

(~~B~~C.) State Regulatory inspections of a milk plant or portion of a milk plant that is listed to produce aseptically processed and packaged Grade "A" milk and/or milk products and/or retort processed after packaged Grade "A" low-acid milk and/or milk products shall be conducted in accordance with the *Grade "A" PMO* at least once every six (6) months. The milk plant's APPS and/or RPPS, respectively, as defined by the *Grade "A" PMO,* shall be inspected by FDA, or the State Regulatory Agency when designated by FDA, in accordance with the applicable requirements of 21 CFR Parts 108, 110 and 113 at a frequency determined by FDA.

(~~C~~D.) For milk plants or portions of milk plants that are listed to produce aseptically processed and packaged Grade "A" milk and/or milk products and/or retort processed after packaged Grade "A" low-acid milk and/or milk products, the APPS and/or RPPS, respectively, as defined by the *Grade "A" PMO,* shall be exempt

from Items 7p, 10p, 11p, 12p, 13p, 15p, 16p, 17p, 18p, and 19p of the *Grade "A" PMO*. These ~~items~~ Items, which are dedicated only to the APPS or RPPS, respectively, shall comply with the applicable portions of 21 CFR Parts 108, 110 and 113. The rest of the milk plant, including the receiving area, shall be inspected in accordance with the *Grade "A" PMO* and rated and listed in accordance with the current NCIMS requirements. (Refer to Appendix S. Aseptic Processing and Packaging Program and Retort Processed after Packaging Program of the *Grade "A" PMO).*

(~~D~~E.) When the APPS is utilized to produce aseptically processed and packaged Grade "A" milk and/or milk products and pasteurized and/or ultra-pasteurized Grade "A" milk and/or milk products, the APPS shall be inspected and tested by the Regulatory Agency in accordance with the requirements cited in Section 7 of the *Grade "A" PMO*.

(~~E~~F.) NCIMS HACCP listed aseptic and/or retort milk plants shall be inspected/audited and regulated under the NCIMS voluntary HACCP Program with the exception of the APPS or RPPS, respectively, which shall be inspected and regulated under the NCIMS Aseptic Processing and Packaging Program and/or Retort Processed after Packaging Program, respectively. Provided that FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS ~~for~~ (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products) shall also be completed and submitted.

2.) Criteria and Procedures for Denial or Withdrawal of a Listing
In addition to the current NCIMS requirements for a listing, the identification of any ACLE element on FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS ~~for~~ (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products) by a SRO or FDA Regional Milk Specialist as not being in compliance, requires that a listing shall be immediately denied or withdrawn. …

3. COMPUTATION OF SANITATION COMPLIANCE RATINGS

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f. If, upon receipt, one (1) or more shipper(s) of unattached raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging violates the bacterial and/or cooling temperature standards, the violations are debited against the rating of the receiving station(s) and/or transfer station(s) shipping the milk, prior to combining the ratings in accordance with the methods described above.

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D. COMPUTATION OF ENFORCEMENT RATINGS

For all NCIMS HACCP listings, including aseptic and/or retort milk plants, complete FORM FDA 2359n-NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT. (Refer to Section H, #19 for an example.) Enforcement ratings shall be made for dairy farms that are listed with milk plants, receiving stations, or transfer stations that are listed under the NCIMS HACCP listing procedure. These enforcement ratings shall be made using the procedures for raw milk for pasteurization, ultra-pasteurization, aseptic processed and packaging and retort processed after packaging addressed in 2. of this Section. …
Page 18:

2. RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING ONLY

a. When an individual shipper offers for sale only raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging directly from dairy farms, known as a BTU, and there are ~~no~~ not any milk plant(s), receiving and/or transfer station(s) involved, all Items in Part I-DAIRY FARMS, FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2) shall be evaluated. The total of the credit column of Part I will be the Enforcement Rating and ~~should~~ shall be recorded on Page 1 of this Form, in the appropriate location. (Refer to Section H, #s 1, 9 and 11 for examples.) …

3. RECEIVING STATION OR TRANSFER STATION

a. When an individual shipper offers for sale raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging, which is shipped from a receiving station or transfer station, with one (1) or more dairy farms rated with it, all Items in Part II-MILK PLANTS, except Numbers 5 and 7, and all Items on Part III-INDIVIDUAL SHIPPER RATING on FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), shall be evaluated. When a receiving station and/or transfer station receives and trans-ships raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging from one (1) or more rated and listed BTUs and wishes a separate listing for its facilities, all Items in Part II, except Numbers 5 and 7, and all Items in Part III, except Number 1 shall be evaluated. The procedures outlined in D., 3., b and D., 4., a.3.) ~~should~~ shall be followed in computing the Enforcement Rating of the receiving station and/or transfer station.

Page 19:

4. MILK PLANTS

a. For NCIMS aseptic milk plants and retort milk plants, all Items in Part II-MILK PLANTS, except Number 5, and all Items on Part III-INDIVIDUAL SHIPPER RATING on FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), shall be evaluated. The total weight, which

can be earned in Part II, is eighty-five (85). Therefore, the sum of the total credits earned in Part II ~~should~~ shall be divided by eighty-five (85) and multiplied by 100. …

Page 20:

b. Milk Plant with an Unattached Supply of Raw Milk

1.) When an individual shipper of pasteurized milk and/or milk products imports all raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging from outside the jurisdiction of the Regulatory Agency in which the milk plant is located, only Parts II and III of FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), shall be evaluated. If an Item requires more than one (1) test or determination, i.e., Part II, Numbers 2, 4, 5, 6, 7, 8, 9, and 10, then compliance is also based on the proportion of tests or determinations, which according to the Regulatory Agency's records, were made at the required frequency. …

Page 21:

c. Milk Plant with an Attached Supply of Raw Milk

1.) When an individual shipper of pasteurized milk and/or milk products receives raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging from an attached supply(ies) within the jurisdiction of the Regulatory Agency in which the plant is located, Parts I, II, and III, on FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2) shall be evaluated. If raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging is received from both attached and unattached supplies, only those sources from attached supplies ~~will~~ shall be evaluated in Part I. If an Item requires more than one (1) test or determination, i.e., Part II, Numbers 2, 4, 5, 6, 7, 8, 9, and 10, then compliance is also based on the proportion of tests or determinations, which according to the Regulatory Agency's records, were made at the required frequency. …

E. **PREPARATION OF THE SROs REPORT** …

2. SUMMARY OF RATING RESULTS

Sanitation Compliance Ratings computed in accordance with procedures previously described and other data pertinent to the shipper are entered in the SUMMARY OF RATING RESULTS on FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION A. REPORT OF MILK SANITATION RATING (PAGE 1). When the Sanitation Compliance Rating of raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging has been combined with the rating(s) of unattached supplies in accordance with the conditions and procedures found under F. PUBLICATION OF THE

"INTERSTATE MILK SHIPPER'S REPORTS", Sections 2., c., 2.) or 2., c., 3.)B.); the combined rating, rather than the rating of the attached supply is entered in the summary. …

4. RECOMMENDATIONS OF THE SRO …

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For all NCIMS HACCP listings, including aseptic and/or retort milk plants, complete FORM FDA 2359n-NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT, which includes an evaluation of the following: (Refer to Section H, #19 for an example.) …

b. Milk plant, receiving station or transfer station audited by ~~the~~ a HACCP trained State Regulatory ~~Agency~~ auditor at the minimum required frequency, and follow-up conducted as required; …

d. Pasteurization equipment tested at required frequency (~~not~~ Not applicable to receiving stations, ~~and~~ transfer stations, aseptic and retort milk plants); …

f. Samples of milk plant's milk and/or milk products collected at the required frequency and all necessary laboratory examinations made (~~not~~ Not applicable to receiving stations ~~and~~ /transfer stations); …

F. **PUBLICATION OF THE "INTERSTATE MILK SHIPPER's REPORT"** …

Page 24:

2. PREPARATION OF THE "INTERSTATE MILK SHIPPER's REPORT"

a. Individual Shipper of Raw Milk for Pasteurization, Ultra-Pasteurization, Aseptic Processing and Packaging or Retort Processed after Packaging …

This shipper is commonly referred to as a BTU. Following the computation of the Sanitation Compliance Rating on FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING and Part I of FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), the resultant data ~~will~~ shall be transferred to FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT. The earliest rating date shall be the date of the first day of the rating. (Refer to Section H, #s 16 and 17 for examples.) …

b. Receiving Station or Transfer Station

Following the computation of the Sanitation Compliance Rating on FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER

PACKAGING, FORM FDA 2359L-STATUS OF MILK PLANTS, and Parts I, II and III of FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), the resultant data ~~will~~ shall be transferred to FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT. The earliest rating date shall be the date of the first day of the rating. When receiving and/or transfer stations wish a separate listing and receive raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging from one (1) or more rated and listed BTUs for trans-shipment, the procedures to be followed shall be that of Section F. PUBLICATION OF THE "INTERSTATE MILK SHIPPER's REPORT, 2., c.2) or 2., c.3). …

Page 27:

4. PREPARATION OF THE "INTERSTATE MILK SHIPPER's REPORT" FOR ASEPTIC PROCESSING AND PACKAGING PROGRAM AND/OR RETORT PROCESSED AFTER PACKAGING PROGRAM LISTINGS

The provisions of this Section apply to milk plants and receiving stations listed under the NCIMS Aseptic Processing and Packaging Program and/or the NCIMS Retort Processed after Packaging Program listing procedure, except that FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS ~~for~~ (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products) shall be submitted with FORM FDA 2359i for each NCIMS aseptic milk plant listing to the PHS/FDA Regional Office for quality assurance review. …

Page 29:

G. **EXAMPLES OF RATING, NCIMS HACCP LISTING, ~~AND~~ ASEPTIC PROCESSING AND PACKAGING PROGRAM, AND RETORT PROCESSED AFTER PACKAGING PROGRAM LISTING FORMS** ...

6. FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING……

13. FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS ~~for~~ (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products) ……

Pages 31, 50, 53, 57 and 59:

FORM FDA 2359j- MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (Page 2)
MILK PLANT-PART II

Item 2: Milk plant and receiving station(s) inspected once every three (3) months; aseptic and retort milk plant and transfer station(s) once every six (6) months

Item 5: Pasteurization equipment tested at required frequency (Not required for aseptic and retort milk plants)

INDIVIDUAL SHIPPER RATING-PART III

Individual Shipper of Pasteurized Milk and Milk Products:
Aseptic and Retort Milk Plants

(10/~~11~~13)

Pages 35, 36, 61 and 62:

FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION

FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING

(10/~~08~~13) **PAGE 1**

(10/~~08~~13) **PAGE 2**

Pages 44 and 71:

FORM FDA 2359n-NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT

A narrative description shall be provided as a part of all NCIMS HACCP Listings and FDA Audits, including aseptic and/or retort milk plants with NCIMS HACCP Listings. This report shall include an evaluation of the following requirements:

4. Pasteurization equipment tested at required frequency. (Not applicable to receiving and transfer stations and aseptic and retort milk plants.)
6. Samples of milk plant's milk and/or milk products collected at the required frequency and all necessary laboratory examinations made. (Not applicable to receiving/transfer stations.) …
(10/~~11~~13)

Pages 46 and 76:

Department of Health and Human Services Food and Drug Administration	**NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS** (Low-Acid (pH greater than 4.6) Aseptic Milk and/or Milk Products)

(To be included with all NCIMS Aseptic Processing and Packaging Program and Retort Processed after Packaging Program State Ratings/HACCP Listings and FDA Check Ratings/HACCP Audits.)

MILK PLANT	DATE OF RATING
ADDRESS	LICENSE/PERMIT NO.
RATING AGENCY	

EXPLANATION OF CONCERNS NOTED REGARDING CRITICAL LISTING ELEMENTS UNDER THE NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND RETORT PROCESSED AFTER PACKAGING PROGRAM.

(Use additional sheets as necessary.)

A narrative description shall be provided as a part of all NCIMS Aseptic Processing and Packaging Program and Retort Processed after Packaging Program State Ratings/HACCP Listings and FDA Check Ratings/HACCP Audits. This report shall include an evaluation of the following requirements:

1. Is the milk plant registered with FDA LACF and are all of the milk plant's low-acid aseptic and/or retort processed after packaging Grade "A" milk and/or milk products covered by a filing with the FDA LACF using Form FDA 2541c, or Form FDA 2341a, respectively, or equivalent electronic filing?

2. Are the milk plant's filed scheduled processes for all of its low-acid aseptic and/or retort processed after packaging Grade "A" milk and/or milk products developed by a recognized Process Authority qualified as having expert knowledge of thermal processing requirements?

3. Are the operators of the milk plant's aseptic processing and packaging systems and/or retort processed after packaging systems under the supervision of a person who has attended a school approved by the FDA (such as Better Process Control School or recognized equivalent)?

4. Is the milk plant currently under an "Order of Determination of Need" for an Emergency Permit?

FORM FDA 2359p (10/~~11~~13)

Page 47:

H. **EXAMPLES OF HOW TO PROPERLY COMPLETE RATING, NCIMS HACCP LISTING, ~~AND~~ ASEPTIC PROCESSING AND PACKAGING PROGRAM, AND RETORT PROCESSED AFTER PACKAGING PROGRAM LISTING FORMS**

Page 48:

Page 77:

FORM FDA 2359j- MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (Page 2)

(Example: Aseptic or Retort Milk Plant)

SHIPPER ASEPTIC OR RETORT DAIRY

DATE OF RATING 10/8-9/~~2012~~ 2014

MILK PLANT-PART II

Item 2: Milk plant and receiving station(s) inspected once every three (3) months; aseptic and retort milk plant and transfer station(s) once every six (6) months

Item 5: Pasteurization equipment tested at required frequency (Not required for aseptic and retort milk plants)

INDIVIDUAL SHIPPER RATING-PART III

Individual Shipper of Pasteurized Milk and Milk Products:
Aseptic and Retort Milk Plants

REMARKS

#4-Violation of Item 7(b) (4 pts)-Submerged water inlet in the CIP make-up tank; Item 15b(c) (5 pts)-Cross connection between the raw milk storage silo #2 and the CIP system in the receiving area; and Item 1(a) (1 pt)-The flooring in the APPS (or RPPS) room was in very poor condition~~,~~. All existed but were not debited on the last inspection.
#7-Aseptic (or Retort) 2% chocolate milk, with vitamins A & D added, did not have a vitamin assay conducted during ~~2011~~ 2013.
#3-Aseptic (or Retort) nonfat milk was not labeled as Grade "A" and "Keep Refrigerated After Opening".

(10/~~11~~13) …

APPENDIX A.

GUIDELINES FOR COMPUTING ENFORCEMENT RATINGS
(FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2)) …

Page 85:

PART II. MILK PLANTS …

2. Milk plants and receiving stations inspected at least once every three (3) months (transfer stations, ~~and~~ aseptic milk plants and retort milk plants once every six (6) months) (*Grade "A" PMO*, Section 5 - INSPECTION OF MILK PLANTS). Prorate by number of inspections in compliance with the required frequency. …

Page 86:

b. Transfer stations, ~~and~~ aseptic milk plants and retort milk plants inspected at least once every six (6) months. …

5. Pasteurization equipment tested at required frequency (*Grade "A" PMO*, Section 7 - STANDARDS FOR MILK AND MILK PRODUCTS and APPENDIX I. - PASTEURIZATION EQUIPMENT AND CONTROLS-TESTS). Prorate by number of units per quarter that were correctly tested within the required testing frequency vs. total number of units.

NOTE: Not required for aseptic and retort milk plants, except when the APPS is utilized to produce aseptically processed and packaged Grade "A" milk and/or milk products and pasteurized and/or ultra-pasteurized Grade "A" milk and/or milk products. The APPS shall then be tested by the Regulatory Agency in accordance with the requirements cited in Section 7 of the *Grade "A" PMO*.

a. Total required tests performed based on pasteurization system(s) equals the # number of Vat Pasteurizers, plus the number of HTST Pasteurizers, plus the number of HHST

Pasteurizers, plus the number of ~~APPS~~ APPSs, if applicable as cited above, at the milk plant. …

Page 88:

7. Samples of each milk plant's milk and milk products collected at the required frequency and all necessary laboratory examinations made (*Grade "A" PMO,* Section 6 - THE EXAMINATION OF MILK AND MILK PRODUCTS). Prorate by number of products in compliance.

a. During any consecutive six (6) months, at least four (4) samples of raw milk, after receipt by the milk plant, including aseptic and retort milk plants, shall be collected, prior to pasteurization, ultra-pasteurization, ~~or~~ aseptic processing and packaging, or retort processed after packaging, in four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days. …

d. Assays of Vitamin A, D, and/or A and D fortified milk and milk products, including aseptically processed and packaged low-acid milk and/or milk products and retort processed after packaging low-acid milk and/or milk products, made at least annually in an IMS Listed Laboratory. Credit for vitamin-fortified products is not given unless vitamin analysis is completed and records are available. Each fortified product is evaluated separately.

Document: 2011 EML (Introduction; and Section 2)
Pages: 1 and 9

*Make the following changes to the **INTRODUCTION** on Page 1:*

State Central Milk Laboratory: A State owned and operated Official Laboratory with analysts employed by the State working in conjunction with the State Regulatory Agency designated as the primary State laboratory for the examination of producer samples of Grade 'A' raw and commingled raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging. pasteurized milk and/or milk products, and dairy waters, as necessary.

Officially Designated Laboratory: An officially designated laboratory is a commercial laboratory authorized to do official work by the Regulatory Agency, or a milk industry laboratory officially designated by the Regulatory Agency for the examination of producer samples of Grade 'A' raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging and commingled milk tank truck samples of raw milk for drug residues. …

*Make the following changes to **SECTION 2: PROFICIENCY TESTING PROGRAM** on Page 9:*

An acceptable annual proficiency testing program shall meet the following applicable criteria:

1. When an analyst examines both raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging and pasteurized milk and/or milk products, a minimum of twenty-two (22) samples shall be examined by the analyst using those procedures for which the analyst has been approved unless excused for due cause. The laboratory tests, categories, types and recommended duplicates of milk products are shown in Table 1, page 27.

2. When an analyst examines only raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging, a minimum of fourteen (14) samples shall be examined by the analyst using those procedures for which the analyst has been approved unless excused for due cause. The laboratory tests and recommended duplicates of samples are shown in Table 1, page 27. …

The following text is a mandatory part of this solution but will not be placed in an NCIMS document.

NOTE: *This Proposal shall take immediate effect upon the issuance of the IMS-a, Actions from the 2013 National Conference on Interstate Milk Shipments, following FDA's concurrence with the NCIMS Executive Board.*

As part of the NCIMS Aseptic Program addressing aseptically processed and packaged Grade "A" low-acid milk and/or milk products and retort processed after packaged Grade "A" low-acid milk and/or milk products; and the Aseptic Pilot Program addressing aseptically processed and packaged Grade "A" acidified and fermented high-acid milk and/or milk products, an NCIMS Aseptic Program Committee (APC) shall be formed in accordance with NCIMS *Procedures*. The APC shall be responsible for the oversight of the NCIMS Aseptic Program addressing aseptically processed and packaged Grade "A" low-acid milk and/or milk products and retort processed after packaged Grade "A" low-acid milk and/or milk products; and the Aseptic Pilot Program addressing aseptically processed and packaged Grade "A" acidified and fermented high-acid milk and/or milk products in consultation with FDA, including the development of forms, documents and guidance necessary to implement, evaluate and provide training as well as study current and new aseptic technology and its application. The APC shall provide a report to the 2015 NCIMS.

This Proposal also authorizes FDA to make appropriate editorial changes to the NCIMS documents as needed, in accordance with NCIMS *Procedures*, resulting from Proposals that are passed at the 2013 NCIMS Conference, and concurred with by FDA, related to the wording addressing aseptically processed and packaged Grade "A" low-acid milk and/or milk products and retort processed after packaged Grade "A" low-acid milk and/or milk products.

All milk plants producing aseptically processed and packaged Grade "A" acidified and fermented high-acid milk and/or milk products, as defined by the PMO and regulated under the NCIMS program shall participate in the Aseptic Pilot Program for those milk and/or milk products.

Proposal: 228
Document: 2011 PMO (Table of Contents; Section 7-Table I; and Appendix B)
Pages: xi, 29, 30 and 135

*Make the following changes to the **TABLE OF CONTENTS** on Page xi:*

APPENDIX B. MILK SAMPLING, HAULING AND TRANSPORTATION……

V. ~~MILK TANK TRUCK PERMITTING AND INSPECTION~~REQUIREMENTS FOR THE SAMPLING OF RAW SHEEP MILK THAT HAS BEEN FROZEN PRIOR TO BEING TESTED FOR APPENDIX N DRUG RESIDUE ……

VI. MILK TANK TRUCK PERMITTING AND INSPECTION ……

*Make the following changes to the **SECTION 7. STANDARDS FOR GRADE "A" MILK AND MILK PRODUCTS-TABLE 1. Chemical, Physical, Bacteriological, and Temperature Standards** on Pages 29 and 30:*

Pages 29 and 30:

Table 1. Chemical, Physical, Bacteriological, and Temperature Standards

GRADE "A" RAW MILK AND MILK PRODUCTS FOR PASTEURIZATION, ULTRA-PASTEURIZATION OR ASEPTIC PROCESSING AND PACKGING	Temperature*****…...	Cooled to 10ºC (50ºF) or less within four (4) hours or less, of the commencement of the first milking, and to 7°C (45ºF) or less within two (2) hours after the completion of milking. Provided, that the blend temperature after the first milking and subsequent milkings does not exceed 10ºC (50ºF). **NOTE:** Milk sample submitted for testing cooled and maintained at 0ºC (32ºF) to 4.4ºC (40ºF), where sample temperature is >4.4ºC (40ºF), but ≤7.0ºC (45°F) and less than three (3) hours after collection has not increased in temperature.
	Bacterial Limits.....	Individual producer milk not to exceed 100,000 per mL prior to commingling with other producer milk. Not to exceed 300,000 per mL as commingled milk prior to pasteurization. **NOTE:** Tested in conjunction with the drug residue/inhibitory substance test.
	Drugs *****.....……	No positive results on drug residue detection methods as referenced in Section 6 - Laboratory Techniques.
	Somatic Cell Count*...	Individual producer milk not to exceed 750,000 per mL.
GRADE "A" PASTEURIZED MILK AND MILK PRODUCTS	Temperature.....	Cooled to 7ºC (45ºF) or less and maintained thereat. **NOTE:** Milk sample submitted for testing cooled and maintained at 0ºC (32ºF) to 4.4ºC (40ºF), where sample temperature is >4.4ºC (40ºF), but ≤7.0ºC (45°F) and less than three (3) hours after collection has not increased in temperature.
	Bacterial Limits**…...	Not to exceed 20,000 per mL, or gm.*** **NOTE:** Tested in conjunction with the drug residue/inhibitory substance test.
	Coliform.....	Not to exceed 10 per mL. Provided, that in the case of bulk milk transport tank shipments, shall not exceed 100 per mL. **NOTE:** Tested in conjunction with the drug residue/inhibitory substance test.
	Phosphatase****.....	Less than 350 milliunits/L for fluid products and other milk products by approved electronic phosphatase procedures.
	Drugs**.....….	No positive results on drug residue detection methods as referenced in Section 6 - Laboratory Techniques which have been found to be acceptable for use with pasteurized milk and milk products.

GRADE "A" ULTRA-PASTEURIZED (UP) MILK AND MILK PRODUCTS	Temperature.....	Cooled to 7ºC (45ºF) or less and maintained thereat.
	Bacterial Limits**…..	Not to exceed 20,000 per mL, or gm.***
	Coliform…….....	Not to exceed 10 per mL. Provided, that in the case of bulk milk transport tank shipments, shall not exceed 100 per mL.
	Phosphatase****.....	Phosphatase testing of UP milks is not required.
	Drugs**.....…..	There are no validated and accepted drug residue tests for Ultra-Pasteurized Milk and Milk Products
GRADE "A" PASTEURIZED CONCENTRATED (CONDENSED) MILK AND MILK PRODUCTS	Temperature……	Cooled to 7°C (45°F) or less and maintained thereat unless drying is commenced immediately after condensing.
	Coliform……	Not to exceed 10 per gram. *Provided,* that in the case of bulk milk transport tank shipments shall not exceed 100 per gram.
GRADE "A" NONFAT DRY MILK AND DRY MILK AND MILK PRODUCTS	Bacterial Estimate……. Coliform……	Not to Exceed: 10,000 per gram 10 per gram
GRADE "A" WHEY FOR CONDENSING AND/OR DRYING	Temperature……	Maintained at a temperature of 45°F (7°C) or less, or 57°C (135°F) or greater, except for acid-type whey with a titratable acidity of 0.40% or above, or a pH of 4.6 or below.
GRADE "A" PASTEURIZED CONDENSED WHEY AND WHEY PRODUCTS	Temperature……..	Cooled to 10°C (50°F) or less during crystallization, within 72 hours of condensing.
	Coliform Limit……..	Not to exceed 10 per gram.
GRADE "A" DRY WHEY, GRADE "A" DRY WHEY PRODUCTS, GRADE "A" DRY BUTTERMILK, AND GRADE "A" DRY BUTTERMILK PRODUCTS	Coliform Limit……..	Not to exceed 10 per gram.

* Goat Milk 1,500,000/mL

** Not applicable to acidified or cultured products, eggnog and flavored (non-chocolate) milk and milk products.

*** Results of the analysis of dairy products which are weighed in order to be analyzed will be reported in # per gm. (Refer to the current edition of the *SMEDP*.)

**** Not applicable to UP products that have been thermally processed at or above 138^0C (280^0F) for at least two (2) seconds to produce a product which has an extended shelf life (ESL) under refrigerated conditions; and condensed products.

***** Raw sheep milk samples that have previously been frozen may be tested for Appendix N drug residue if the samples meet the sampling requirements cited in Appendix B.

NOTE: It is not allowed to test frozen raw milk samples for bacteria or somatic cells.

Make the following changes to ***APPENDIX B. MILK SAMPLING, HAULING AND TRANSPORTATION*** *on Page 135:*

V. ~~MILK TANK TRUCK PERMITTING AND INSPECTION~~ REQUIREMENTS FOR THE SAMPLING OF RAW SHEEP MILK THAT HAS BEEN FROZEN PRIOR TO BEING TESTED FOR APPENDIX N DRUG RESIDUE

Raw sheep milk samples that have previously been frozen may be tested for Appendix N drug residue provided that the sampling protocol shall be approved by the Regulatory Agency in which the dairy farm is located. The sampling protocol shall address the following items:

1. Samples shall be taken by a bulk milk hauler/sampler that is permitted by the Regulatory Agency in which the dairy farm is located.
2. The sampling protocol shall assure that representative samples are taken.
3. A storage protocol that assures that the raw sheep milk and samples are frozen within 24 hours of sample collection in accordance with the handling of the negative control as specified in the FDA/NCIMS 2400 Form for the test kit that is being used.
4. The collected raw sheep milk and samples are stored in a freezer(s) that is properly maintained and temperature monitored in accordance with the FDA/NCIMS 2400 Form General Requirements.
5. Samples delivered to the testing laboratory for testing within sixty (60) days of the freezing of the raw sheep milk.
6. An appropriate sample chain–of-custody shall be utilized to assure sample identification and handling.
7. Copies of the approved sampling protocol shall be on file with the Regulatory Agency and shall be available at the dairy farm, receiving milk plant and the laboratory performing the testing. If a copy of the sampling protocol is not available at the dairy farm, receiving milk plant or laboratory performing the testing, a copy shall be made available within twenty-four (24) hours of being requested by the Regulatory Agency.

If the sampling protocol has not been approved by the Regulatory Agency; is not being followed; the sampling protocol has been modified without the Regulatory Agency's approval or the dairy farm, receiving milk plant or laboratory performing the testing does not obtain a copy within twenty-four (24) hours of being requested by the Regulatory Agency it shall be considered an Appendix N violation for the dairy farm and/or receiving milk plant.

Proposal: 201
Document: 2011 PMO (Section 1)
Page: 6

Make the following changes to ***SECTION 1. DEFINITIONS*** *on Page 6:*

Z. **MILK PRODUCTS:** Grade "A" Milk and Milk Products include:

1. All milk and milk products with a standard of identity provided for in 21 CFR Part 131, excluding 21 CFR 131.120 Sweetened Condensed Milk.
2. Cottage cheese (21 CFR 133.128) and dry curd cottage cheese (21 CFR 131.129)2.
3. Whey and whey products as defined in 21 CFR 184.1979, 184.1979a, 184.1979b, 184.1979c, and Section 1, Definition SS of this *Ordinance*.
4. Modified versions of these foods listed above in Items 1 and 2, pursuant to 21 CFR 130.10-requirements for foods named by use of a nutrient content claim and a standardized term.
5. Milk and milk products as defined in Items 1, 2, 3 and 4 above, packaged in combination with food(s) not included in this definition that are appropriately labeled with a statement of identity to describe the food(s) in final packaged form, e.g., "cottage cheese with pineapple" and "fat free milk with plant sterols".
6. Products not included in Items 1-5 are Grade "A" milk products which have a minimum of 2.0% milk protein (Total Kjeldahl Nitrogen (TKN) X 6.38) and a minimum of sixty-five percent (65%) by weight milk, milk product or a combination of milk products.

Safe and suitable (as defined in 21 CFR 130.3(d)) non-grade "A" dairy ingredients, can be utilized in the products defined in Items 1-6 when added to a level needed for a functional or technical effect, and limited by Good Manufacturing Practices (GMPs) and are either:

a. Prior sanctioned or otherwise approved by FDA, or
b. GRAS (generally recognized as safe), or
c. An approved food additive listed in the CFR.

Except that with respect to those products which have a federal standard of identity, only ingredients provided for in the standard may be utilized.

NOTE: Non-grade "A" dairy ingredients may be used after the Regulatory Agency, in consultation with FDA, has reviewed and accepted information supporting that the use is to achieve a functional or technical effect in the finished milk or milk product(s). Supporting information shall be submitted by the milk plant and/or the ingredient manufacturer for review and approval by the Regulatory Agency and FDA prior to manufacturing and selling the finished milk or milk product(s). Once the Regulatory Agency, in consultation with FDA, has accepted the use of a non-grade "A" ingredient to achieve a functional or technical effect in the finished milk or milk product(s), any formulation or processing changes related to the non-grade "A" dairy ingredient shall be immediately communicated to the Regulatory Agency, and may result in the resubmission of supporting data, if it is determined by the Regulatory Agency, in consultation with FDA, that the change could potentially affect the functional or technical effect of the finished milk or milk product(s).

The supporting information shall include but is not limited to:

a. A statement of the proposed usage of a non-grade "A" dairy ingredient, including the expected functional and/or technical effect(s) in the finished milk or milk product(s) and justification of why this cannot be performed by a currently available Grade "A" dairy ingredient;
b. Non-grade "A" dairy ingredient description, composition and required usage level;
c. The finished milk or milk product(s) description including the current, if applicable, and proposed formula(s) including the current, if applicable, and proposed labeling information (e.g. statement of identity, ingredient declaration) and:

d. Applicable and recognized analytical measurements and/or organoleptic observations and evaluations that objectively demonstrate that the non-grade "A" dairy ingredient provides a specific functional and/or technical effect(s) that could not be achieved when using a currently available Grade "A" dairy ingredient(s) when used at similar concentrations and with similar proximates, i.e. protein, fat, ash, lactose, moisture, etc.

When a non-grade "A" dairy ingredient is used to increase weight or volume of the milk or milk product, or displace grade Grade "A" dairy ingredients, this use is not a suitable functional or technical effect.

Proposal: 203
Document: 2011 PMO (Sections 1-Definition HH and 7-Item 16p)
Pages: 8, 9 and 83

*Make the following changes to **SECTION 1. DEFINITION HH** on Pages 8 and 9:*

Page 8:

Temperature	Time
Batch (Vat) Pasteurization	
63ºC (145ºF)*	30 minutes
Continuous Flow (HTST and HHST) Pasteurization	
72ºC (161ºF)*	15 seconds
89ºC (191ºF)	1.0 second
90ºC (194ºF)	0.5 seconds
94ºC (201ºF)	0.1 seconds
96ºC (204ºF)	0.05 seconds
100ºC (212ºF)	0.01 seconds

Page 9:

Temperature	Time
Batch (Vat) Pasteurization	
69ºC (155ºF)	30 minutes
Continuous Flow (HTST) Pasteurization	
80ºC (175ºF)	25 seconds
83ºC (180ºF)	15 seconds

*Make the following changes to **SECTION 7, ITEM 16p. PASTEURIZATION AND ASEPTIC PROCESSING AND PACKAGING** on Page 83:*

Temperature	Time
Batch (Vat) Pasteurization	
63ºC (145ºF)*	30 minutes
Continuous Flow (HTST and HHST) Pasteurization	
72ºC (161ºF)*	15 seconds
89ºC (191ºF)	1.0 second
90ºC (194ºF)	0.5 seconds
94ºC (201ºF)	0.1 seconds
96ºC (204ºF)	0.05 seconds
100ºC (212ºF)	0.01 seconds

Temperature	Time
Batch (Vat) Pasteurization	
69ºC (155ºF)	30 minutes
Continuous Flow (HTST) Pasteurization	
80ºC (175ºF)	25 seconds
83ºC (180ºF)	15 seconds

Proposal: 205
Document: 2011 PMO (Section 4)
Page: 15

*Make the following changes to **SECTION 4. LABELING** on Page 15:*

6. In the case of condensed or dry milk products the following shall also apply:
   a. The identity of the ~~Regulatory Agency issuing such permit~~ milk plant where condensed and/or dried; and if distributed by another party, the name and address of the distributor shall also be shown by a statement, such as "Distributed by".

Proposal: 206
Document: 2011 PMO (Section 5; and Appendix B)
Pages: 19 and 130

*Make the following changes to **SECTION 5. INSPECTION OF DAIRY FARMS AND MILK PLANTS** on Page 19:*

ADMINISTRATIVE PROCEDURES

INSPECTION FREQUENCY: For the purposes of determining the inspection frequency for dairy farms, transfer stations and milk plants or the portion of a milk plant that is IMS listed to produce aseptically processed and packaged milk or milk products, the interval shall include

the designated six (6) month period plus the remaining days of the month in which the inspection is due

For the purposes of determining the inspection frequency for all other milk plants and receiving stations, the interval shall include the designated three (3) month period plus the remaining days of the month in which the inspection is due.

For the purposes of determining the inspection frequency for bulk milk hauler/samplers, industry plant samplers and dairy plant samplers, the interval shall include the designated twenty-four (24) month period plus the remaining days of the month in which the inspection is due. …

Make the following changes to ***APPENDIX B. MILK SAMPLING, HAULING AND TRANSPORTATION*** *on Page 130:*

I. MILK SAMPLING AND HAULING PROCEDURES

The industry plant sampler or bulk milk hauler/sampler is a person responsible for the collection of official samples for regulatory purposes at a milk plant, receiving station, or transfer station as outlined in Appendix N. These industry plant samplers are employees of the dairy plant, receiving station or transfer station and are evaluated at least once each two (2) year period by a SSO or a properly delegated Sampling Surveillance Regulatory Official. These industry plant samplers are evaluated using FORM FDA 2399-MILK SAMPLE COLLECTOR EVALUATION REPORT (Dairy Plant Sampling – Raw and Pasteurized Milk), which is derived from the most current edition of *SMEDP*. (Refer to Appendix M.)

NOTE: For the purposes of determining the inspection frequency for bulk milk hauler/samplers, industry plant samplers and dairy plant samplers, the interval shall include the designated twenty-four (24) month period plus the remaining days of the month in which the inspection is due. ….

Document: 2011 MMSR (Appendix A)
Page: 94

Make the following changes to ***GUIDANCE FOR COMPUTING ENFORCEMENT CREDIT FOR PART I, ITEM 9 AND/OR PART II, ITEM 8 OF FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2)*** *on Page 94:*

Item 5. Sampler (Including Dairy Plant and Industry Plant Samplers at the Receiving Site)
Evaluated Every Two (2) Years and Reports Properly Filed

a. Samplers shall have their sampling collection procedures evaluated by a certified SSO or a properly delegated Sampling Surveillance Regulatory Official (dSSO) every two (2) years. SSOs or ~~properly delegated Sampling Surveillance Regulatory Officials~~ dSSOs are not required to be evaluated for sampling collection procedures.

NOTE: Use *Grade "A"* PMO, Section 5, **ADMINISTRATIVE PROCEDURES**, **INSPECTION FREQUENCY** as a guide: "For the purposes of determining the inspection frequency for bulk milk hauler/samplers, industry plant samplers and dairy plant samplers, the interval shall include the designated twenty-four (24) month period plus the remaining days of the month in which the inspection is due." …

NOTE: This proposal shall take immediate effect upon the issuance of the IMS-a, Actions from the 2013 National Conference on Interstate Milk Shipments, following FDA's concurrence with the NCIMS Executive Board.

Proposal: 207
Document: 2011 PMO (Sections 6 and 7-Table 1; and Appendixes G and O)
Pages: 23-27, 29, 30, 214-217 and 354

Make the following changes to ***SECTION 6. THE EXAMINATION OF MILK AND MILK PRODUCTS*** *on Pages 23-27:*

Page 23:

SECTION 6. THE EXAMINATION OF MILK AND MILK PRODUCTS

3. During any consecutive six (6) months, at least four (4) samples of pasteurized milk, ultra-pasteurized milk, flavored milk, flavored reduced fat or low fat milk, flavored nonfat (skim) milk, each fat level of reduced fat or low fat milk and each milk product defined in this *Ordinance*, shall be collected by the Regulatory Agency in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days from every milk plant. All pasteurized and ultra-pasteurized milk and milk products required sampling and testing is to be ~~done~~ conducted only when there are test methods available that are validated by FDA and accepted by the NCIMS. ~~Products with no~~ Milk and/or milk products that do not have validated and accepted methods are not required to be tested. (Refer to M-a-98, latest revision, for the specific milk and/or milk products that have FDA validated and NCIMS accepted test methods.) Aseptically processed and packaged milk and milk products shall be exempt from the sampling and testing requirements of this Item. …

Page 24:

All pasteurized and ultra-pasteurized milk and milk products required sampling and testing to be done only when there are test methods available that are validated by FDA and accepted by the NCIMS, otherwise there would ~~be no~~ not be a requirement for sampling. Required bacterial counts, coliform counts, drug tests, phosphatase and cooling temperature determinations shall be performed on Grade "A" pasteurized and ultra-pasteurized milk and milk products defined in this *Ordinance* only when there are validated and accepted test methodology. (Refer to M-a-98, latest revision, for the specific milk and/or milk products that have FDA validated and NCIMS accepted test methods.) …

Page 25:

Assays of milk and/or milk products as defined in this *Ordinance*, including aseptically processed and packaged milk and/or milk products, to which vitamin(s) A and/or D have been added for fortification purposes, shall be ~~made~~ conducted at least annually in a laboratory, which has been accredited by FDA and which is acceptable to the Regulatory Agency, using test methods acceptable to FDA or other official methodologies, which gives statistically equivalent results to the FDA methods. (Refer to M-a-98, latest revision, for the specific milk and/or milk products that have FDA validated and NCIMS accepted test methods for vitamins.) Vitamin testing laboratories are accredited if they have one (1) or more certified analysts and meet the quality control requirements of the program established by FDA. Laboratory accreditation and analyst certification parameters are specified in the Evaluation of Milk Laboratories (EML) manual. …

Page 26:

1. ~~Standard plate~~ Bacterial count at 32ºC (~~agar~~ Standard Plate Count or Petrifilm Aerobic Count ~~method~~ methods). ...

3. Coliform ~~test with solid media or Petrifilm method~~ count at 32ºC ~~for all milk and milk products, and the~~ (Coliform Plate Count, Petrifilm Coliform Count and/or High Sensitivity Coliform Count ~~method~~ methods) for all milk and milk products~~, except unflavored whole, reduced or low fat and nonfat (skim) milk~~. …

5. Beta lactam methods which have been independently evaluated or evaluated by FDA and have been found acceptable by FDA and the NCIMS for detecting Beta lactam drug residues in raw milk, or pasteurized milk, or ~~that~~ a particular type of pasteurized milk product at current safe or tolerance levels, shall be used for each Beta lactam drug of concern~~;~~. ~~except~~ This does not apply to those milk products for which there are not any approved Beta lactam drug test kits available. (Refer to M-a-85, latest revision, for the approved drug tests and M-a-98, latest revision, for the specific milk and/or milk product for which there are approved drug tests available.) Regulatory action shall be taken on all confirmed positive Beta lactam results. (Refer to Appendix N.) A result shall be considered positive for Beta lactam if it has been obtained by using a method, which has been evaluated and deemed acceptable by FDA and accepted by the NCIMS at levels established in memoranda transmitted periodically by FDA as required by Section IV of Appendix N.

Page 27:

NOTE: Milk from animals not currently in the *Grade "A" PMO* may be labeled as Grade "A" and IMS listed upon FDA's acceptance of validated *Grade "A" PMO*, Section 6 and Appendix N. test methods for the animal to be added. (Refer to M-a-98, latest revision, for the specific milk and/or milk products that have FDA validated and NCIMS accepted test methods) …

Make the following changes to ***SECTION 7. STANDARDS FOR GRADE "A" MILK AND MILK PRODUCTS-TABLE 1*** *on Pages 29 and 30:*

Pages 29 and 30:

Table 1. Chemical, Physical, Bacteriological, and Temperature Standards
(Refer to M-a-98, Latest Revision, for FDA Validated and NCIMS Accepted Tests Methods.) …

GRADE "A" PASTEURIZED MILK AND MILK PRODUCTS	Temperature ……..	Cooled to …..
	Bacterial Limits**..	Not to exceed….
	Coliform ……	Not to exceed….
	Phosphatase ~~****~~.. **(Delete last two *s)**	Less than ….
	Drugs**** ……..	No positive results on drug residue detection methods as referenced in Section 6-Laboratory Techniques which have been found to be acceptable for use with ~~pasteurized~~ Pasteurized ~~milk~~ Milk and/or ~~milk products~~ Milk Products. (Refer to M-a-98, latest revision.)
GRADE "A" ULTRA-PASTEURIZED (UP) MILK AND MILK PRODUCTS	Temperature ……..	Cooled to 7°C (45°F) or less and maintained thereat
	Bacterial Limits**...	Not to exceed 20,000 per mL, or gm*** **NOTE:** Tested in conjunction with the drug residue/inhibitory substance test,
	Coliform ……	Not to exceed 10 per mL. Provided, that in the case of bulk milk transport tank shipments, shall not exceed 100 per mL.
	~~Phosphatase****…~~	~~Phosphatase testing of UP milks is not required~~
	Drugs**** …….	~~There are no validated and accepted drug residue tests for Ultra-Pasteurized Milk and Milk Products~~ No positive results on drug residue detection methods as referenced in Section 6-Laboratory Techniques which have been found to be acceptable for use with Ultra-Pasteurized Milk and/or Milk Products. (Refer to M-a-98, latest revision.)

...

* Goat Milk 1,500,000/mL
** Not applicable to acidified or cultured milk and/or milk products, eggnog, ~~and flavored (non-chocolate) milk and milk products~~ cottage cheese, and other milk and/or milk products as identified in the latest revision of M-a-98.
*** Results of the analysis of dairy products which are weighed in order to be analyzed will be reported in # per gm. (Refer to the current edition of the *SMEDP*.)
**** Not applicable to ~~UP products that have been thermally processed at or above 138^{0}C (280^{0}F) for at least two (2) seconds to produce a product which has an extended shelf life (ESL) under refrigerated conditions; and condensed products~~ acidified or cultured milk and/or milk products, eggnog, cottage cheese, pasteurized and ultra-pasteurized flavored (non-chocolate) milk and/or milk products and other milk and/or milk products as identified in the latest revision of M-a-98.

Make the following changes to ***APPENDIX G. CHEMICAL AND BACTERIOLOGICAL TESTS*** *on Pages 214-217:*

APPENDIX G. CHECMICAL AND BACTERIOLOGICAL TESTS

I. PRIVATE WATER SUPPLIES AND RECIRCULATED WATER – BACTERIOLOGICAL ..

Page 214:

Apparatus, Methods and Procedure: Tests performed shall conform with the current edition of *SMEWW* or with FDA approved, EPA promulgated methods for the examination of water and waste water or the applicable FDA 2400 Series Forms. (Refer to M-a-98, latest revision.)
…

II. PASTEURIZATION EFFICIENCY - ~~FIELD~~ PHOSPHATASE TEST

Page 215:

Procedure: Refer to the applicable FDA 2400 Series Forms and M-a-98, latest revision, for the specific milk and/or milk products for which there are approved phosphatase tests available. ~~for details on phosphatase tests~~. …

Page 216:

V. DETECTION OF DRUG RESIDUES IN MILK …

The allergenic properties of certain drugs in common use make their presence in milk potentially hazardous to consumers. Also, substantial losses of byproducts may be sustained by the milk industry each year because of the inhibitory effects of drug residues on the culturing process. Drug residues shall be tested for, using tests provided for in Section 6 of this *Ordinance*. These tests are specified in memoranda from the FDA. (Refer to the latest ~~edition~~ revision of M-a-85 for the approved drug tests, ~~and~~ the FDA 2400 Series Forms for each

specific test method and M-a-98, latest revision, for the specific milk and/or milk products for which there are approved drug tests available.)

Page 217:

VI. ANALYSIS OF MILK AND MILK PRODUCTS FOR VITAMIN A AND D CONTENT …

Methods: Vitamin testing shall be performed using test methods acceptable to FDA and other official methodologies that give statistically equivalent results to the FDA methods. (Refer to M-a-98, latest revision, for the specific milk and/or milk products that have FDA validated and NCIMS accepted test methods for vitamins.) …

*Make the following changes to **APPENDIX O. VITAMIN FORTIFICATION OF FLUID MILK PRODUCTS** on Page 354:*

TESTING METHODS

Test methods used for the detection of vitamins A and/or D shall be acceptable to FDA or other official methodologies that give statistically equivalent results to the FDA methods. Vitamin analysis shall be conducted in a laboratory accredited by FDA and acceptable to the Regulatory Agency. (Refer to M-a-98, latest revision, for the specific milk and/or milk products that have FDA validated and NCIMS accepted test methods for vitamins.) …

Document: 2011 MMSR (Section C; and Appendix A)
Pages: 11 and 88

*Make the following changes to **C. RATING METHODS FOR MILK PLANTS, RECEIVING STATIONS AND TRANSFER STATIONS** on Page 11:*

b. Recording of Laboratory and Other Test Data …

1.) Regulatory Agency records are used in determining compliance with bacterial, coliform, phosphatase, drug residue, and cooling temperature requirements. The acceptance of data from official or officially designated laboratories is contingent upon the utilization of standard procedures by the laboratories concerned. Accordingly, it is necessary for the SRO to determine from the official State Laboratory Certifying Agency that both sampling and laboratory procedures have been approved in accordance with the methods of the current edition of the *EML*. Ratings and HACCP listing audits shall not be conducted when an approved laboratory has not been utilized by the Regulatory Agency for the necessary tests. …

3.) The SRO may utilize Regulatory Agency's records in determining compliance with those Items of sanitation, which require laboratory tests to complete the evaluation. Official records of Equipment Tests may also be used in lieu of performing such Equipment Tests during the rating. Provided, that the SRO is satisfied as to the

competency of the Regulatory Agency's personnel to perform these Equipment Tests as described in Appendix I. of the *Grade "A" PMO.*

NOTE: All pasteurized and ultra-pasteurized milk and/or milk products required sampling and testing is to be conducted only when there are test methods available that are validated by FDA and accepted by the NCIMS. Milk and/or milk products that do not have validated and accepted methods are not required to be tested. (Refer to M-a-98, latest revision, for the specific milk and/or milk products that have FDA validated and NCIMS accepted test methods.)

The sampling and testing of aseptically processed and packaged Grade "A" milk and/or milk products is not required, with the exception of the annual vitamin assay analysis to which vitamin(s) A and/or D have been added for fortification purposes. The sampling and testing requirements of Section 6 of the *Grade "A" PMO* for raw milk for aseptic processing and packaging is required.

Make the following changes to ***APPENDIX A. GUIDELIINES FOR COMPUTING ENFORCEMENT RATINGS*** *on Page 88:*

7. Samples of each milk plant's milk and/or milk products collected at the required frequency and all necessary laboratory examinations made (*Grade "A" PMO,* Section 6 - THE EXAMINATION OF MILK AND MILK PRODUCTS). Prorate by the number of milk and/or milk products in compliance. (Refer to M-a-98, latest revision, for the FDA validated and NCIMS accepted test methods for the specific milk and/or milk products.) …

c. All required examinations performed on each sample (bacterial, coliform, drug residue, phosphatase, and cooling temperature) in an official or officially designated laboratory.

NOTE: All pasteurized and ultra-pasteurized milk and/or milk products required sampling and testing is to be conducted only when there are test methods available that are validated by FDA and accepted by the NCIMS. Milk and/or milk products that do not have validated and accepted methods are not required to be tested. (Refer to M-a-98, latest revision, for the specific milk and/or milk products that have FDA validated and NCIMS accepted test methods.)

d. Assays of Vitamin A, D, and/or A and D fortified milk and/or milk products, including aseptically processed and packaged milk and/or milk products, ~~made~~ conducted at least annually in an IMS Listed Laboratory. Credit for vitamin-fortified milk and/or milk products is not given unless vitamin analysis is completed and records are available. Each vitamin fortified product is evaluated separately. (Refer to M-a-98, latest revision, for the specific milk and/or milk products that have FDA validated and NCIMS accepted test methods for vitamins.) …

NOTE: *This Proposal shall take immediate effect upon the issuance of the IMS-a, Actions from the 2013 National Conference on Interstate Milk Shipments, following FDA's concurrence with the NCIMS Executive Board.*

Proposal: 208
Document: 2011 PMO (Section 6; and Appendix N)
Pages: 23-27 and 342-351

Make the following changes to ***SECTION 6. THE EXAMINATION OF MILK AND MILK PRODUCTS*** *on Pages 23-27:*

Page 23:

SECTION 6. THE EXAMINATION OF MILK AND MILK PRODUCTS …

It shall be the responsibility of the industry plant sampler to collect a representative sample of milk ~~from each milk tank truck or from a properly installed and operated aseptic sampler, which is approved for use by the Regulatory Agency and FDA to collect representative samples, prior to transferring milk from a milk tank truck.~~ for Appendix N testing from the following:

1. Each milk tank truck or from a properly installed and operated aseptic sampler, which is approved for use by the Regulatory Agency and FDA to collect representative samples, prior to transferring milk from a milk tank truck; and/or
2. Each raw milk supply that has not been transported in bulk milk pickup tankers or from a properly installed and operated in-line sampler or aseptic sampler, which is approved for use by the Regulatory Agency and FDA to collect representative samples, prior to transferring the milk from a farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. for processing at that location.

~~1.~~ During any consecutive six (6) months, at least four (4) samples of raw milk …
~~2.~~ During any consecutive six (6) months, at least four (4) samples of raw milk …
~~3.~~ During any consecutive six (6) months, at least four (4) samples of pasteurized milk, …

Page 24:

Whenever a pesticide residue test is positive, an investigation shall be made to determine the cause and the cause shall be corrected. An additional sample shall be taken and tested for pesticide residues and ~~no~~ milk and/or milk products as defined in this *Ordinance* shall not be offered for sale until it is shown by a subsequent sample to be free of pesticide residues or below the actionable levels established for such residues. …

Page 25:

Each milk plant regulated under the NCIMS voluntary HACCP Program shall adequately document its response to each regulatory sample test result that exceeds any maximum level specified in Section 7 of this *Ordinance*. The Regulatory Agency ~~will~~ shall monitor and verify that appropriate action(s) was taken by the milk plant.
Examinations and tests to detect adulterants, including pesticides, shall be conducted, as the Regulatory Agency requires. When the Commissioner of the FDA determines that a potential

problem exists with animal drug residues or other contaminants in the milk supply, samples shall be analyzed for the contaminant by a method(s) determined by FDA to be effective in determining compliance with actionable levels or established tolerances. This testing ~~will~~ shall continue until such time that the Commissioner of the FDA is reasonably assured that the problem has been corrected. The determination of a problem is to be based upon: …

Assays of milk and/or milk products as defined in this *Ordinance*, including aseptically processed and packaged milk and/or milk products, to which vitamin(s) A and/or D have been added for fortification purposes, shall be ~~made~~ conducted at least annually in a laboratory, which has been accredited by FDA and which is acceptable to the Regulatory Agency, using test methods acceptable to FDA or other official methodologies, which gives statistically equivalent results to the FDA methods. Vitamin testing laboratories are accredited if they have one (1) or more certified analysts and meet the quality control requirements of the program established by FDA. Laboratory accreditation and analyst certification parameters are specified in the Evaluation of Milk Laboratories (EML) manual.
In addition, all ~~facilities~~ milk plants fortifying milk and/or milk products with vitamins ~~must~~ shall keep volume control records. These volume control records ~~must~~ shall cross reference the form and amount of vitamin D, vitamin A and/or vitamins A and D used with the amount of milk and/or milk products produced and indicate a percent of expected use, plus or minus.

ADMINISTRATIVE PROCEDURES …

Page 26:

5. Beta lactam methods which have been independently evaluated or evaluated by FDA and have been found acceptable by FDA and the NCIMS for detecting Beta lactam drug residues in raw milk, or pasteurized milk, or ~~that~~ a particular type of pasteurized milk product at current safe or tolerance levels, shall be used for each Beta lactam drug of concern~~,~~. ~~except~~ This does not apply to those milk products for which there are not any approved Beta lactam drug test kits available. (Refer to M-a-85, latest revision, for the approved Beta lactam drug tests.) Regulatory action shall be taken on all confirmed Beta lactam positive results. (Refer to Appendix N.) A result shall be considered positive for Beta lactam if it has been obtained by using a method, which has been evaluated and deemed acceptable by FDA and accepted by the NCIMS at levels established in memoranda transmitted periodically by FDA as required by Section IV of Appendix N.
6. Screening and Confirmatory Methods for the Detection of Abnormal Milk: The results of the screening test or confirmatory test shall be recorded on the official records of the dairy farm and a copy of the results sent to the milk producer.
When a warning letter has been sent, because of excessively high somatic cell counts, an official inspection of the dairy farm should be made by regulatory personnel or certified industry personnel. This inspection should be made during milking time. …

b. Goat Milk: Direct Microscopic Somatic Cell Count or Electronic Somatic Cell Count may be used for screening raw goat milk samples, to indicate a range of somatic cell levels, as long as the somatic cell standard for goat milk remains 1,500,000/mL. Screening for official purposes ~~must~~ shall be conducted by an analyst (s) certified for that procedure.

Only the Pyronine Y-Methyl Green stain or "New York modification" Single Strip Direct Microscopic Somatic Cell Count test procedures shall be used to confirm the level of somatic cells in goat milk by certified analysts.

c. Sheep Milk: Any of the following confirmatory or screening test procedures shall be used: Single Strip Direct Microscopic Somatic Cell Count or Electronic Somatic Cell Count. When results from the Single Strip Direct Microscopic Somatic Cell Count procedure exceed the 750,000/mL standard set forth in this *Ordinance*, the count ~~must~~ shall have been derived from, or be confirmed by, the Pyronine Y Methyl-Green Stain or the "New York modification". …

Page 27:

10. All standards used in the development and use of drug residue detection methods designed for *Grade "A" PMO* monitoring programs ~~will~~ shall be referenced to a United States Pharmacopeia (USP) standard when available. When a USP standard is not available, then the original method ~~must~~ shall define the standard to be used.
11. Procedural or reagent changes for official tests ~~must~~ shall be submitted to FDA for acceptance prior to being used by certified NCIMS milk laboratories.

SAMPLING PROCEDURES: *SMEDP* contains guidance for the sampling of milk and milk products. Optionally, sample collection time may be identified in military time (24 hour clock). (Refer to Appendix G. for a reference to drug residues in milk and/or milk products and the conditions under which a positive phosphatase reaction may be encountered in properly pasteurized milk or cream. Refer to Appendix B. for reference to farm bulk milk hauling programs regarding training, licensing/permitting, routine inspection and the evaluation of sampling procedures.)
When samples of raw milk for pasteurization are taken at a milk plant prior to pasteurization, they shall be drawn following adequate agitation from randomly selected storage tanks/silos. All counts and temperatures ~~should~~ shall be recorded on a milk-ledger form as soon as reported by the laboratory. A computer or other information retrieval system may be used. …

*Make the following changes to the **APPENDIX N. DRUG RESIDUE TESTING AND FARM SURVEILLANCE** on Pages 342-351:*

Page 342:

I. INDUSTRY RESPONSIBILITIES

MONITORING AND SURVEILLANCE:

Industry shall screen all bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers, regardless of final use, for Beta lactam drug residues. Additionally, other drug residues shall be screened for by employing a random sampling program on bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers when the Commissioner of the FDA determines that a potential problem exists as cited in Section 6 of this *Ordinance*. The random bulk milk pickup

tanker and/or all raw milk supplies that have not been transported in bulk milk pickup tankers sampling program shall represent and include, during any consecutive six (6) months, at least four (4) samples collected in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days. Samples collected under this random sampling program shall be analyzed as specified by FDA. (Refer to Section 6 of this *Ordinance*.)

The bulk milk pickup tanker shall be sampled after the last producer has been picked up and before any additional commingling. These bulk milk pickup tanker samples may be collected ~~from~~ using an approved aseptic sampler. The sample ~~must~~ shall be representative. Bulk milk pickup tanker testing shall be completed prior to processing the milk. ~~Industry plant samplers shall be evaluated according to the requirements specified in Section 6. THE EXAMINATION OF MILK AND MILK PRODUCTS and at the frequency addressed in Section 5. INSPECTION OF DAIRY FARMS AND MILK PLANTS of this *Ordinance*.~~ Bulk milk pickup tanker samples ~~found to be~~ confirmed positive for drug residues shall be retained as determined necessary by the Regulatory Agency. ~~All presumptive positive test results for drug residues from analysis done on commingled raw milk tanks, bulk milk pickup tankers, farm raw milk tanks (only milk offered for sale) or finished milk or milk product samples must be reported to the Regulatory Agency of the State in which the testing was conducted.~~

All raw milk supplies that have not been transported in bulk milk pickup tankers shall be sampled prior to processing the milk. The sample(s) shall be representative of each farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. Testing of all raw milk supplies that have not been transported in bulk milk pickup tankers shall be completed prior to processing the milk.

NOTE: On-farm producer/processors that plan to store or ship their raw sheep milk frozen, shall sample their raw sheep milk prior to freezing. The sample shall be obtained by a bulk milk hauler/sampler permitted in the State where the dairy farm is located. The raw sheep milk sample shall then be tested in a certified laboratory or screening facility. If this is the on-farm producer/processor's only raw sheep milk supply, this testing would suffice for the required Appendix N testing for all raw milk supplies that have not been transported in bulk milk pickup tankers, which are required to be completed prior to processing the milk. In the case of sheep milk dairy farms, the raw milk sample may be frozen in accordance with a sample protocol approved by the Regulatory Agency of the State in which the dairy farm is located as specified in Appendix B and transported to a certified laboratory for testing. The test results, or raw milk samples, shall clearly distinguish the lot number of the frozen raw sheep milk and accompany the frozen raw sheep milk to the plant.

All presumptive positive test results for drug residues from analysis conducted on commingled raw milk tanks, bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers, farm raw milk tanks/silos (only milk offered for sale) or finished milk or milk product samples shall be reported to the Regulatory Agency of the State in which the testing was conducted. Bulk milk pickup tanker and/or all raw milk supplies that have not been transported in bulk milk pickup tankers samples confirmed positive for drug residues shall be retained or disposed of as determined by the Regulatory Agency.

Industry plant samplers shall be evaluated according to the requirements specified in Section 6. THE EXAMINATION OF MILK AND MILK PRODUCTS and at the frequency addressed in Section 5. INSPECTION OF DAIRY FARMS AND MILK PLANTS of this *Ordinance*.

REPORTING AND FARM TRACE BACK:

When a bulk milk pickup tanker and/or a raw milk supply that has not been transported in bulk milk pickup tankers is found to be presumptive positive for drug residues, the Regulatory Agency of the State in which the testing was conducted, shall be immediately notified of the results and the ultimate disposition of the raw milk.
The producer samples from the bulk milk pickup tanker, found to be positive for drug residues, shall be individually tested to determine the farm of origin. The samples shall be tested as directed by the Regulatory Agency.
When a farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc, is (are) used for a milk plant's raw milk supply(ies) that has (have) not been transported in bulk milk pickup tankers, is (are) found to be positive (confirmed) for drug residues, the farm of origin of the drug residue has consequently already been determined and further testing is not required to determine the farm of origin.
Further pickups or use of the violative individual producer's milk shall be immediately discontinued, until such time, that subsequent tests are no longer positive for drug residues.

RECORD REQUIREMENTS:

Results of all testing may be recorded in any format acceptable to the Regulatory Agency that includes at least the following information:

Page 343:

1. Identity of the person doing the test;
2. Identity of the bulk milk pickup tanker or farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. used for the storage of all raw milk supplies that have not been transported in bulk milk pickup tankers being tested*;
3. Date/time the test was performed (Time, Day, Month, and Year);
4. Identity of the test performed/lot #/any and all controls (+/-);
5. Results of the test;
6. Follow-up testing if the initial test was positive/any and all controls (+/-);
7. Site where test was performed, and
8. Prior test documentation shall be provided for a presumptive positive load.

*Include the BTU number(s) of the dairy farms present on the bulk milk pickup tanker and/or all raw milk supplies that have not been transported in bulk milk pickup tankers with the above information.

Records of all sample results shall be maintained for a minimum of six (6) months by the industry at the location where the tests were run, and/or another location as directed by the Regulatory Agency.

II. REGULATORY AGENCY RESPONSIBLITIES

Upon receipt of notification from industry of a bulk milk pickup tanker and/or a raw milk supply that has not been transported in bulk milk pickup tankers, which contains milk from another State(s), is found to be presumptive positive for drug residues it is the responsibility of the Regulatory Agency of the receiving State to notify the Regulatory Agency(ies) of all States of origin.

MONITORING AND SURVEILLANCE:

Regulatory Agencies shall monitor industry surveillance activities during either routine or unannounced, on-site quarterly inspections to collect samples from bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers and to review industry records of ~~the~~ their sampling program. Samples should be collected and analyzed from at least ten percent (10%) of the bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers scheduled to arrive on the day of the inspection. The method used shall be appropriate for the drug being analyzed and shall be capable of detecting the same drugs at the same concentrations as the method being used by industry. Alternately, the Regulatory Agency or Laboratory Evaluation Officer (LEO) may take known samples with them on the audit visit and observe the industry analyst test the samples. Receiving locations that choose to certify all receiving analysts, certified under the provisions of the NCIMS Laboratory Certification Program, are exempt from the sample collection requirements of this Section. Receiving locations where all approved receiving Industry Analysts and Industry Supervisors successfully participate in a biennial on-site evaluation and annual split sample comparisons by LEOs are also exempt from the sample collection requirements of this Section.
A review shall include, but not be limited to, the following:

1. Is the program an appropriate routine monitoring program for the detection of drug residues?
2. Is the program utilizing appropriate test methods?
3. Is each producer's milk represented in a testing program for drug residues and tested at the frequency prescribed in Section I.-INDUSTRY RESPONSIBILITIES ~~A.~~ of this Appendix for drug residues?

Page 344:

4. Is the program assuring timely notification to the appropriate Regulatory Agency of positive results, the ultimate disposition of the bulk milk pickup tanker and/or a raw milk supply that has not been transported in bulk milk pickup tankers~~,~~ and of the trace back to the farm of origin?

5. Is the dairy farm pickup and/or use of the violative individual producer's milk suspended until subsequent testing establishes the milk is no longer positive for drug residues?

To satisfy these requirements:

a. There should be an agreement between the Regulatory Agency and industry that ~~would specify~~ specifies how this notification is to take place. This notification ~~must~~ shall be "timely" for example by telephone or fax, and supported in writing.

b. ~~This~~ The ultimate disposition should either be prearranged in an agreement between the Regulatory Agency and the industry, or physically supervised by the Regulatory Agency. The milk should be disposed of in accordance with provisions of M-I-06-5 or an FDA and Regulatory Agency reviewed and accepted Beta lactam milk diversion protocol for use as animal feed.

c. All screening test positive (confirmed) loads ~~must~~ shall be broken down (producer trace back) using the same or an equivalent test method (M-I-96-10, latest revision). Confirmation tests (load and producer trace back/permit action) shall be performed by an Official or Officially Designated Laboratory or Certified Industry Supervisor. Positive producers shall be handled in accordance with this Appendix.

d. When a farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. is (are) used for a milk plant's raw milk supply(ies) that has (have) not been transported in bulk milk pickup tankers, is (are) found to be positive (confirmed) for drug residues, the farm of origin of the drug residue has consequently already been determined and further testing is not required to determine the farm of origin. Confirmation tests shall be performed by an Official or Officially Designated Laboratory or Certified Industry Supervisor. Positive producers shall be handled in accordance with this Appendix.

~~d~~e. The suspension and discontinuance of farm bulk milk tank pick up and/or the use of raw milk supplies that have not been transported in bulk milk pickup tankers is the responsibility of the industry; under the direction and supervision of the Regulatory Agency. At the discretion of the Regulatory Agency, records should be maintained by industry and/or the Regulatory Agency that:

(1) Establish the identity of the producer for raw milk supplies that have not been transported in bulk milk pickup tankers that tested positive or the producer and the identity of the load that tested positive; and

(2) Establish that ~~no~~ milk is not picked up or used from the drug residue positive ~~testing~~ producer until the Regulatory Agency has fulfilled their obligations under Section II-ENFORCEMENT of this Appendix and has cleared the milk for pick up and/or use.

Sufficient records should be reviewed to assure that all ~~farm~~ bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers are sampled before additional commingling at the milk receiving facility and the results were made available to the appropriate BTU(s).

The Regulatory Agency shall also perform routine sampling and testing for drug residues determined to be necessary as outlined in Section 6 of this *Ordinance.*

ENFORCEMENT:

If testing reveals milk positive for drug residues, the milk shall be disposed of in a manner that removes it from the human or animal food chain, except where acceptably reconditioned under FDA Compliance Policy Guide (CPG 7126.20). The Regulatory Agency shall determine the producer(s) responsible for the violation.
Suspension: Any time milk is found to test as a confirmed positive for a drug residue, the Regulatory Agency shall immediately suspend the producer's Grade "A" permit or equally effective measures shall be taken to prevent the sale of milk containing drug residues.

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Penalties: Future ~~pick-ups~~ pickups and/or use of the violative individual producer's milk are prohibited until subsequent testing reveals the milk is free of drug residue. The penalty shall be for the value of all milk on the contaminated load and/or raw milk supply that has not been transported in bulk milk pickup tankers plus any costs associated with the disposition of the contaminated load or raw milk supply that has not been transported in bulk milk pickup tankers. The Regulatory Agency may accept certification from the violative producer's milk marketing cooperative or purchaser of milk as satisfying the penalty requirements.
Reinstatement: The Grade "A" producer's permit may be reinstated, or other action taken, to allow the sale of milk for human food, when a representative sample taken from the producer's milk, prior to commingling with any other milk, is no longer positive for drug residue.
Follow-Up: Whenever a drug residue test is positive, an investigation shall be made to determine the cause. The farm inspection is completed by the Regulatory Agency or its agent to determine the cause of the residue and actions taken to prevent future violations including:

1. On-farm changes in procedures necessary to prevent future occurrences as recommended by the Regulatory Agency.
2. Discussion and education on the Drug Residue Avoidance Control measures outlined in Appendix C. of this *Ordinance.*

Permit Revocation: After a third violation in a twelve (12) month period, the Regulatory Agency shall initiate administrative procedures pursuant to the revocation of the producer's Grade "A" permit under the authority of Section 3. Permits of this *Ordinance*, due to repeated violations.

REGULATORY AGENCY RECORDS:

In regards to the industry reporting a positive tanker and/or a raw milk supply that has not been transported in bulk milk pickup tankers result, the Regulatory Agency's records ~~should~~ shall indicate the following:

1. What were the Regulatory Agency's directions?
2. When was the Regulatory Agency notified? By whom?
3. What was the identity of the load or farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. when used for a milk plant's raw milk supply(ies) that has (have) not been transported in bulk milk pickup tankers?
4. What screening and/or confirmatory test(s) were used and who were the analyst(s)?
5. What was the disposition of the adulterated milk?

6. Which producer(s) was responsible?
7. Record of negative test results prior to subsequent milk pickup and/or use from the violative producer(s).

III. TESTING PROGRAM FOR DRUG RESIDUES ESTABLISHED

DEFINITIONS:

For purposes of this Appendix the following definitions are to be used:

1. **Presumptive Positive:** A presumptive positive test is a positive result from an initial testing of a bulk milk pickup tanker and/or a raw milk supply that has not been transported in bulk milk pickup tankers using an M-a-85 (latest revision) approved test, which has been promptly repeated in duplicate with positive and negative controls that give the proper results using the same test, on the same sample, with one (1) or both of these duplicate retests giving a positive result.

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2. **Screening Test Positive (Load or Raw Milk Supply that has Not been Transported in Bulk Milk Pickup Tankers Confirmation):** A screening test positive result is obtained when the presumptive positive sample is tested in duplicate, using the same or equivalent (M-I-96-10, latest revision) test as that used for the presumptive positive, with a positive and negative control that give the proper results, and either or both of the duplicates are positive ~~and the controls give the proper results~~. A screening test positive (load or farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. when used for a milk plant's raw milk supply(ies) that has (have) not been transported in bulk milk pickup tankers confirmation) is to be ~~preformed~~ performed by an Official State Laboratory, Officially Designated Laboratory or Certified Industry Supervisor using the same or an equivalent test (M-I-96-10, latest revision).
3. **Producer Trace Back/Permit Action:** A producer trace back/permit action test is performed after a screening test positive load is identified by an Official State Laboratory, Officially Designated Laboratory or Certified Industry Supervisor using the same or an equivalent (M-I-96-10, latest revision) test as was used to obtain the screening test positive (load confirmation). A confirmed producer test positive result is obtained in the same manner as a confirmation (screening test positive) for a load. After an initial positive result (producer presumptive positive) is obtained on a producer sample, that sample is then tested in duplicate using the same test as was used to obtain the producer presumptive positive result. This testing is performed with a positive and negative control and if either or both of the duplicates are positive and the controls give the proper results, the producer sample is confirmed as positive.

NOTE: When a farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. is used for a milk plant's raw milk supply(ies) that has not been transported in bulk milk pickup tankers, is found to be positive (confirmed)

for drug residues, the farm of origin for the drug residue has consequently already been determined and further testing is not required to determine the farm of origin.

4. **Individual Producer Load:** An individual producer bulk milk pickup tanker is a bulk milk pickup tanker, or a compartment(s) of a bulk milk pickup tanker, that contains milk from only one (1) dairy farm.

5. **Individual On-Farm Producer/Processor's Raw Milk Supply:** An individual on-farm producer/processor's raw milk supply may be transported in bulk milk pickup tankers; and/or their raw milk supply may be stored in a farm bulk milk tank(s)/silo(s) on the dairy farm that directly feeds the batch (vat) pasteurizer(s) or constant-level tank of a HTST pasteurization system or piped from the a farm bulk milk tank(s)/silo(s) to a raw milk tank(s) and/or silo(s) in the milk plant that feeds the batch (vat) pasteurizer(s) or constant-level tank of a HTST pasteurization system; and/or other raw milk storage containers.

~~5~~6. **Industry Analyst:** A person under the supervision of ~~the~~ a Certified Industry Supervisor or Industry Supervisor who is assigned to conduct screening of bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers for Appendix N. drug residue requirements.

~~6~~7. **Industry Supervisor/Certified Industry Supervisor:** An individual trained by ~~the~~ a State LEO who is responsible for the supervision and training of Industry Analysts who test milk tank trucks and/or all raw milk supplies that have not been not transported in bulk milk pickup tankers for Appendix N. drug residue requirements.

~~7~~8. **Certified Industry Supervisor:** An Industry Supervisor who is evaluated and listed by a State LEO as certified to conduct drug residue screening tests at industry drug residue screening sites for *Grade "A" PMO,* Appendix N. regulatory actions (confirmation of bulk milk pickup tankers, farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), or other raw milk storage container(s), etc. when used for a milk plant's raw milk supply(ies) that has (have) not been transported in bulk milk pickup tankers, producer trace back and/or permit action).

CERTIFIED INDUSTRY SUPERVISORS; EVALUATION AND RECORDS:

Reference: *EML*

1. **Certified Industry Supervisors/Industry Supervisors/Industry Analysts:** Regulatory Agencies may choose to allow Industry Supervisors to be certified. Under this program, these Certified Industry Supervisors may officially confirm presumptive positive bulk milk pickup tanker loads and/or all raw milk supplies that have not been transported in bulk milk pickup tankers, and confirm producer milk for regulatory purposes (producer trace back/permit action). In the implementation of Appendix N. of this *Ordinance,* the LEO ~~will~~ shall use the appropriate Appendix N. FDA 2400 Series Form when evaluating Official State Laboratories, Officially Designated Laboratories or Certified Industry Supervisors, Industry Supervisors and Industry Analysts.

The Certified Industry Supervisor/Industry Supervisor shall report to the LEO the ~~result~~ results of all competency evaluations performed on Industry Analysts. The names of all Certified Industry Supervisors, Industry Supervisors and Industry Analysts, as well as their training and evaluation status, shall be maintained by the State LEO and updated as replacement, additions and/or removals occur. The State LEO shall verify (document) that each Certified Industry

Supervisor and/or Industry Supervisor has established a program that ensures the proficiency of the Industry Analysts they supervise. The State LEO shall also verify that each Industry Supervisor and Industry Analyst has demonstrated proficiency in performing drug residue analysis at least biennially. Verification may include an analysis of split samples and/or an on-site performance evaluation or another proficiency determination that the State LEO and the FDA Laboratory Proficiency Evaluation Team (LPET) agree is appropriate.

Page 347:

Failure by the Industry Supervisor or Industry Analyst to demonstrate adequate proficiency to the LEO shall lead to their removal from the LEO list of Industry Supervisors and/or Industry Analysts. Reinstatement of their testing status shall only be possible by completing retraining and/or successfully analyzing split samples and/or passing an on-site evaluation or otherwise demonstrating proficiency to the LEO. (Refer to the *EML*, which describes the certification requirements for Certified Industry Supervisors and the training requirements for Industry Supervisors and Industry Analysts.)

2. **Sampling and Testing of Bulk Milk Pickup Tankers:** The bulk milk pickup tanker shall be sampled after the last producer has been picked up and before any additional commingling. The sample ~~must~~ shall be representative. The sample analysis shall be completed before the milk is processed.

3. **Sampling and Testing of Raw Milk Supplies that have Not been Transported in Bulk Milk Pickup Tankers:** All raw milk supplies that have not been transported in bulk milk pickup tankers shall be sampled prior to processing the milk. The sample(s) shall be representative of each farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), or other raw milk storage container(s) supply. Testing of all raw milk supplies that have not been transported in bulk milk pickup tankers shall be completed prior to processing the milk.

~~3~~4. **Bulk Milk Pickup Tanker Unloaded Prior to Negative Test Result:** If the bulk milk pickup tanker is unloaded and commingled prior to obtaining a negative test result and the screening test is presumptive positive, the Regulatory Agency shall be immediately notified. ~~The~~ If the bulk milk tanker sample is confirmed positive, then the commingled milk is adulterated and unacceptable for human consumption regardless of any subsequent test results from the commingled milk. The milk shall be disposed of under the supervision of the Regulatory Agency.

5. **Raw Milk Supplies that have Not been Transported in Bulk Milk Pickup Tankers Processed Prior to Negative Results:** If the raw milk supply that has not been transported in bulk milk pickup tankers is processed prior to obtaining a negative test result and the screening test is presumptive positive, the Regulatory Agency shall be immediately notified. If the sample of the raw milk supply that has not been transported in bulk milk pickup tankers is confirmed positive, then the processed milk is adulterated and unacceptable for human consumption regardless of any subsequent test results from the raw milk supply and/or pasteurized milk or milk products. The processed milk shall be disposed of under the supervision of the Regulatory Agency.

BULK MILK PICKUP TANKER AND/OR ALL RAW MILK SUPPLIES THAT HAVE NOT BEEN TRANSPORTED IN BULK MILK PICKUP TANKERS SCREENING TEST:

1. **Performance Tests/Controls:** Each lot of test kits purchased shall be tested by positive (+) and negative (-) controls, as defined in the SCREENING TESTS NECESSARY TO IMPLEMENT THE PROVISIONS OF APPENDIX N. FOR BULK MILK PICKUP TANKERS AND/OR ALL RAW MILK SUPPLIES THAT HAVE NOT BEEN TRANSPORTED IN RAW BULK MILK PICKUP TANKERS of this Section, in each screening facility prior to its initial use and each testing day thereafter. Records of all positive (+) and negative (-) control performance tests shall be maintained.

2. **Initial Drug Testing Procedures:** The following procedures apply to testing bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers for drug residues following the provisions of Appendix N. Industry analysts may screen bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers and receive or reject milk. Milk plants, receiving stations, transfer stations and other screening locations may choose to participate in the Industry Supervisor Certification Program.

a. Industry Presumptive Positive Options: There are two (2) industry options for the milk represented by a presumptive positive sample:

(1) The Regulatory Agency involved (origin and receipt) shall be notified. The appropriate Regulatory Agency shall take control of the presumptive positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers. A written copy of the presumptive positive test results shall follow the initial Regulatory Agency notification. Testing for confirmation of that presumptive positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers shall be in an Official State Laboratory, Officially Designated Laboratory or by a Certified Industry Supervisor at a location acceptable to the Regulatory Agency. Documentation of prior testing shall be provided to the analyst performing the load and/or raw milk supply that has not been transported in bulk milk pickup tankers confirmation. The presumptive positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers may be re-sampled, at the direction of the Regulatory Agency, prior to analysis with the same or equivalent test (M-I-96-10, latest revision), as was used to obtain the presumptive positive result. This analysis shall be done in duplicate with positive (+) and negative (-) controls. If either or both of the duplicate samples are positive and the positive (+) and negative (-) controls give the correct reactions, the sample is deemed a Screening Test Positive (Confirmed Load and/or Raw Milk Supply that has Not been Transported in Bulk Milk Pickup Tankers). A written copy of the test results shall be provided to the Regulatory Agency. The milk, which that sample represents, is no longer available for sale or processing into human food.

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(2) The owner of the presumptive positive milk may reject the load and/or raw milk supply that has not been transported in bulk milk pickup tankers without further testing. At that time the milk represented by the presumptive positive test is not available for

sale or processing into human food. The milk cannot be re-screened. The Regulatory Agency involved (origin and receipt) shall be notified. Under this option, producer trace backs shall be conducted for the reject load.

NOTE: When a farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. is used for a milk plant's raw milk supply(ies) that has not been transported in bulk milk pickup tankers, is found to be positive (confirmed) for drug residues, the farm of origin for the drug residue has consequently already been determined and further testing is not required to determine the farm of origin.

3. **Re-Sampling:**

a. Presumptive Results: Occasionally, an error in sampling or a suspicious test result is discovered after a presumptive result is initially obtained. When this happens, the Regulatory Agency may allow the industry to re-sample the bulk milk pickup tanker and/or raw milk supply that has not been transported in bulk milk pickup tankers. The reasons that made the re-sampling necessary shall be clearly documented in testing records and reported to the Regulatory Agency. This written record shall be provided to the Regulatory Agency and shall be maintained with the record of the testing for that load and/or raw milk supply that has not been transported in bulk milk pickup tankers.

b. Screening Test Results: Re-sampling or additional analysis of screening test results should be discouraged. However, the Regulatory Agency may direct re-sampling and/or analysis, when it has determined that procedures for sampling and/or analysis did not adhere to accepted NCIMS practices (*SMEDP,* FDA 2400 Series Forms, Appendix N. and the applicable FDA interpretative or informational memoranda). This decision by the Regulatory Agency ~~must~~ shall be based on objective evidence. A Regulatory Agency allowing re-sampling ~~must~~ shall plan a timely follow-up to identify the problem and initiate corrective action to ensure the problem that led to the need for re-sampling is not repeated. If re-sampling and/or analysis is necessary, it shall include a review of the samplers, analysts, and/or laboratories to identify the problem(s) and initiate corrective action to ensure the problem(s) is not repeated. The reasons that made the re-sampling or analysis necessary shall be clearly documented in testing records maintained by the Regulatory Agency, and shall be maintained with the record of the testing for that load and/or raw milk supply that has not been transported in bulk milk pickup tankers.

4. **Producer Trace Back:** All screening test positive (confirmed) loads ~~must~~ shall be broken down (producer trace back) using the same or an equivalent test method (M-I-96-10, latest revision). Confirmation tests (load and producer trace back/permit action) shall be performed in an Official State Laboratory, or Officially Designated Laboratory or by a Certified Industry Supervisor. Positive producers shall be handled in accordance with this Appendix.

NOTE: When a farm bulk milk tank(s)/silos, milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. is used for a milk plant's raw milk supply(ies) that has not been transported in bulk milk pickup tankers, is found to be positive (confirmed) for drug residues, the farm of origin for the drug residue has consequently already been determined and further testing is not required to determine the farm of origin.

Assuring Representative Samples From Individual-Producer Loads And Multiple-Farm Tank Loads From An Individual Producer: Representative samples shall be secured from each farm storage tank(s)/silo(s) of milk prior to loading onto a bulk milk pickup tanker and/or other raw milk supply transportation method at the dairy farm. The representative sample(s) shall travel with the bulk milk pickup tanker and/or other raw milk supply transportation method to a designated location acceptable to the Regulatory Agency.

Record Requirements: Results of all testing may be recorded in any format acceptable to the Regulatory Agency that includes at least the following information:

Page 349:

1. Identity of the person doing the test;
2. Identity of the bulk milk pickup tanker or farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo, or other raw milk storage container(s), etc. used for the storage of raw milk supplies that have not been transported in bulk milk pickup tankers being tested*;
3. Date/time the test was performed (Time, Day, Month and Year);
4. Identity of the test performed/lot #/any and all controls (+/-);
5. Results of the test, if the analysis results are positive the record ~~should~~ shall show:
   a. The identity of each producer contributing to the positive load;
   b. Who at the Regulatory Agency was notified;
   c. When did this notification take place; and
   d. How was this notification accomplished.
6. Follow-up testing if initial test was positive/any and all controls (+/-);
7. Site where test was performed; and
8. Prior test documentation shall be provided for a presumptive positive load.

*Include the BTU number(s) of the dairy farms present on the bulk milk pickup tanker and/or all raw milk supplies that have not been transported in bulk milk pickup tankers with the above information.

SCREENING TESTS NECESSARY TO IMPLEMENT THE PROVISIONS OF APPENDIX N. FOR BULK MILK PICKUP TANKERS AND/OR ALL RAW MILK SUPPLIES THAT HAVE NOT BEEN TRANSPORTED IN BULK MILK PICKUP TANKERS:

1. **Performance Tests/Controls (+/-):**
   a. Each lot of kits purchased is tested by positive (+) and negative (-) controls.
   b. Each screening facility runs a positive (+) and negative (-) control performance test each testing day.
   c. All NCIMS Approved Bulk Milk Pickup Tanker and/or All Raw Milk Supplies that have Not been Transported in Bulk Milk Pickup Tankers Screening Tests Include ~~The~~ the Following Format: All presumptive positive test results are to be repeated in duplicate as soon as possible at the direction of the Regulatory Agency on the same sample with single positive (+) and negative (-) controls by a certified analyst (Official State Laboratory, Officially Designated Laboratory or Certified Industry Supervisor) using the same or

equivalent test (M-I-96-10, latest revision). If the duplicate tests are negative, with appropriate (+/-) control ~~(+/-)~~ results, ~~are negative (-),~~ the bulk milk pickup tanker and/or all raw milk supplies that have not been transported in raw milk bulk milk pickup tankers is reported as negative. If one (1) or both duplicate test(s) is positive (+), the test result is reported to the Regulatory Agency of the State in which the testing was conducted, as a screening test positive (confirmed).

d. All positive (+) controls used for drug residue testing kits are labeled to indicate a specific drug and concentration level for that drug.

(1) For tests that have been validated and only detect Penicillin, Ampicillin, Amoxicillin and Cephapirin, the positive (+) control is Pen G @ 5 ± 0.5 ppb.

(2) For test kits validated for the detection of Cloxacillin, the positive (+) control may be Cloxacillin @ 10 ± 1 ppb.

(3) For test kits validated for one (1) drug residue only, the positive (+) control is ± 10% of the safe level/tolerance of the drug residue detected.

2. **Work Area:**
   a. Temperature within specifications of the test kit manufacturer's labeling.
   b. Adequate lighting for conducting the test kit procedure.
3. **Test Kit Thermometers:**
   a. Thermometer traceable to a NIST Certified Thermometer.
   b. Graduation interval not greater than 1°C.
   c. Dial thermometers are not used to determine the temperatures of samples, reagents, refrigerators, or incubators in milk laboratories.

Page 350:

4. **Refrigeration:**
   a. Test kit reagent storage temperature specified by manufacturer.
5. **Balance (Electronic):**
   a. 0.01 g for preparation of positive (+) controls.
   b. Balance with appropriate sensitivity for calibration of pipetting devices within a tolerance of ± 5%. These devices may be calibrated at another location acceptable to the State LEO.
6. **Screening Test Sampling Requirements:**
   a. Temperature of milk in the bulk milk pickup tanker and/or all raw milk supplies that have not been transported in bulk milk pickup tankers determined and recorded.
   b. Representative bulk milk pickup tanker and/or all raw milk supplies that have not been transported in bulk milk pickup tankers sample for drug residue testing collected.
   c. Samples tested within seventy-two (72) hours of collection.
7. **Screening Test Volumetric Measuring Devices:**
   a. Single use devices provided by kit manufacturers are acceptable for Appendix N. screening analysts.
   b. NCIMS Certified Laboratories require calibrated pipetting/dispensing devices. These devices may be calibrated at another location acceptable to the State LEO.
   c. Measuring devices with tips bearing calibration lines provided by test kit manufacturers are acceptable for Appendix N. screening.

IV. ESTABLISHED TOLERANCES AND/OR SAFE LEVELS OF DRUG RESIDUES

"Safe levels" are used by FDA as guides for prosecutorial discretion. They do not legalize residues found in milk that are below the safe level. In short, FDA uses the "safe levels" as prosecutional guidelines and in full consistency with CNI v. Young stating, in direct and unequivocal language, that the "safe levels" are not binding. They do not dictate any result; they do not limit the Agency's discretion in any way; and they do not protect milk producers, or milk from court enforcement action.
"Safe levels" are not and cannot be transformed into tolerances that are established for animal drugs under Section 512 (b) of the *FFD&CA* as amended. "Safe levels" do not:

1. Bind the courts, the public, including milk producers, or the Agency, including individual FDA employees; and
2. Do not have the "force of law" of tolerances, or of binding rules.

Notification, changes or additions of "safe levels" ~~will~~ shall be transmitted via Memoranda of Information (M-I's).

V. APPROVED METHODS

Regulatory Agencies and industry shall use tests from the most recent revision of M-a-85 for analysis of bulk milk pickup tankers and/or all raw milk supplies that have not been transported in raw milk bulk milk pickup tankers for Beta lactam residues, following the testing procedures specified in Section III of this Appendix. Association of Official Analytical Chemists (AOAC) First Action and AOAC Final Action methods are accepted in accordance with Section 6 of this *Ordinance*. Drug residue detection methods shall be evaluated at the safe level or tolerance. Regulatory action based on each test kit method may be delayed until the evaluation is completed and the method is found to be acceptable to FDA and complies with the provisions of Section 6 of this *Ordinance*.

The following text is a mandatory part of this solution but will not be placed in an NCIMS document.

This Proposal also authorizes FDA to make appropriate editorial changes to the NCIMS documents as needed, in accordance with NCIMS *Procedures*, resulting from Proposals that are passed at the 2013 NCIMS Conference, and concurred with by FDA, related to appropriate wording cited in this Proposal addressing drug residue testing and other citations, i.e. will and must changed to shall, as cited throughout this Proposal.

Proposal: 210
Document: 2011 PMO (Section 6)
Page: 25

Make the following changes to ***SECTION 6. THE EXAMINATION OF MILK AND MILK PRODUCTS*** *on Page 25:*

Examinations and tests to detect adulterants, including pesticides, shall be conducted, as the Regulatory Agency requires. When the Commissioner of the FDA determines that a potential problem exists with animal drug residues or other contaminants in the milk supply, samples shall be analyzed for the contaminant by a method(s) determined by FDA to be effective in determining compliance with actionable levels or established tolerances. This testing will continue until such time that the Commissioner of the FDA is reasonably assured that the problem has been corrected. The determination of a potential problem is to be based on relevant scientific information. ~~The determination of a problem is to be based upon:~~

~~1. Sample survey results;~~
~~2. USDA tissue residue data from cull and veal dairy animals;~~
~~3. Animal drug disappearance and sales data;~~
~~4. State feed back; and~~
~~5. Other relevant information.~~

Proposal: 303
Document: 2011 PMO (Section 6; and Appendixes G and N
Pages: 25, 214-216, 346 and 348

Make the following changes to ***SECTION 6. THE EXAMIONATION OF MILK AND MILK PRODUCTS*** *on Page 25:*

LABORATORY TECHNIQUES: Procedures for the collection, including the use of approved in-line samplers and approved aseptic samplers for milk tank trucks or for farm bulk milk tanks and/or silos, and the holding of samples; the selection and preparation of apparatus, media and reagents; and the analytical procedures, incubation, reading and reporting of results, shall be in substantial compliance with the FDA/NCIMS 2400 ~~Series~~ Forms, *SMEDP* and *OMA*. The procedures shall be those specified therein for: …

Make the following changes to the ***APPENDIX G. CHEMICAL AND BACTERIOLOGICAL TESTS*** *on Pages 214-216****:***

Page 214:

I. PRIVATE WATER SUPPLIES AND RECIRCULATED WATER – BACTERIOLOGICAL …

Apparatus, Methods and Procedure: Tests performed shall conform with the current edition of *SMEWW* or with FDA approved, EPA promulgated methods for the examination of water and waste water or the applicable FDA/NCIMS 2400 ~~Series~~ Forms….

II. PASTEURIZATION EFFICIENCY – FIELD PHOSPHATASE TEST …

Page 215:

Procedure: Refer to the applicable FDA/NCIMS 2400 ~~Series~~ Forms for details on phosphatase tests.

Page 216:

V. DETECTION OF DRUG RESIDUES IN MILK …

The allergenic properties of certain drugs in common use make their presence in milk potentially hazardous to consumers. Also, substantial losses of byproducts may be sustained by the milk industry each year because of the inhibitory effects of drug residues on the culturing process. Drug residues shall be tested for, using tests provided for in Section 6 of this *Ordinance*. These tests are specified in memoranda from the FDA. (Refer to the latest edition of M-a-85 and the FDA/NCIMS 2400 ~~Series~~ Forms for each specific test method.)

*Make the following changes to the **APPENDIX N. DRUG RESIDUE TESTING AND FARM SURVEILANCE** on Pages 346 and 348:*

Page 346:

CERTIFIED INDUSTRY SUPERVISORS; EVALUATION AND RECORDS: …

1. **Certified Industry Supervisors/Industry Supervisors/Industry Analysts:** Regulatory Agencies may choose to allow Industry Supervisors to be certified. Under this program, these Certified Industry Supervisors may officially confirm presumptive positive tanker loads and confirm producer milk for regulatory purposes (producer trace back/permit action). In the implementation of Appendix N. of this *Ordinance,* the LEO will use the appropriate Appendix N. FDA/NCIMS 2400 ~~Series~~ Form when evaluating Official State Laboratories, Officially Designated Laboratories or Certified Industry Supervisors, Industry Supervisors and Industry Analysts. …

BULK MILK PICKUP TANKER SCREENING TEST: …

Page 348:

b. Screening Test Results: Re-sampling or additional analysis of screening test results should be discouraged. However, the Regulatory Agency may direct re-sampling and/or analysis, when it has determined that procedures for sampling and/or analysis did not adhere to accepted NCIMS practices (*SMEDP,* FDA/NCIMS 2400 ~~Series~~ Forms, Appendix N. and the applicable FDA interpretative or informational memoranda).

Document: 2011 PROCEDURES (Sections IV and VI; and Related Documents)
Pages: 8, 27 and 68

*Make the following changes to **SECTION IV. OVERSIGHT AND RESPONSIBILITIES** on Page 8:*

4. Laboratory Evaluations

a. PHS/FDA shall evaluate and approve the laboratory facilities and procedures of State Laboratory Approval Agencies to assure compliance with FDA/NCIMS 2400 ~~Series Evaluation~~ Forms and, where appropriate, the current edition of *Official Methods of Analysis of AOAC INTERNATIONAL (OMA)*.

b. PHS/FDA shall periodically evaluate milk laboratories of participating States to assure compliance with FDA/NCIMS 2400 ~~Series Evaluation~~ Forms, and where appropriate, the current edition of *OMA*. …

Make the following changes to ***SECTION VI. STANDARDS*** *on Page 27:*

I. **LABORATORY PROCEDURES**

Laboratory procedures used to examine milk and milk products of interstate milk shippers shall conform to the procedures in the current revisions of the ~~NCIMS/FDA~~ FDA/NCIMS 2400 ~~Series~~ Forms and the *OMA,* using only methods approved by the NCIMS. …

Make the following changes to ***RELATED DOCUMENTS*** *on Page 68:*

FDA/NCIMS 2400 ~~Series Evaluation~~ Forms, USPHS/FDA, U.S. Department of Health and Human Services, ~~Summit-Argo~~ Bedford Park, Illinois 60501, Current Edition.

Document: 2011 EML (Introduction; Sections 1, 3 and 5; References; and Example Report #1 and Example Report #2)
Pages: 1, 3, 4, 5, 6, 8, 16, 21, 23, 26, 30, and 33

Make the following changes to the ***INTRODUCTION*** *on Page 1:*

The State Laboratory Evaluation Officer (State LEO) will use the appropriate ~~FDA~~ FDA/NCIMS 2400 ~~Series~~ Forms when evaluating official laboratories, officially designated laboratories, CIS, IS and IA. The Federal Laboratory Evaluation Officer (Federal LEO) will use the appropriate ~~FDA~~ FDA/NCIMS 2400 ~~Series~~ Forms when evaluating State Central Milk Laboratories and State LEOs. Appropriate ~~FDA~~ FDA/NCIMS 2400 ~~Series~~ Forms are those forms that have been approved by the NCIMS Laboratory Committee working cooperatively with the Food and Drug Administration (FDA) and the NCIMS Executive Board, and are effective ~~90~~ ninety (90) days after executive board approval. Approved forms shall be issued within ~~90~~ ninety (90) days of NCIMS Executive Board approval. If the FDA is unable to release the approved forms within the ~~90~~ ninety (90) day time frame, FDA/LPET shall issue a draft version of the FDA/NCIMS 2400 ~~Series~~ forms ~~90~~ ninety (90) days after NCIMS Executive Board approval.

Make the following changes to ***SECTION 1: LABORATORY EVALUATION PROGRAM*** *on Pages 3, 4, 5, 6 and 8:*

Page 3:

… The evaluation shall be made using the most recent approved Official Milk Laboratory Evaluation Forms (~~FDA~~ FDA/NCIMS 2400 ~~Series~~ Forms). The Federal or State LEO shall determine if the laboratory facilities, equipment, records and techniques of analysts are in compliance with the ~~FDA~~ FDA/NCIMS 2400 ~~Series~~ Forms. …

… The narrative report must be sufficiently detailed to allow readers to determine what is being cited without having to refer to the ~~FDA~~ FDA/NCIMS 2400 ~~Series~~ Forms. …

… Reports to the Official Milk Laboratories/CIS must include the narrative report and may include copies of the completed ~~FDA~~ FDA/NCIMS 2400 ~~Series~~ Forms. …

Page 4:

3. The laboratory facilities, equipment and records shall meet the requirements stated on the ~~FDA~~ FDA/NCIMS 2400 ~~Series~~ Forms, as determined by an on-site evaluation. …

4. Analyst performance is in compliance during an on-site evaluation, with procedures required by the ~~FDA~~ FDA/NCIMS 2400 ~~Series~~ Forms and the PMO.

Page 5:

1. The laboratory facilities, equipment, procedures and records must meet the requirements stated on the appropriate ~~FDA~~ FDA/NCIMS 2400 ~~Series~~ Forms and for CIS, appropriate Appendix N FDA/NCIMS 2400 ~~Series~~ Forms, as determined by an on-site evaluation.

Page 6:

1. The laboratory facilities, equipment, procedures and records must meet the requirements stated on the appropriate FDA/NCIMS 2400 ~~Series~~ Forms associated with the Appendix N program.

3. Analyst performance is in compliance with procedures required by the approved ~~FDA~~ FDA/NCIMS 2400 ~~Series~~ Forms associated with the Appendix N program.

Page 8:

2. The laboratory must maintain one certified BactoScan analyst (see current FDA/NCIMS 2400 ~~series form~~ Form) for training and ongoing oversight of the BIO.

3. Refer to the BIO approved training procedures at the end of the BactoScan FDA/NCIMS 2400 ~~series form~~ Form.

Make the following changes to ***SECTION 3: CERTIFICATION OF LABORATORY EVALUATION OFFICERS*** *on Page 16:*

Initial certification of a State LEO shall be based on meeting the following critiera:

1. The individual must be a State government employee and demonstrate competence in evaluating milk testing laboratories and analysts' performance of milk laboratory test methods or Appendix N procedures as stated on the ~~FDA~~ FDA/NCIMS 2400 ~~Series~~ Forms when accompanied by a representative of the FDA/ LPET on an initial check laboratory survey. …

Recertification of the State LEO will occur triennially, and will be based in satisfacorily meeting the following criteria:

1. The individual must be a State government employee and demonstrate continued competence in evaluating milk testing laboratories and analysts' performance of milk laboratory test methods or Appendix N procedures as stated on the ~~FDA~~ FDA/NCIMS 2400 ~~Series~~ Forms when accompanied by a representative of the FDA/LPET on a check laboratory survey.

*Make the following changes to **SECTION 5: GUIDE FOR CONDUCTING LABORATORY EVALUATIONS** on Page 21:*

1. Do the samples arrive at the laboratory as specified in the appropriate ~~FDA~~ FDA/NCIMS 2400 ~~Series~~ Forms?

*Make the following changes to **SECTION 6: LABORATORY EVALUATION REPORTS** on Page 23:*

~~FDA~~ FDA/NCIMS 2400 ~~Series~~ Forms shall be completely identified with the name of the laboratory, the laboratory number, its location, date and the name of the individual making the evaluation when the option to send them with the narrative report is used. …

… If the completed evaluation forms do not accompany the narrative report, the report must be sufficiently detailed to allow readers to determine what is being cited without having to refer to the ~~FDA~~ FDA/NCIMS 2400 ~~Series~~ Forms. Each form used shall have the revision date noted. Additional narrative reports, without ~~FDA~~ FDA/NCIMS 2400 ~~Series~~ Forms, are to be sent to others that need to be informed as to the outcome of the laboratory survey.

*Make the following change to **REFERENCE** on Pages 26:*

1. Copies of the ~~FDA~~ FDA/NCIMS 2400 ~~Series~~ Forms can be obtained from Federal or State LEO(s).

*Make the following change to the **EXAMPLE REPORT #1** on Page 30:*

… These are usually considered to be good laboratory practices but are not listed in the ~~FDA~~ FDA/NCIMS 2400 ~~Series~~ Forms and are not debitable items.

*Make the following change to the **EXAMPLE REPORT #2** on Page 33:*

… These are usually considered to be good laboratory practices but are not listed in the ~~FDA~~ FDA/NCIMS 2400 ~~Series~~ Forms and are not debitable items.

Proposal: 211
Document: 2011 PMO (Section 7-Table 1; and Appendixes B, C, H and O)
Pages: 29, 132, 133, 136, 151, 219 and 356

Make the following changes to ***SECTION 7. STANDARDS FOR GRADE "A" MILK AND MILK PRODUCTS*** *on Page 29:*

TABLE 1. CHEMICAL, PHYSICAL, BACTERIOLOGICALAND TEMPERATURE STANDARDS

GRADE "A" RAW MILK AND MILK PRODUCTS FOR PASTEURIZATION, ULTRA- PASTEURIZATION OR ASEPTIC PROCESSING AND PACKAGING

Temperature....

NOTE: Milk sample submitted for testing cooled and maintained at 0ºC (32ºF) to ~~4.4~~ 4.5ºC (40ºF), where sample temperature is >~~4.4~~ 4.5ºC (40ºF), but ≤7.0ºC (45°F) and less than three (3) hours after collection has not increased in temperature.

GRADE "A" PASTEURIZED MILK AND MILK PRODUCTS

Temperature…

NOTE: Milk sample submitted for testing cooled and maintained at 0ºC (32ºF) to ~~4.4~~ 4.5ºC (40ºF), where sample temperature is >~~4.4~~ 4.5ºC (40ºF), but ≤7.0ºC (45ºF) and less than three (3) hours after collection has not increased in temperature.

Make the following changes to ***APPENDIX B. MILK SAMPLING, HAULING AND TRANSPORTATION*** *on Pages 132, 133 and 136:*

EVALUATION OF BULK MILK HAULER/SAMPLER PROCEDURES: …

Page 132:

2. **Equipment Requirements:**
a. Sample rack and compartment to hold all samples collected.
b. Refrigerant to hold temperature of milk samples between 0ºC- ~~4.4~~ 4.5ºC (32ºF- 40°F). …

Page 133:

7. **Sampling Responsibilities:**

a. All sample containers and single-service sampling tubes used for sampling shall comply with all the requirements that are in the current edition of *SMEDP*. Samples shall be cooled to and held between 0°C (32°F) and ~~4.4~~ 4.5°C (40°F) during transit to the laboratory. …

V. TANK TRUCK PERMITTING AND INSPECTION

Page 136:

MILK TANK AND TRUCK STANDARDS: …

1. **Samples and Sampling Equipment:** (When provided) …

g. Samples are maintained at an acceptable temperature 0ºC-~~4.4~~ 4.5ºC (32ºF-40ºF) and a temperature control sample is provided.

Make the following change to ***APPENDIX C. DAIRY FARM CONSTRUCTION STANDARDS AND MILK PRODUCTION*** *on Page 151:*

IV. GUIDELINES FOR CONVENTIONAL STALL BARN WITH GUTTER GRATES OVER LIQUID MANURE STORAGE …

For Example: …

Use two (2) fans of 3,264 each and two (2) fans of 4,896 cfm each to make up the total. Build two (2) fan houses. Mount one 3,264 cfm and one 4,896 cfm fan in each. Operate one 3,264 cfm fan continuously. Thermostatically control the second 3,264 cfm fan at ~~4.4~~ 4.5ºC (40°F). …

Make the following change to ***APPENDIX H. PASTEURIZATION EQUIPMENT AND PROCEDURES AND OTHER EQUIPMENT*** *on Page 219:*

I. HTST PASTEURIZATION

OPERATION OF HTST PASTEURIZATION SYSTEMS

9. The warm milk or milk product passes through the cooling section, where coolant, on the sides of thin stainless steel surfaces opposite the pasteurized milk or milk product, reduces its temperature to ~~4.4~~ 4.5°C (40°F) and below.

Make the following change to ***APPENDIX O. VITAMIN FORTIFICATION OF FLUID MILK PRODUCTS*** *on Page 356:*

PROBLEMS INVOLVED WITH FORTIFICATION…

Vitamin A and D fortified skim milk products are subject to decreases in vitamin A, because the vitamin is no longer protected by fat as it is in whole milk. In fluid skim or low fat milk, added vitamin A deteriorates gradually during normal storage of the milk at ~~4.4~~ 4.5°C (40°F)

in the dark but is destroyed rapidly when the milk is exposed to sunlight in transparent glass bottles or translucent plastic containers.

Document: Various FDA 2400 Forms

And several 2400 series forms that refer to sample storage temperature or refrigerator temperature as 0.0 - 4.4°C.

Proposal: 105
Document: 2011 PMO (Section 7-Items 9r and 11p)
Pages: 45 and 67

*Make the following changes to the **SECTION 7, ITEM 9r-UTENSILS AND EQUIPMENT – CONSTRUCTION** on Page 45:*

NOTE: 3-A Sanitary Standards and Accepted Practices for dairy equipment are ~~promulgated jointly by the Sanitary Standards Subcommittee of the Dairy Industry Committee, the Committee on Sanitary Procedure of the International Association for Food Protection and the Milk Safety Team, Center for Food Safety and Applied Nutrition, Food and Drug Administration, Public Health Service, Department of Health and Human Services.~~ developed by 3-A Sanitary Standards, Inc. (3-A SSI). 3-A SSI is comprised of equipment fabricators, processors, and regulatory sanitarians, which include State milk regulatory officials, USDA, Agricultural Marketing Service, Dairy Programs, the PHS/FDA, Center for Food Safety and Applied Nutrition, Milk Safety Team, academic representatives and others.

Equipment manufactured in conformity with 3-A Sanitary Standards and Accepted Practices complies with the sanitary design and construction standards of this *Ordinance*. For equipment not displaying the 3-A Symbol, the 3-A Sanitary Standards and Accepted Practices may be used by Regulatory Agencies as guidance in determining compliance with this Section.

*Make the following changes to the **SECTION 7, ITEM 11p-CONSTRUCTION AND REPAIR OF CONTAINERS AND EQUIPMENT** on Page 67:*

NOTE: 3-A Sanitary Standards and Accepted Practices for dairy equipment are ~~promulgated jointly by the Sanitary Standards Subcommittee of the Dairy Industry Committee, the Committee on Sanitary Procedure of the International Association for Food Protection and the Milk Safety Team, Center for Food Safety and Applied Nutrition, Food and Drug Administration, Public Health Service, Department of Health and Human Services.~~ developed by 3-A Sanitary Standards, Inc. (3-A SSI). 3-A SSI is comprised of equipment fabricators, processors, and regulatory sanitarians, which include State milk regulatory officials, USDA, Agricultural Marketing Service, Dairy Programs, the PHS/FDA, Center for Food Safety and Applied Nutrition, Milk Safety Team, academic representatives and others.

Equipment manufactured in conformity with 3-A Sanitary Standards and Accepted Practices complies with the sanitary design and construction standards of this *Ordinance*. For equipment

not displaying the 3-A Symbol, the 3-A Sanitary Standards and Accepted Practices may be used by Regulatory Agencies as guidance in determining compliance with this Section.

Proposal: 106
Document: 2011 PMO (Section 7-Items 14r and 15p(B); and Appendix Q)
Pages: 49, 77, 78, 360 and 361

Make the following changes to the ***SECTION 7, ITEM 14r-PROTECTION FROM CONTAMINATION*** *on Page 49:*

Milking and milkhouse operations, equipment and facilities shall be located and conducted to prevent any contamination of milk, containers, utensils and equipment. ~~No milk~~ Milk shall not be strained, poured, transferred or stored unless it is properly protected from contamination.
After sanitization, all containers, utensils and equipment shall be handled in such a manner as to prevent the contamination of any milk product-contact surface.
Vehicles used to transport milk from the dairy farm to the milk plant, receiving station or transfer station shall be constructed and operated to protect their contents from sun, freezing and contamination. Such vehicles shall be kept clean, inside and out, and ~~no~~ any substance capable of contaminating the milk shall not be transported with the milk.

PUBLIC HEALTH REASON

Because of the nature of milk and its susceptibility to contamination by disease producing bacteria and other contaminants, every effort ~~should~~ shall be made to provide adequate protection for the milk at all times. This ~~should~~ shall include the proper placement of equipment so that work areas in the milking barn and milkhouse are not overcrowded. The quality of any air that is used for the agitation or movement of milk or is directed at a milk product-contact surface ~~should~~ shall be such that it will not contaminate the milk.
The effect of sanitization of equipment can be nullified if the equipment is not protected after sanitizing.
To protect milk during transportation, delivery vehicles ~~must~~ shall be properly constructed and operated.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when: …

2. During ~~processing~~ milking and milkhouse operations, pipelines and equipment, used to contain or conduct milk ~~and milk products~~, shall be effectively separated from tanks/silos and/or circuits containing cleaning and/or sanitizing solutions. This can be accomplished by:
   a. Physically disconnecting all connection points between tanks/silos and/or circuits containing cleaning and/or sanitizing solutions from pipelines and equipment used to contain or conduct milk; or
   b. Separation of all connection points between such circuits by at least two (2) automatically controlled valves with a drainable opening to the atmosphere between the

valves; or by a single-bodied double seat mixproof valve, with a drainable opening to the atmosphere between the seats, if:

(1) The drainable opening to the atmosphere (vent) is equal to the largest pipeline connected to the mixproof valve or the following exception:

If the cross sectional area of the vent opening is less than that of the largest pipe diameter for the double seat valve, the maximum pressure in the space between the two (2) valve seats for the double seat valve shall be equivalent to or less than the maximum pressure in the space between two (2) blocking seats of two (2) automatically controlled compression type valves (three (3)-way valve to the drain and a two (2)-way valve separating product lines from cleaning and sanitizing solution lines.)

(2) Both valves, and valve seats in the case of single-bodied double seat valves, are position detectable and capable of providing an electronic signal when not properly seated in the blocked position. (Refer to Appendix H., I., Position Detection Devices.)

(3) The valve vent, including piping between blocking valves, is not cleaned until milk has been removed or isolated, except in the case of a properly designed and operated system. This drainable opening to the atmosphere may be cleaned while milk is isolated by one (1) of the blocking valves. A properly designed and operated system shall incorporate the following:

i) During CIP, a valve actuation of the cleaning/sanitizing solution blocking valve may be used for cleaning the valve vent, including piping between blocking valves, provided there shall not be pressurization of cleaning solutions on the exterior of the valve isolating milk that can equal or exceed the pressure of the milk being isolated, and

ii) During CIP with a valve actuation for cleaning the valve vent, including piping between blocking valves, the position detection of the valve isolating milk from the valve vent, including piping between blocking valves, and the position detection of the vent open to the atmosphere, shall be monitored and interlocked with the pump or source of liquid pressure, such that if it is determined they are not properly positioned, the pump or source of liquid pressure will be immediately de-energized.

(4) These valves, or valve seats in the case of single-bodied double seat valves, are part of an automatic fail-safe system that shall prevent the contamination of milk with cleaning and/or sanitizing solutions. Automatic fail-safe systems shall be unique to each particular installation but are normally based on the premise that both blocking valve seats are properly seated in the blocked position before the CIP cleaning system can be activated for the cleaning circuit containing this valve arrangement, except as provided in (**7**) below.

(5) The system shall not have manual override capability, except for testing and inspection.

(6) Controls for the fail-safe system are tested and secured as directed by the Regulatory Agency in order to prevent unauthorized changes.

(7) The vent, including piping between blocking valves, is not cleaned until milk has been removed or isolated, except in the case of a properly designed and operated single-bodied double seat valve, in which case, the vent, including piping between blocking valves, may be cleaned while milk is present in one (1) of the valve housings. A properly designed and operated single-bodied double-seat valve shall incorporate the

following:

i) There shall not be any impingement of cleaning liquid on the opposite valve seat gasket during seat lifting, even in the case of damaged or missing gaskets; and

ii) The pressure in the critical seat area of the valve vent cavity, even in the case of damaged or missing gaskets, shall be demonstrated to be atmospheric or less at all times; and

iii) During a seat-lift operation, the position of the seat opposite to the seat being lifted shall be monitored by a position detection device that is interlocked with the cleaning pump or source of the CIP cleaning solution pressure such that if this opposite seat is determined to be other than fully closed, the cleaning pump or source of the CIP cleaning solution pressure shall be immediately de-energized; and

iv) The single-bodied double seat valve vent cavity cleaning option shall have an Automated Fail-Safe Control System and the Control System shall comply with applicable provisions of Appendix H. Pasteurization Equipment and Procedures, Section VI. Criteria for the Evaluation of Computerized Systems for Grade "A" Public Health Controls.

(8) Variations from the above specifications may be individually evaluated and found to also be acceptable if the level of protection is not compromised. …

Make the following changes to ***SECTION 7, ITEM 15p-PROTECTION FROM CONTAMINATION*** *on Pages 77 and 78:*

Page 77:

15p.(B)

1. During processing, pipelines and equipment used to contain or conduct milk and/or milk products shall be effectively separated from tanks/silos and/or circuits containing cleaning and/or sanitizing solutions. This can be accomplished by:

a. Physically disconnecting all connection points between tanks/silos and/or circuits containing cleaning and/or sanitizing solutions from pipelines and equipment used to contain or conduct milk and/or milk products; or

b. Separation of all connection points … between the seats, if:

(1) The drainable opening to the atmosphere (vent) is equal to the largest pipeline connected to the mixproof valve or one (1) of the following exceptions:

i) If the cross sectional area of the vent opening is less than that of the largest pipe diameter for the double seat valve, the maximum pressure in the space between the two (2) valve seats for the double seat valve shall be equivalent to or less than the maximum pressure in the space between the two (2) blocking seats of two (2) automatically controlled compression type valves (three (3)-way valve to the drain and a two (2)-way valve separating product lines from cleaning and/or sanitizing solution lines); or

ii) In low pressure, gravity drain applications, i.e., cheese curd transfer lines from cheese process vats where the product line is the same size or larger than the cleaning and/or sanitizing solution line, the vent may be the size of the solution line and the valves or valve seats ~~need~~ are not required to be position detectable. In

order to accept this variation, the valve(s) ~~must~~ shall fail to the blocked position upon loss of air or power, and there shall not be any pumps capable of pushing milk and/or milk product, cleaning solutions, and/or sanitizing solutions into this valve arrangement. …

Page 78:

(3) These valves, or valve seats in the case of single-bodied double seat valves, are part of an automatic fail-safe system that ~~will~~ shall prevent the contamination of milk and/or milk product with cleaning and/or sanitizing solutions. Automatic fail-safe systems ~~will~~ shall be unique to each particular installation but are normally based on the premise that both blocking valve seats are properly seated in the blocked position before the CIP cleaning system can be activated for the cleaning circuit containing this valve arrangement, except as provided in (6) below. …

(6) The vent is not cleaned until milk and/or milk products have been removed or isolated, except in the case of a properly designed and operated single-bodied double seat valve, in which case, the vent may be cleaned while milk and/or milk products are present in one (1) of the valve housings. A properly designed and operated single-bodied double-seat valve ~~will~~ shall incorporate the following:

i) There shall not be any impingement of cleaning liquid on the opposite valve seat gasket during seat lifting, even in the case of damaged or missing gaskets; ~~and~~

ii) The pressure in the critical seat area of the valve vent cavity, even in the case of damaged or missing gaskets, shall be demonstrated to be atmospheric or less at all times; ~~and~~

iii) During a seat-lift operation, the position of the seat opposite to the seat being lifted shall be monitored by a ~~proximity switch~~ position detection device that is interlocked with the cleaning pump or source of the CIP cleaning solution pressure such that if this opposite seat is determined to be other than fully closed, the cleaning pump or source of the CIP cleaning solution pressure ~~will~~ shall be immediately de-energized; and …

Make the following changes to ***APPENDIX Q. OPERATION OF AUTOMATIC MILKING INSTALLATIONS FOR THE PRODUCTION OF GRADE "A" RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION OR ASEPTIC PROCESSING AND PACKAGING*** *on Pages 360 and 361:*

Page 360:

This Appendix is intended to clarify how AMIs are to be constructed, installed, perform, monitored, maintained, etc. to be considered in compliance with the *Grade "A" PMO*. It is formatted to follow the Items as outlined in Section 7. STANDARDS FOR GRADE "A" RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION OR ASEPTIC PROCESSING AND PACKAGING. Both requirements and recommendations are ~~discussed~~ provided.

ITEM 1r. ABNORMAL MILK

AMIs shall have the capability to identify and discard milk from animals that are producing milk with abnormalities. Odor is currently evaluated on a farm bulk milk tank/silos basis and ~~should be no~~ shall not be any different for a herd using AMI technology.
Animals producing milk with abnormalities shall be diverted to a holding pen to be milked immediately prior to the milking system being cleaned and sanitized, …

ITEM 2r. MILKING BARN, STABLE OR PARLOR - CONSTRUCTION

The AMI milker box shall be treated the same as any other milking parlor. The goal is a clean environment in which to milk animals. All ventilation air ~~must~~ shall come from outside the cattle housing area. ~~It is recommended that the~~ The AMI should be located to provide a clean access for all personnel.

ITEM 9r. UTENSILS AND EQUIPMENT - CONSTRUCTION

AMIs are the same as any other milking system from a sanitary construction and installation standpoint and shall meet the same standards as a conventional milking system in respect to construction, installation, inspectability, the fit and finish of the milk product-contact surfaces, etc. …

Page 361:

ITEM 12r. UTENSILS AND EQUIPMENT – STORAGE

AMIs shall have positive air ventilation systems in operation whenever the milking system is ~~cleaning~~ being cleaned and/or sanitized. The air for this ventilation system ~~must~~ shall come from outside the cattle housing area and ~~should~~ shall be as clean and dry as practical. This positive air ventilation system ~~may~~ shall also ~~need to~~ run during milking if needed to minimize ~~odor~~ odors, moisture and/or for pest control.

ITEM 13r. MILKING - FLANKS, UDDERS AND TEATS

AMI manufacturers shall submit data to FDA to show that the teat prepping system employed in their milking system is equivalent to Item 13r., **ADMINISTRATIVE PROCEDURES** #4: "Teats shall be treated with a sanitizing solution just prior to the time of milking and shall be dry before milking." Each AMI installer shall provide the dairy producer and the Regulatory Agency with a copy of this ~~approval~~ FDA acceptance, including a detailed description of the ~~approved~~ accepted equivalent procedure. Each dairy producer shall keep a copy ~~on file~~ of the accepted teat prep protocol along with the appropriate AMI manufacturer's teat prep protocol verification procedures on file at the dairy farm.

ITEM 14r. PROTECTION FROM CONTAMINATION

The teat cups (inflations) of the milking cluster ~~need to~~ shall be adequately shielded, or variations may be individually evaluated and found to also be acceptable by FDA and the Regulatory Agency, during the ~~udder~~ teat prepping process to assure that contaminants ~~may~~ shall not enter through the teat ~~cup~~ cups and get into the milk.
AMIs are designed to automatically shift from ~~milk to wash~~ milking to cleaning/sanitizing positions; therefore, adequate separation of milk and CIP solution shall be provided to minimize the risk of cross contamination of milk with cleaning and/or sanitizing solutions. A fail-safe valve system providing protection equivalent to an inter-wired block-and-bleed valve arrangement, as referenced in Item ~~15p,(B)~~ 14r, shall be located as needed to prevent cross contamination. Separation shall be provided between~~,~~ milk with abnormalities and milk intended for sale, and between cleaning/sanitizing solutions and milk intended for sale.
Each dairy producer shall keep a copy of the AMI manufacturer's testing verification procedures for the fail-safe valve systems on file at the dairy farm.
AMIs, which have a ~~pipe~~ wash line extending into the wash vat that is continuously connected to the milking system, shall have a valving ~~system~~ arrangement that provides for an air break equal to the diameter of the wash line.

ITEM 18r. RAW MILK COOLING

For AMIs, the raw milk for pasteurization shall be cooled to 10ºC (50ºF) within four (4) hours or less after starting the milking operation and the milk shall be cooled within two (2) more hours to 7ºC (45ºF). The milk in the farm bulk milk ~~storage~~ tank/silos ~~temperature should~~ shall not exceed 7ºC (45ºF) after that ~~point~~ time. ~~Bulk~~ Farm bulk milk tank/silos recording thermometers are recommended if not already required by this *Ordinance*.

Proposal: 107
Document: 2011 PMO (Section 7-Item 15r)
Pages: 50 and 51

Make the following changes to ***SECTION 7, ITEM 15r-DRUG AND CHEMICAL CONTROL*** *on Pages 50 and 51:*

Page 50:

Cleaners and sanitizers shall be stored in properly identified, dedicated end-use containers.
Animal drugs and drug administration equipment shall be stored in such a way that milk, milking equipment, wash vats and hand sinks are not subject to contamination.
Animal drugs shall be properly labeled and segregated, lactating from non-lactating. Unapproved drugs shall not be used.

For the purpose of this Item, drugs intended for use in dry dairy animals shall be stored with the "Non-lactating Drugs". Therefore, drugs intended for use in dairy calves, dairy heifers, dairy bulls and dry dairy cows shall be segregated from drugs for cows that are currently being

milked. This required storage system shall also be followed for drugs intended for use in goats, sheep and other dairy animals.
The only drugs that shall be stored with the "Lactating Drugs" are drugs that are specifically indicated on the drug label or on a veterinarian's label for extra-label drug use to be used in a specific class/species of lactating dairy animals. For the purpose of complying with this Item "lactating dairy animals" shall mean those dairy animals that are currently producing milk. …

ADMININSTRATIVE PROCEDURES-

This Item is deemed to be satisfied when: …

Page 51:

3. Drugs intended for the treatment of non-lactating dairy animals are segregated from those drugs used for lactating dairy animals. Separate shelves in cabinets, refrigerators or other storage facilities satisfy this Item. …

Proposal: 108
Document: 2011 PMO (Section 7-Items 16r and 17r; and Appendixes B and J)
Pages: 51, 52, 132 and 321

*Make the following changes to **SECTION 7, ITEM 16r-PERSONNEL - HANDWASHING FACILITIES** on Pages 51 and 52:*

Page 51:

Adequate handwashing facilities shall be provided, including a lavatory fixture with hot and cold, or warm running water, soap or detergent and individual sanitary towels or other approved hand-drying devices, convenient to the milkhouse, milking barn, stable, parlor and flush toilet.…

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when: …

Page 52:

2. Handwashing facilities include soap or detergent, hot and cold, or warm running water, individual sanitary towels or other approved hand-drying devices and a lavatory fixture. Utensil wash and rinse vats shall not be considered as handwashing facilities. …

*Make the following changes to **SECTION 7, ITEM 17r-PERSONNEL - CLEANLINESS** on Page 52:*

Hands shall be washed clean and dried with an individual sanitary towel or other approved hand-drying device immediately before milking, before performing any milkhouse function and immediately after the interruption of any of these activities. Milkers and bulk milk hauler/samplers shall wear clean outer garments while milking or handling milk, milk containers, utensils, or equipment….

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. Hands are washed, clean and dried with an individual sanitary towel or other approved hand-drying device immediately before milking; before performing any milkhouse function; and immediately after the interruption of any of these activities. …

Make the following changes to ***APPENDIX B. MILK SAMPLING, HAULING AND TRANSPORTATION*** *on Page 132:*

2. **Equipment Requirements:** …

   i. Single service sanitary towels shall be provided for bulk tanks with a measuring rod.

3. **Milk Quality Checks:** …

   b. Wash hands thoroughly and dry with a clean ~~single-service~~ individual sanitary towel or ~~acceptable air dryer~~ other approved hand-drying device immediately prior to measuring and/or sampling the milk. …

4. **Milk Measurements:** …

   b. Carefully insert the measuring rod, after it has been wiped dry with a ~~single-service~~ clean individual sanitary towel, into the tank. Repeat this procedure until two (2) identical measurements are taken. Record measurements on the farm weight ticket. …

Make the following changes to ***APPENDIX J. STANDARDS FOR THE FABRICATION OF SINGLE-SERVICE CONTAINERS AND CLOSURES FOR MILK AND MILK PRODUCTS*** *on Page 321:*

8. HANDWASHING FACILITIES

a. Hot and cold and/or warm running water, soap, ~~air dryers or~~ individual sanitary towels or other approved hand-drying devices shall be convenient to all fabricating areas. Provided, that solvent or soft soap dispensers, containing sanitizers, may be used if water is not available. When individual sanitary towels are used, covered trash containers shall be provided.

Proposal: 109
Document: 2011 PMO (Section 7-Items 18r and 17p)
Pages: 53 and 109

Make the following changes to ***SECTION 7, ITEM 18r-RAW MILK COOLING*** *on Page 53:*

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when: …

2. Recirculated cooling water, which is used in plate or tubular coolers and/or heat exchangers, including those systems in which a freezing point depressant is used, is from a safe source and protected from contamination. Such water shall be tested semiannually and shall comply with the Bacteriological Standards of Appendix G. Samples shall be taken under the direction of the Regulatory Agency and examination shall be conducted in a laboratory acceptable to the Regulatory Agency. Recirculated cooling water systems, which become contaminated through repair work or otherwise, shall be properly treated and tested before being returned to use. Freezing point depressants and other chemical additives, when used in recirculating systems, shall be non-toxic under conditions of use. Propylene glycol and all additives shall be either U.S. Pharmacopeia (USP) Grade, Food Grade or GRAS. To determine if recirculated cooling water samples have been taken at the frequency established in this Item, the interval shall include the designated six (6) month period plus the remaining days of the month in which the sample is due.

Make the following changes to ***SECTION 7, ITEM 17p*****-COOLING OF MILK AND MILK PRODUCTS** *on Page 109:*

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when: …

11. Recirculated cooling water, which is used in plate or tubular coolers and/or heat exchangers, including those systems in which a freezing point depressant is used, is from a safe source and protected from contamination. Such water shall be tested semiannually and shall comply with the Bacteriological Standards of Appendix G. Samples shall be taken by the Regulatory Agency and examination shall be conducted in an Official Laboratory. Recirculated cooling water systems, which become contaminated through repair work or otherwise, shall be properly treated and tested before being returned to use. Freezing point depressants and other chemical additives, when used in recirculating systems, shall be non-toxic under conditions of use**.** Propylene glycol and all additives shall be either U.S. Pharmacopeia (USP) Grade, Food Grade or GRAS. To determine if recirculated cooling water samples have been taken at the frequency established in this Item, the interval shall include the designated six (6) month period plus the remaining days of the month in which the sample is due.

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Proposal: 104
Document: 2011 PMO (Section 7-Item 7p)
Pages: 61 and 62

*Make the following changes to **SECTION 7, ITEM 7p-WATER SUPPLY** on Pages 61 and 62:*

ADMINISTRATIVE PROCEDURES[8]

This Item is deemed to be satisfied when:

Page 61:

4. All containers and tanks used in the transportation of water are sealed and protected from possible contamination. These containers and tanks shall be subjected to a thorough cleaning and a bacteriological treatment prior to filling with potable water to be used at the milk plant. To minimize the possibility of contamination of the water during its transfer from the potable tanks to the elevated or groundwater storage at the milk plant, a suitable pump, hose and fittings shall be provided. When the pump, hose and fittings are not being used, the outlets shall be capped and stored in a suitable dust-proof enclosure so as to prevent their contamination. The storage tank at the milk plant shall be constructed of impervious material; provided with a dust and rainproof cover; and also provided with an approved vent and roof hatch. All new reservoirs or reservoirs which have been cleaned shall be disinfected prior to placing them into service. (Refer to Appendix D.) …

*Renumber remaining **ADMINISTRATIVE PROCEDURES** accordingly.*

Page 62:

~~7~~8. Samples for bacteriological testing of individual water supplies are taken upon the initial approval of the physical structure; each six (6) months thereafter; and when any repair or alteration of the water supply system has been made. Provided, that when water is hauled to the milk plant, such water shall be sampled for bacteriological examination at the point of use and submitted to an official laboratory at least four (4) times in separate months during any consecutive six (6) months. Samples shall be taken by the Regulatory Agency and examinations shall be conducted in an official laboratory. To determine if water samples have been taken at the frequency established in this ~~Section~~ Item, the interval shall include the designated six (6) month period plus the remaining days of the month in which the sample is due.

*Renumber remaining **ADMINISTRATIVE PROCEDURES** accordingly*

Proposal: 113
Document: 2011 PMO (Section 7-Item 15p(A))
Page: 76

Make the following changes to ***SECTION 7, ITEM 15p-PROTECTION FROM CONTAMINATION*** *on Page 76:*

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when: …
19. Water piping and raw milk and milk product lines and vessels may be separated by one (1) fail-safe valve that upon loss of air or power shall move to a position that will close or block the water lines from milk or milk product lines or vessels. Water piping conducting water, which has undergone an equivalent process to pasteurization as described in Item 15p.(B)2. and pasteurized milk and milk product lines or vessels may also be separated by one (1) fail-safe valve. In addition, a sanitary check-valve or a sanitary valve arrangement(s) that is equally effective shall be located between the fail-safe valve and the milk product line(s) and/or vessel(s). Sanitary piping shall be used downstream from the sanitary check-valve. Provisions shall be made for cleaning this sanitary piping.

Proposal: 116
Document: 2011 PMO (Section 7-Item 16p(D); and Appendix I)
Pages: 101, 102 and 277-315

Make the following changes to ***SECTION 7, ITEM 16p(D)-PASTEURIZATION RECORDS, EQUIPMENT TESTS AND EXAMINATIONS*** *on Pages 101 and 102:*

Page 101:

2. **EQUIPMENT TESTS AND EXAMINATIONS:**
The Regulatory Agency shall perform the indicated ~~tests~~ Tests on the following instruments and devices identified in Table 4 initially ~~on~~ upon installation; ~~and~~ at least once each three (3) months thereafter, including the remaining days of the month in which the equipment ~~tests~~ Tests are due; ~~and~~ whenever any alteration or replacement is made which may affect the proper operation of the instrument or device; or whenever a regulatory seal has been broken. Provided, that the pasteurization holding time ~~tests~~ Tests shall be conducted at least ~~every~~ once each six (6) months thereafter, including the remaining days of the month in which the equipment ~~check~~ Test is due.

On an emergency basis, pasteurization equipment may be tested and temporarily sealed by a milk plant employee provided the following conditions are met:

a. The individual applying the seal(s) ~~is~~ shall be employed by the milk plant in which the ~~seal~~ seal(s) was removed; …

d. The individual ~~is~~ shall be in possession of authorization from the Regulatory Agency to perform these pasteurization equipment tests;

e. The individual ~~will~~ shall immediately notify the Regulatory Agency of the time of the shutdown that would necessitate the breaking and removal of the regulatory seal(s). Permission to test and ~~seal~~ reseal the equipment ~~must~~ shall be obtained for each specific

incident. The individual ~~will~~ shall also notify the Regulatory Agency of the identity of the pasteurization equipment controls affected, the cause, if known, of the pasteurization equipment failure, the repairs made and the results of the pasteurization equipment testing. Test results for the Pasteurization Equipment Testing shall be recorded on a similar document for all milk plants. (Refer to the reference in Appendix M. for an example.) The individual ~~will~~ shall provide to the Regulatory Agency the identity and volume of milk and/or milk products processed during the period that the temporary ~~seals~~ ~~were~~ seal(s) was applied ~~to the Regulatory Agency~~;

f. If regulatory ~~tests reveal~~ pasteurization equipment testing reveals that the pasteurization equipment or controls are not in compliance with the provisions of this *Ordinance*, all milk and/or milk products that were processed during ~~that~~ this period may be recalled by the Regulatory Agency;

g. The Regulatory Agency or a properly trained regulatory official, commissioned by the responsible ~~State~~ Regulatory Agency, of each participating non-U.S. country or political subdivision thereof, ~~will~~ shall remove the temporary seal(s), retest the pasteurization equipment and apply the regulatory seal(s) within ten (10) working days of the notification by ~~industry~~ the milk plant; and

h. ~~No~~ Grade "A" milk and/or milk products ~~will~~ shall not be processed after ten (10) working days of the notification by the milk plant without the affected pasteurization equipment being tested and sealed by the Regulatory Agency or a properly trained regulatory official, commissioned by the responsible ~~State~~ Regulatory Agency, of each participating non-U.S. country or political subdivision thereof.

Page 102:

In the case of milk plants with HACCP Plans regulated under the NCIMS voluntary HACCP Program, pasteurization equipment may be tested and sealed by industry personnel acceptable to the Regulatory Agency, if the following conditions are met:

a. Test results for the Pasteurization Equipment Testing shall be recorded on a similar document for all milk plants. (Refer to the reference in Appendix M. for an example.)

b. Industry personnel conducting the Pasteurization Equipment Testing ~~must~~ shall be adequately trained and ~~must~~ shall be able to demonstrate an acceptable understanding and ability to conduct these pasteurization equipment tests to the Regulatory Agency.

(1) Industry ~~must~~ shall physically demonstrate to the Regulatory Agency that they understand and can perform the required pasteurization equipment tests according to the requirements of this *Ordinance*.

(2) The Regulatory Agency shall accept a field practical exercise, a written exam, formal classroom training, on-the-job training or any combination of these except that, if industry personnel do not physically demonstrate the appropriate capability to perform the pasteurization equipment tests to the satisfaction of the Regulatory Agency, they are not acceptable for conducting such pasteurization equipment tests.

(3) Continued training such as, but not limited to, on-the-job training with supervision or an acceptable pasteurizer training course ~~should~~ shall be completed before they reapply for pasteurizer equipment testing approval.

c. Pasteurization Equipment Tests shall be conducted at a frequency not less than the requirements of this *Ordinance*. Industry shall have responsibility for the performance of

all required pasteurization equipment tests. At least each six (6) months the Regulatory Agency shall physically supervise these pasteurization equipment tests. Regulatory supervised pasteurization equipment tests shall include the semi-annual HTST and HHST pasteurization equipment tests, if applicable. These six (6) month pasteurization equipment tests ~~should~~ shall be performed at a time that is mutually convenient to all parties. Because these pasteurization equipment tests are required to support a CCP, the industry is responsible for conducting these pasteurization equipment tests even in the absence of the regulatory official.

d. Upon initial installation or extensive modification of any pasteurization equipment, pasteurization equipment tests shall be physically supervised or conducted by the Regulatory Agency.

e. Sealing guidance for pasteurization equipment by industry is as follows:
   (1) All pasteurization equipment that is required to be sealed within this *Ordinance* shall also be sealed under the HACCP System. The sealing shall be done by a trained, qualified individual who is acceptable to the milk plant and the Regulatory Agency; and
   (2) The Regulatory Agency may verify any pasteurization equipment sealing and evaluate (accept or reject) the skills and knowledge of the individual performing the sealing.

f. During an audit, the auditor may conduct any or all of the Pasteurization Equipment Tests. The auditor ~~should~~ shall, through a combination of the physical examination of the pasteurization equipment and a records review, satisfy themselves that the pasteurization equipment is properly installed and operated.

Make the following changes to ***APPENDIX I. PASTEURIZATION EQUIPMENT AND CONTROLS – TESTS*** *on Pages 277-315:*

Page 277:

TIME MEASURING DEVICE

An Accurate Time Measuring Device may include but is not limited to a stopwatch, digital watch, conductivity device timer and any other device which keeps time accurately.

STOPWATCH …

II. TEST PROCEDURES

~~Equipment and field~~ Pasteurization equipment Tests ~~to~~ listed and referenced below shall be performed by the Regulatory Agency~~,~~; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, as cited in Item 16p.(D); or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, as cited in Item 16p.(D) ~~are listed and suitably referenced below~~. The results of the Tests shall be recorded on ~~suitable~~ appropriate forms and filed, as the Regulatory Agency shall direct. (Refer to Appendix M.) Regulatory seals shall be installed where required at the commissioning of a new pasteurization system. If the public health control(s) is within a computer system used to manage the functions of the public health control device(s) that

operate the pasteurization system, the computer shall be in compliance with Appendix H. VI before the access to the computer program is sealed. Whenever a regulatory seal has been broken, the pasteurization equipment shall be re-sealed after the appropriate testing has been conducted by the Regulatory Agency or qualified industry personnel in compliance with Item 16p.D and are found to be in compliance with the applicable Test procedure(s).

NOTE: If the pasteurization system fails one (1) or more of the required Tests, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

If it is required to break a regulatory seal to conduct any of the following Tests, it shall be replaced by the Regulatory Agency or HACCP qualified personnel acceptable to the Regulatory Agency, after testing has been completed and compliance has been verified.

NOTE: For various pieces of equipment approved for pasteurization systems, Testing Procedures which have been reviewed specifically for that equipment are included within the FDA accepted operations manual for the equipment and/or within the Memorandum of Milk Ordinance Equipment Compliance (M-b) issued upon FDA's review and acceptance of the equipment. These Testing Procedures shall be used.

TEST 1.

INDICATING THERMOMETERS - TEMPERATURE ACCURACY

Reference: Item 16p.(A), (B) and (D)
Application: To all indicating thermometers, including airspace thermometers, if applicable, used for the measurement of milk and/or milk product temperature during pasteurization and/or ultra-pasteurization~~, including airspace thermometers~~. Do not run this Test if the liquid column has been split or the capillary tube is broken.
Frequency: Upon installation; at least once each three (3) months thereafter; whenever the thermometer has been repaired and/or replaced; or whenever the regulatory seal on a digital ~~sensor~~ sensing element or a digital control box has been broken.
Criteria: Within ± 0.25ºC (± 0.5ºF) for pasteurization and ultra-pasteurization indicating thermometers and ± 0.5ºC (± 1ºF) for airspace thermometers, in a specified scale range. Provided, that on a batch ~~pasteurizers~~ pasteurizer used solely for thirty (30) minute pasteurization of milk and/or milk products at temperatures above 71°C (160°F), the indicating ~~thermometers~~ thermometer shall be accurate to within ± 0.5°C (± 1°F).
Apparatus:
1. Test thermometer meeting the specifications cited in Section I of this Appendix;
2. Water, oil or other suitable media bath and agitator; and
3. Suitable means of heating the media bath.

Method: Both the indicating and/or airspace thermometer, if applicable, and test ~~thermometers~~ thermometer shall be exposed to water, oil or other suitable media of a uniform

temperature. The ~~Indicating~~ indicating thermometer and/or airspace thermometer, if applicable, reading is compared to the reading of the test thermometer.

Procedure:

1. Prepare a ~~quantity of water, oil or other suitable~~ media ~~in a~~ bath, by raising the temperature of the media to within 2ºC (3ºF) of the ~~appropriate~~ lowest sealed cut-out pasteurization or ultra-pasteurization temperature, or minimum legal indicating or airspace temperature for batch pasteurization.
2. Stabilize the media bath temperature and agitate rapidly.
3. Continue agitation and insert the indicating and/or airspace thermometer, if applicable, and test ~~thermometers~~ thermometer to the indicated immersion point.
4. Compare ~~both~~ the thermometer readings at ~~the~~ a temperature within the test range.
5. Repeat the comparison of the thermometer readings.
6. If the results of this Test are outside the **Criteria** noted above, the indicating thermometer or airspace thermometer, if applicable, shall be adjusted by milk plant personnel to agree with the test thermometer, retest and record the action taken on the appropriate Form.

~~6~~7. When compliance is achieved and/or verified, ~~Record~~ record the thermometer readings~~,~~ from both comparisons and record the thermometer identification or location on the appropriate Form.

~~7~~8. ~~Install~~ Re-seal ~~seals~~ as appropriate ~~on~~ the ~~sensors~~ sensing elements and control boxes of the digital thermometers.

~~Corrective~~ Action: ~~Do not run the Test if the mercury column has been split or capillary tube is broken. The thermometer should be returned to the factory for repair. When the indicating thermometer differs from the test thermometer by more than 0.25ºC (0.5ºF) and the airspace thermometer by more than 0.5ºC (1ºF), the indicating thermometer should be adjusted to agree with the test thermometer. Retest the thermometer after adjustment~~. If the pasteurization or ultra-pasteurization system fails this Test, the pasteurization or ultra-pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

TEST 2.

TEMPERATURE RECORDING AND RECORDER-CONTROLLER THERMOMETERS - TEMPERATURE ACCURACY

Reference: Item 16p.(A), (B) and (D)

Application: To all ~~mercury-actuated~~ temperature recording and recorder-controller thermometers ~~controllers~~ used to record milk and/or milk product temperatures during pasteurization and/or ultra-pasteurization, except those which are electronic or computer controlled.

Frequency: Upon installation; at least once each three (3) months thereafter; ~~whenever the recording pen-arm setting requires frequent adjustment;~~ when the sensing element has been repaired and/or replaced; or ~~when~~ whenever ~~a~~ the regulatory seal has been broken.

Criteria: Within ± 0.5ºC (± 1ºF), in a specified scale range as described in **Procedure** 1 below. Provided, that on a batch ~~pasteurizers~~ pasteurizer used solely for thirty (30) minute pasteurization of milk and/or milk products at temperatures above 71°C (160°F), the temperature recording ~~thermometers~~ thermometer shall be accurate to within ± 1°C (± 2°F), between 71°C (160°F) and 77°C (170°F).

Apparatus:

1. The indicating thermometer, which was previously tested against a known accurate test thermometer;
2. Water, oil or other suitable media bath and agitator;
3. Suitable means of heating the media bath; and
4. Ice.

NOTE: When this Test is performed on ~~mercury-actuated~~ temperature recorder-controllers used with HHST pasteurization systems that operate at or above the boiling point of water, an oil or other suitable media bath shall be substituted for the processing (operating) temperature water mentioned in **Procedures** 1, 4, 5, 6, and 7 as well as the boiling water mentioned in **Procedures** 2, 3 and 5. The temperature of the oil bath that is used in place of the boiling water shall be above the normal operating range but below the highest temperature division on the chart.

Method: The testing of a ~~mercury-actuated~~ temperature recording or recorder-controller thermometer for temperature accuracy involves the determination of whether or not the temperature pen-arm will return to within ± 0.5ºC (± 1ºF)~~,~~ or ± 1°C (± 2°F) as provided for in the **Criteria** above, of its previous setting, after exposure to high heat and melting ice.

Procedure:

1. Heat a media bath to a constant temperature, utilizing one (1) of the following temperatures:
    a. Lowest sealed cut-out pasteurization temperature; or
    b. Minimum legal indicating or airspace pasteurization temperature for batch pasteurization.

Provided, that on a batch pasteurizer used solely for thirty (30) minute pasteurization of milk and/or milk products at temperatures above 71°C (160°F), this test shall be conducted with a media bath temperature above 71°C (160°F) and below 77°C (170°F).

Immerse the temperature recording or recorder-controller thermometer sensing element into the media bath. After a stabilization period of five (5) minutes, ~~Adjust~~ if necessary, adjust the temperature recording or recorder-controller thermometer pen to read exactly as the previously tested indicating thermometer~~, in the temperature range for the process being used, after a stabilization period of five (5) minutes, at a constant temperature~~. The media bath shall be rapidly agitated throughout ~~the~~ this stabilization period.

2. Prepare a second media bath by heating the media bath to the boiling point of water, or in the case of HHST pasteurization systems, to a temperature above the normal operating range but below the highest temperature division on the chart, and maintain temperature. Prepare a third ~~container~~ media bath with ~~melting~~ ice and water. Place all media baths within working distance of the temperature recording or recorder-controller thermometer temperature-sensing element(s).

3. Immerse the temperature recording or recorder-controller thermometer sensing element into ~~the boiling water, or in the case of HHST pasteurization systems into~~ the hot media bath ~~described~~ as prepared in **Procedure** 2, above, for not less than five (5) minutes.
4. Remove the temperature recording or recorder-controller thermometer sensing element from the ~~boiling water or other~~ hot media bath and immerse it in the media bath as prepared in **Procedure** 1 above. ~~at a temperature within the temperature range for the process being used.~~ Allow a five (5) minute stabilization period for both the indicating and temperature recording or recorder-controller thermometers. Compare the readings of the indicating and temperature recording or recorder-controller thermometers. The temperature recording or recorder-controller thermometer reading ~~should~~ shall be within ± 0.5ºC (± 1ºF) or ± 1°C (± 2°F) as provided for in the **Criteria** above, of the indicating thermometer reading.
5. Remove the temperature recording or recorder-controller thermometer sensing element from the media bath in the temperature range for the process being used~~,~~ and immerse it in the ~~melting~~ ice and water bath for not less than five (5) minutes.
6. Remove the temperature recording or recorder-controller thermometer sensing element from the ice and water bath and immerse it in the ~~a~~ media bath as prepared in **Procedure** 1**.** above. ~~at a temperature, range for the process being used.~~ Allow a five (5) minute stabilization period for both the indicating and temperature recording or recorder-controller thermometers. Compare the readings of the indicating and temperature recording or recorder-controller thermometers. The temperature recording or recorder-controller thermometer reading ~~should~~ shall be within ± 0.5ºC (± 1ºF), or ± 1°C (± 2°F) as provided for in the **Criteria** above, of the indicating thermometer reading.
7. When compliance is achieved and/or verified, ~~Re-seal~~ re-seal the ~~regulatory controls~~ thermometer sensing elements and recorder-controller as necessary and record the indicating and temperature recording thermometer or recorder-controller thermometer readings obtained from **Procedures** 1, 4, and 6 above on the appropriate Form.
~~**Corrective** **Action:**~~ If the temperature recording or recorder-controller thermometer pen does not return to ± 0.5ºC (± 1ºF)~~,~~ or ± 1°C (± 2ºF) as provided ~~above, of indicating thermometer reading at~~ in **Procedures** 4 and 6 above, the temperature recording or recorder-controller thermometer shall be repaired or replaced by milk plant personnel ~~as necessary~~. If the pasteurization or ultra-pasteurization system fails this Test, the pasteurization or ultra-pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

TEST 3.

TEMPERATURE RECORDING AND RECORDER-CONTROLLER THERMOMETERS - TIME ACCURACY

Reference: Item 16p.(A), (B) and (D)
Application: To all temperature recording and recorder-controller thermometers used to record the time of pasteurization and/or ultra-pasteurization.

Frequency: Upon installation; at least once each three (3) months thereafter; whenever the temperature recorder-controller thermometer or programmable recording thermometer has been repaired and/or replaced; or whenever the regulatory seal ~~of~~ on a ~~programmable~~ temperature recorder-controller thermometer or programmable recording thermometer or sensing element has been broken.
Criteria: The recorded time of pasteurization or ultra-pasteurization shall not exceed the true elapsed time.
Apparatus: An accurate time measuring device.
~~1. A watch, graduated at intervals not to exceed one (1) minute, and accurate to within five (5) minutes in twenty-four (24) hours; and~~
~~2. A pair of dividers or any other suitable device for measuring short distances.~~
Method: A ~~Comparison~~ comparison of the recorded time over a period of not less than thirty (30) minutes with ~~a watch of known accuracy~~ an accurate time measuring device. ~~For recorders utilizing electric clocks, check the cycle on the faceplate of the clock with a known cycle and observe that the clock is in operating condition.~~
Procedure:
1. Determine if the recording chart is appropriate for the temperature recording or recorder-controller thermometer. Insure that the recording chart pen is aligned with the time arc of the recording chart at both the center and the outside edge.
2. Inscribe a reference mark at the pen point on the recording chart and record the time.
3. At the end of thirty (30) minutes ~~by~~ utilizing ~~the watch~~ an accurate time measuring device, inscribe a second reference mark at the pen point position on the recording chart.
4. Determine the distance between the two (2) reference marks and compare the distance with the time-scale divisions on the recording chart at the same temperature.
~~5. For electric clocks, remove the faceplate and compare the cycle specification on the faceplate with the current cycle utilized.~~
~~6~~5. Re-seal the ~~regulatory controls~~ sensing elements and recorder-controller as necessary; enter the ~~findings~~ results on the recording chart and initial the recording chart; and record the ~~results~~ beginning and ending times on the appropriate Form.
~~**Corrective** **Action:**~~ If the recorded time is incorrect, the ~~clock~~ temperature recording or recorder-controller thermometer device ~~should~~ shall be adjusted or repaired by milk plant personnel. If the pasteurization or ultra-pasteurization system fails this Test, the pasteurization or ultra-pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

TEST 4.

TEMPERATURE RECORDING AND RECORDER-CONTROLLER THERMOMETERS - ~~CHECK~~ CHECKED AGAINST INDICATING ~~THERMOMETERS~~ THERMOMETER

Reference: Item 16p.(A), (B) and (D)

Application: To all temperature recording and recorder-controller thermometers used to record milk and/or milk product temperatures during pasteurization or ultra-pasteurization, and for batch pasteurizer digital combination airspace/recording thermometers with a continuous recording of the airspace temperature and where the airspace temperature is read and recorded on the recording chart only at the start of the pasteurization or ultra-pasteurization holding period.

Frequency: Upon installation; ~~and~~ at least once each three (3) months thereafter ~~by the Regulatory Agency, or HACCP qualified industry person, acceptable to the Regulatory Agency, qualified under Item 16p(D)2~~; whenever the temperature recording or recorder-controller thermometer has been repaired and/or replaced; whenever the regulatory seal ~~is~~ has been broken; and daily; and immediately after a recording chart has been changed by ~~the~~ milk plant personnel ~~for the HTST and HHST pasteurization systems~~.

Criteria: The temperature recording thermometer and recorder-controller thermometer shall not read higher than the indicating or airspace thermometer, which were previously tested against a known accurate test thermometer.

Apparatus: No supplementary materials required.

Method: This Test requires only that the reading of the temperature recording thermometer, recorder-controller thermometer or airspace recording thermometer be compared with the indicating thermometer at a time when both are exposed to a stabilized temperature at or above the minimum legal pasteurization temperature.

Procedure:

1. ~~While~~ When the indicating and temperature recording or recorder-controller thermometer ~~temperatures~~ temperature readings are stabilized at or above the minimum legal pasteurization temperature, read the indicating thermometer.
2. For batch pasteurizers, ~~while~~ when the airspace indicating and recording ~~temperatures~~ temperature readings are stabilized at or above the minimum legal pasteurization temperature, read the airspace thermometer.
3. Immediately ~~record~~ enter the results; the time at which this comparison was made; and ~~identify on~~ initial the recording ~~thermometer~~ chart~~, the observed indicating and/or airspace thermometer temperature reading and the time at which this comparison was made~~. This may be accomplished by inscribing a line intersecting the recorded temperature arc at the pen location or any other ~~methods~~ method acceptable to the Regulatory Agency.
4. Record the observed indicating and temperature recording thermometer or recorder-controller thermometer readings on the appropriate Form.

~~**NOTE:** This Test shall be performed while the pasteurization operating temperatures are within the accurate range for the specific thermometers and charts used.~~

~~**Corrective**~~ **Action:** If the ~~mercury-actuated~~ temperature recording thermometer or recorder-controller thermometer reads higher than the indicating thermometer, the pen or temperature adjusting mechanism shall be adjusted by ~~the~~ milk plant ~~operator~~ personnel to agree with the indicating thermometer.

~~If the digital recording thermometer or recorder-controller thermometer reads higher than the indicating thermometer, the recording temperature should be adjusted to agree with the indicating thermometer. Retest the thermometer after adjustment.~~ If after adjustment the temperature recording thermometer or recorder-controller thermometer fails this Test, the

pasteurization or ultra-pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

TEST 5.

FDD - PROPER ASSEMBLY AND FUNCTION

Reference: Item 16p.(B) and (D)
Application: ~~Parts 1~~ 5.1 to ~~4~~ 5.4 and ~~6~~ 5.6 to ~~8~~ 5.8 below apply to all FDDs used with continuous-flow ~~pasteurizers~~ pasteurization systems. ~~Parts 5~~ 5.5 and ~~9~~ 5.9 below apply only to FDDs used with HTST ~~pasteurizers~~ pasteurization systems.
Frequency: Upon installation; at least once each three (3) months thereafter; whenever the FDD has been repaired and/or replaced; or ~~when~~ whenever ~~a~~ the regulatory seal(s) has been broken.
Criteria: The FDD shall function ~~correctly~~ as required in all operating situations and shall de-energize the timing pump and all other flow-promoting devices capable of causing flow through the FDD, in the event of a FDD malfunction or ~~incorrect assembly~~ when the FDD is incorrectly assembled.

5.1 LEAKAGE PAST THE VALVE SEAT(S)

Apparatus: Suitable tools for the disassembly of the FDD and ~~the~~ any connected sanitary piping.
Method: Observe the valve seat(s) ~~of the FDD~~ for leakage.
Procedure:
1. With the pasteurization system operating on water, place the FDD in the diverted-flow position.
   ~~2~~a. For single stem FDDs, disconnect the forward-flow sanitary piping and observe the valve seat for leakage. Check the leak escape ports to see if they are open~~.~~; or
   ~~3~~b. For dual stem FDDs, observe the leak-detect line discharge or sight glass for leakage.
2. Record the results of the Test on the appropriate Form.

~~Corrective~~ Action: If leakage is ~~noted~~ observed, ~~the FDD must be dismantled and defective gaskets replaced or other~~ suitable repairs shall be made to the FDD by milk plant personnel. If after adjustment and/or repair the FDD fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

5.2 OPERATION OF THE VALVE STEM(S)

Apparatus: Suitable tools for tightening the packing nut on the valve stem~~(s)~~ of a single stem FDD.
Method: Observe the ~~FDD~~ valve stem(s) for ease of movement.
Procedure:
1. For single stem FDDs, ~~When a stem-packing nut is used,~~ tighten the valve stem packing nut ~~it~~ as much as possible. Operate the pasteurization system at maximum ~~normal~~ operating pressure and place the FDD in both forward and diverted-flow several times. The valve stem shall move freely in both forward and diverted-flow positions when the stem-packing nut is fully tightened. Note the freedom of action of the valve stem.
2. For dual stem FDDs, operate the pasteurization system at maximum operating pressure and place the FDD in both forward and diverted-flow several times. The valve stems shall move freely in both forward and diverted-flow positions. Note the freedom of action of the valve stems.
3. Record the results of the Test on the appropriate Form.
~~Corrective~~ Action: If the valve stem(s) action is sluggish, suitable adjustment or repair shall be made by milk plant personnel. ~~The stem shall move freely in all positions, when the stem-packing nut is fully tightened.~~ If after adjustment and/or repair the FDD fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

5.3 DEVICE ASSEMBLY - SINGLE STEM ~~DEVICE~~ FDD

Apparatus: ~~Sanitary fitting wrench~~ Suitable tools for the disassembly of the FDD and ~~the~~ any connected sanitary piping.
Method: When the FDD is improperly assembled and in diverted-flow, ~~(~~below the cut-out temperature~~)~~, observe the function of the timing pump and all other flow-promoting devices capable of causing flow through the FDD.
Procedure:
1. With the pasteurization system in operation, in "Process" mode, and below the cut-in temperature, unscrew by one-half (1/2) turn, the 13H hex nut that holds the top of the valve to the valve body. This ~~should~~ shall de-energize the timing pump and all other flow-promoting devices, which are capable of causing flow through the FDD. In addition, separators and/or downstream vacuum sources shall be effectively valved-out of the pasteurization system. This Test shall be conducted without any sanitary piping connected to the forward-flow port of the FDD. ~~(~~This allows for the movement of the top of the valve when the hex nut is loosened.~~)~~ Re-tighten the 13H hex nut.
2. With the pasteurization system in operation, in "Process" mode, and below the cut-in temperature, remove the connecting key, which is located at the base of the valve stem. The timing pump and all other flow-promoting devices, which are capable of causing flow through the FDD, ~~should~~ shall be de-energized. In addition, separators and/or downstream vacuum sources shall be effectively valved-out of the pasteurization system.

3. Attempt to restart ~~the timing pump and~~ each flow-promoting device capable of causing flow through the FDD. None of these flow-promoting devices ~~should~~ shall start or operate. Separators and/or downstream vacuum sources shall remain effectively valved-out of the pasteurization system
4. Record the results of the Test on the appropriate Form.
~~Corrective~~ Action: If any flow-promoting device fails to respond as indicated above, an immediate ~~checks~~ check of the ~~device~~ FDD assembly and wiring ~~are~~ is required by milk plant personnel to locate and correct the cause of the failure. If after adjustment and/or repair the FDD fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

5.4 DEVICE ASSEMBLY - DUAL STEM ~~DEVICE~~ FDD

NOTE: The Test procedure presented in this Section is typical of Tests accepted by FDA for various specific types of FDDs. Testing details, which may vary, are provided in individual FDD operator's manuals that have been reviewed by FDA and are specified by part number in FDA's Coded Memoranda (M-b's). In each of these ~~FDA~~ M-b accepted Test methods, if the words "metering pump" or "timing pump" are used they shall be understood to mean "timing pump and all other flow-promoting devices, which are capable of causing flow through the FDD".

Apparatus: ~~None~~ No supplementary materials required.
Method: Observe the function of the timing pump and all other flow-promoting devices, which are capable of causing flow through the FDD when the FDD is improperly assembled.
Procedure:
1. With the FDD in diverted-flow, caused by temperature, and the FDD is properly assembled, move the FDD to the forward-flow position by moving the switch to the "Inspect" mode and disconnect the valve stem from the actuator of the valve being tested.
2. Move the FDD to the diverted-flow position by moving the switch to the "Product" mode and turn on the timing pump and all other flow-promoting devices, which are capable of causing flow through the FDD. The timing pump and all other flow-promoting devices ~~must~~ shall be de-energized and ~~must~~ shall not run. If any ~~pump~~ flow-promoting device, which is capable of causing flow through the FDD, starts momentarily and then stops running, it may indicate the improper wiring of the one (1) second time delay as allowed for in 16p(B)2.b.(10). In addition, ~~Separators~~ separators and/or downstream vacuum sources ~~must be~~ shall remain effectively valved-out of the pasteurization system. Move the switch to the "Inspect" mode and properly ~~Reassemble~~ reassemble the FDD ~~by moving it to the forward-flow position and reconnecting the stem to the actuator~~. Start the timing pump and all other flow-promoting devices, which are capable of causing flow through the FDD, to determine if the FDD has been properly reassembled.
3. Repeat ~~the~~ this ~~procedure~~ **Procedure** for the other actuator.
5. Record the results of the Test on the appropriate Form.

~~**Corrective** **Action:**~~ If any of the flow-promoting devices, which are capable of causing flow through the FDD, fail to respond as indicated, an immediate check of the FDD assembly and wiring ~~is required~~ shall be conducted by milk plant personnel to locate and correct the ~~cause~~ problem. If after adjustment and/or repair the FDD fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

5.5 MANUAL DIVERSION

~~(Booster pump installed in the HTST system)~~

Apparatus: ~~None~~ No supplementary materials required.
Method: Observe that the appropriate responses in **Procedures** 1 and 2, as required below, have occurred ~~the response of the system to~~ during the activation and deactivation of manual diversion.
Procedure:
1. With the HTST pasteurization system in operation and the FDD in the forward-flow position, ~~press~~ activate the manual ~~diversion~~ divert control ~~button~~. ~~This should:~~
   a. ~~Cause the~~ The FDD ~~to~~ shall assume the ~~divert~~ diverted-flow position;
   b. ~~De-energize the booster pump;~~ Any flow-promoting device downstream from the FDD, which is capable of causing flow through the FDD, shall be de-energized; and
   c. Any separator and/or ~~downstream~~ vacuum ~~sources~~ source downstream from the FDD ~~must~~ shall be effectively valved out~~; and~~.
   ~~d. The pressure differential between raw and pasteurized milk or milk product in the regenerator should be maintained.~~
2. ~~Operate the HTST system in forward-flow and activate the manual divert button until the raw pressure reaches zero (0) psi. Deactivate the manual divert button and observe the raw milk or milk product and pasteurized milk or milk product pressures. The pressure differential between raw and pasteurized milk or milk product in the regenerator should be maintained~~.
If a booster pump is installed in the HTST pasteurization system and the pasteurization system is in operation with the FDD in the forward-flow position:
   a. Activate the manual divert control. The booster pump shall be de-energized. The required minimum pressure differential of at least 6.9 kPa (1 psi) between raw milk and/or milk product and pasteurized milk and/or milk product in the regenerator shall be maintained.
   b. After the raw pressure reaches zero (0) psi, deactivate the manual divert control and observe that the required minimum pressure differential of at least 6.9 kPa (1 psi) between raw milk and/or milk product and pasteurized milk and/or milk product in the regenerator has been maintained.
3. ~~Re-seal the regulatory controls as necessary.~~ Record the results of the Test on the appropriate Form.
~~**Corrective** **Action:**~~ If the above described required actions do not occur, or the ~~necessary~~ required pressure differential between raw and pasteurized milk and/or milk product is not maintained, ~~the assembly and wiring of~~ the HTST pasteurization system ~~must~~ shall be

immediately reviewed and evaluated by milk plant personnel and the indicated deficiencies corrected or proper adjustments made. If after adjustment and/or repair the FDD fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

5.6 RESPONSE TIME

Apparatus:
1. Water, oil or other suitable media bath and agitator;
2. Suitable means of heating the media bath; and
3. ~~Stopwatch~~ An accurate time measuring device.

Method: Determine that the elapsed time does not exceed one (1) second between the instant of the activation of the FDD control mechanism at cut-out temperature, on declining temperature, and the instant the FDD takes the fully diverted-flow position.

Procedure:
1. With the water, oil or suitable media bath at a temperature above cut-out temperature, allow the water, oil or other suitable media to cool gradually. The moment the cut-out mechanism is activated, start the ~~watch~~ accurate time measuring device. The moment the FDD takes the fully-diverted position, stop the ~~watch~~ accurate time measuring device.
2. ~~Re-seal the regulatory controls as necessary and record~~ Record the results of the Test on the appropriate Form.

~~Corrective~~ Action: If the response time exceeds one (1) second, immediate ~~corrective~~ action ~~must~~ shall be taken by milk plant personnel to correct this FDD deficiency. If after adjustment and/or repair the FDD fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

5.7 TIME DELAY INTERLOCK WITH TIMING PUMP AND OTHER FLOW PROMOTING DEVICES

Application: To all dual stem FDDs with a manual forward-flow control switch.

Apparatus: ~~None~~ No supplementary materials required.

Method: Determine that the ~~device~~ FDD does not assume a manually induced forward-flow position~~,~~ while the timing pump or any other flow-promoting device, which is capable of causing flow through the FDD, is operating.

Procedure: With the pasteurization system operating in forward-flow, move the control switch to the "Inspect" position and observe that the following events automatically occur in sequence:
1. The FDD immediately moves to the diverted-flow position and the timing pump and all other flow-promoting devices, which are capable of causing flow through the FDD, are de-

energized, or in the case of separators and/or downstream vacuum sources, are effectively valved-out of the pasteurization system.
2. The FDD remains in the diverted-flow position ~~while~~ until the timing pump and all other flow-promoting devices, which are capable of causing flow through the FDD, ~~are running down~~ have completely stopped running or in the case of a separator and/or downstream vacuum sources, are effectively ~~valving~~ valved out of the pasteurization system.
3. Then ~~The~~ the FDD ~~may~~ shall assume the forward-flow position ~~only after the timing pump stops turning, and all other flow-promoting devices, which are capable of causing flow through the FDD have also stopped, or in the case of separators or downstream vacuum sources, have been effectively valved-out of the system~~.
~~4. Repeat the above procedure by moving the control switch to the "Cleaned-in-Place" (CIP) position.~~
~~5~~ 4. Record the ~~Test~~ results of the Test on the appropriate Form and seal the control enclosure.
~~Corrective~~ Action: If the above sequence of events do not occur, either a timer adjustment or wiring change is required to be made by milk plant personnel. If after adjustment and/or repair the FDD fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

5.8 CIP TIME DELAY ~~RELAY~~

Application: To all continuous-flow ~~pasteurizer~~ pasteurization systems in which it is desired to run ~~the timing pump and/or other~~ any flow-promoting devices during the CIP cycle ~~without the controls required during product processing~~.
Criteria: When the mode switch on the FDD is moved from "Process" to "CIP", the FDD shall move immediately to the ~~diverted~~ diverted-flow position. It shall remain in the ~~diverted~~ diverted-flow position for at least ten (10) minutes, with all public health controls required in the "Process" mode functioning, before starting its normal cycling in the "CIP" mode. In HTST pasteurization systems, the booster pump shall be de-energized, separators between raw regenerator sections and separators and/or vacuum sources downstream of the FDD, shall be effectively valved-out of the pasteurization system during the required ten (10) minute time delay.
Apparatus: ~~Stopwatch~~ An accurate time measuring device.
Method: Determine that the set point on the "CIP" time delay ~~relay~~ is equal to or greater than the required ten (10) minutes by observing the time when the FDD moves to the forward-flow position or is again capable of moving to the forward-flow position.
Procedure:
1. Operate the ~~pasteurizer~~ pasteurization system in forward-flow, with the mode switch on the FDD controls in the "Process" position, using water above the minimum legal pasteurization temperature. For magnetic flow meter based timing systems, operate the system~~,~~ at a flow-rate below the ~~Flow-Alarm~~ flow alarm set point and above the low-flow or ~~Loss-of-Signal-Alarm~~ loss-of-signal alarm set point.

NOTE: The appropriate temperature sensing elements may be placed in a water, ~~or~~ oil or other suitable media bath to simulate the normal pasteurization temperature ~~of~~ within the holding tube as an alternative to heating the water in the pasteurization system above the minimum legal pasteurization temperature.

2. Move the mode switch on the FDD control to the "CIP" position. The FDD ~~should~~ shall move immediately to the ~~diverted~~ diverted-flow position. Start the ~~stopwatch~~ accurate time measuring device when the FDD moves to the ~~diverted~~ diverted-flow position. ~~Check~~ Confirm that all public health controls required in diverted flow in the "Process" mode are functioning ~~controls that are required to be in operation when the system is in the "Process" mode and in diverted-flow. For example, in HTST systems, the booster pump must stop running. Separators located between regenerator sections or on the pasteurized side of the system must be effectively valved-out and stuffer pumps for such separators must be de-energized. Any downstream vacuum source must be effectively valved out.~~
3. Stop the ~~stopwatch~~ accurate time measuring device when ~~the CIP timer times out~~ the FDD moves to the forward-flow position or is again capable of moving to the forward-flow position. ~~On most systems this is when the FDD moves to the forward position for its initial cycle in the "CIP" mode.~~ At this time, the pasteurization system may be operated without the FDD controls normally required during the "Process" mode during product processing. ~~For example, the booster pump may start at this time.~~
4. Record the results of the Test on the appropriate Form.
5. ~~Install and seal~~ Re-seal the regulatory enclosure over the time delay ~~relay.~~

~~Corrective~~ Action: If the FDD does not remain in the ~~diverted~~ diverted-flow position for at least the required ten (10) minutes after the FDD mode switch is moved from "Process" to "CIP", increase the set point on the time delay ~~relay~~ and repeat this Test ~~procedure~~ **Procedure**. All public health controls required when the pasteurization system is in "Process" mode and in diverted-flow ~~must~~ shall be functional during ~~these~~ this required ten (10) minutes. ~~If any of the public health controls are not functional during these ten (10) minutes, adjustments or repairs are needed. In HTST systems, if the booster pump runs at any time during the ten (10) minute delay, the booster pump wiring is in need of repair.~~ If the above does not occur, either a timer adjustment or wiring change is required to be made by milk plant personnel. If after adjustment and/or repair the FDD fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

5.9 LEAK-DETECT VALVE FLUSH - TIME DELAY

Application: ~~The minimum one (1) second delay applies to~~ To HTST continuous-flow ~~pasteurizers~~ pasteurization systems in which the space between the divert and leak-detect ~~valve~~ valves is not self-draining when the FDD is in the diverted-flow position.

~~The maximum of five (5) seconds for this delay is not applicable if:~~

~~1. The minimum acceptable holding time in diverted-flow can be achieved without the use of a restriction in the divert line; or~~

~~2. The timing system is magnetic flow meter based.~~

Criteria: The space between the divert and leak-detect ~~valve~~ valves ~~will~~ shall be flushed for at least one (1) second and not more than five (5) seconds after the divert valve moves to the forward-flow position and before the leak-detect valve moves to the ~~forward~~ forward-flow position.

The maximum of five (5) seconds delay is not applicable if:

1. The minimum acceptable pasteurization holding time in diverted-flow can be achieved without the use of any restriction in the divert line; or
2. The timing system is magnetic flow meter based.

Apparatus: ~~Stop watch~~ An accurate time measuring device.

Method: Observe the movement of the divert and leak-detect valves to the forward-flow position and measure the time interval between the movement of the two (2) valves.

Procedure:

1. Move the FDD from the diverted-flow position to the forward-flow position either by:
   a. Raising the temperature above the cut-in set point; or

   NOTE: The appropriate temperature sensing elements may be placed in a water, oil or other suitable media bath to simulate the normal pasteurization temperature within the holding tube as an alternative to heating the water in the pasteurization system above the minimum legal pasteurization temperature.

   b. Operating the HTST ~~pasteurizer~~ pasteurization system above the cut-in temperature in manual divert mode and then ~~releasing~~ deactivate the manual divert control.
2. When the divert valve begins to move to the forward-flow position, start the ~~watch~~ accurate time measuring device.
3. When the ~~detect~~ leak-detect valve begins to move to the forward-flow position, stop the ~~watch~~ accurate time measuring device.
4. Record the elapsed time on the appropriate Form.
5. If the elapsed time is at or above one (1) second and at or below five (5) seconds, except as noted in the exceptions in the **Criteria** above, seal the time delay as required.

~~**Corrective**~~ **Action:** If the elapsed time is less than one (1) second or greater than five (5) seconds, except as noted in the exceptions in the **Criteria** above, appropriate changes to the pasteurization system or pasteurization ~~system~~ system's FDD controls ~~must~~ shall be made by milk plant personnel. If after adjustment and/or repair the FDD fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

TEST 6.

BATCH (VAT) PASTEURIZER LEAK-PROTECTOR OUTLET VALVE

Reference: Item 16p.(A) and (D)

Application: To all batch (vat) ~~pasteurizer~~ pasteurizers that have an outlet ~~valves~~ valve.

Frequency: Upon installation; and at least once each three (3) months thereafter.
Criteria: No leakage ~~of milk or milk product~~ past the outlet valve seat in ~~any~~ the closed position.
Apparatus: No supplementary materials required.
Method: By observing whether or not leakage past the outlet valve seat occurs when pressure is exerted against the upstream face of the outlet valve.
Procedure:
1. Utilizing milk, ~~or~~ milk products or water, fill the batch (vat) pasteurizer to the normal operation level ~~so that pressure is exerted against the closed outlet valve~~.

~~**NOTE:** Care must be taken to avoid contamination of the outlet valve.~~

2. Observe the outlet valve in the closed position and determine whether or not ~~any~~ milk, ~~or~~ milk product or water is leaking past the outlet valve seat into the valve outlet.
3. ~~Turn the outlet valve to the just closed position, and examine for any leakage into the valve outlet.~~ Record the results of the Test on the appropriate Form.
~~4. Record the identity of the outlet valve and findings for the office record.~~
~~**Corrective** **Action:** If leakage past the outlet valve seat should occur~~ occurs in ~~any~~ the closed position, the outlet valve plug ~~should~~ shall be ~~re-ground, gaskets replaced,~~ repaired or ~~any other necessary steps shall be taken to prevent leakage~~ replaced by milk plant personnel. If the outlet valve fails this Test, the batch (vat) pasteurizer shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

TEST 7.

INDICATING THERMOMETERS LOCATED ~~ON~~ WITHIN HTST PASTEURIZATION SYSTEMS ~~PIPELINES~~ - THERMOMETRIC RESPONSE

Reference: Item 16p.(B) and (D)
Application: To all ~~continuous-flow pasteurizers~~ HTST pasteurization systems, except for those in which the FDD is located downstream of the pasteurized regenerator section(s) and/or the final cooler section.
Frequency: Upon installation; once each three (3) months thereafter; whenever the indicating thermometer has been repaired and/or replaced; ~~and~~ or whenever the regulatory seal on a digital ~~thermometer~~ sensing element or digital control box has been broken.
Criteria: Four (4) seconds or less ~~under specified conditions~~.
Apparatus:
1. ~~Stopwatch~~ Accurate time measuring device;
2. The indicating thermometer, which was previously tested against a known accurate test thermometer;
3. Water, oil or other suitable media bath and agitator; ~~and~~
4. Suitable means of heating the ~~water~~ media bath~~.~~; and

5. Ice and water media bath

Method: ~~By~~ The measuring of the time required for the reading of the indicating thermometer being tested to increase 7ºC (12ºF) through a specified temperature range. This temperature range ~~must~~ shall include the minimum legal pasteurization ~~temperature~~ temperature(s). ~~The temperature used in the water bath will depend upon the scale range of the thermometer to be tested.~~ If there are multiple cut-in temperatures and one (1) or more are separated by more than 7ºC (12ºF), this Test shall also be conducted for any cut-in temperature(s) not included within the initial 7ºC (12ºF) range as addressed in **Procedure** 1 below.

Procedure:

1. Immerse the indicating thermometer in the ~~water~~ media bath, which has been heated to a temperature at least 11ºC (19ºF) higher than the minimum scale reading on the indicating thermometer. The media bath temperature ~~should~~ shall be 4ºC (7ºF) higher than the ~~maximum required~~ highest pasteurization temperature set point (cut-in temperature) for which the indicating thermometer is being used.
2. Immerse the indicating thermometer in ~~a bucket of~~ an ice ~~cold~~ and water media bath for several seconds to cool it.

NOTE: Continuous agitation of the ~~water baths~~ heated media bath during the performance of **Procedures** 3, 4 and 5 is required. The elapsed time between the end of **Procedure** 1 and the beginning of **Procedure** 3 ~~should~~ shall not exceed fifteen (15) seconds, unless a constant temperature media bath is used to prevent the ~~hot water~~ heated media bath from cooling significantly.

3. Insert the indicating thermometer into ~~a~~ the ~~hot water~~ heated media bath to the proper indicating thermometer bulb immersion depth.
4. Start the ~~stopwatch~~ accurate time measuring device when the indicating thermometer reads 11ºC (19ºF) below the heated media bath temperature.
5. Stop the ~~stopwatch~~ accurate time measuring device when the indicating thermometer reads 4ºC (7ºF) below the heated media bath temperature.
6. Record the ~~thermometric response time for the office record~~ results of the Test on the appropriate Form.

For Example: For ~~a~~ an indicating thermometer used at pasteurization temperature set points of 71.7ºC (161ºF) and 74.4ºC (166ºF), a ~~water~~ media bath at a temperature of 78.3ºC (173ºF) could be used. ~~10.6 ºC~~ 11ºC (19ºF) lower than a 78.3ºC (173ºF) ~~water~~ media bath would be 67.8ºC (154ºF); ~~3.9ºC~~ 4ºC (7ºF) lower than a 78.3ºC (173ºF) ~~water~~ media bath would be 74.4ºC (166ºF). Hence, after immersing the indicating thermometer that has been previously cooled in the ice and water media bath, ~~in~~ into the 78.3ºC (173ºF) bath, the ~~stopwatch~~ accurate time measuring device is started when the thermometer reads 67.8ºC (154ºF) and the accurate time measuring device is stopped when it reads 74.3ºC (166ºF).

NOTE: The ~~Test~~ **Example** included the pasteurization temperature set points of 71.7ºC (161ºF) and 74.4ºC (166ºF). If the pasteurization temperature set points had been 71.7ºC (161ºF) and 79.4ºC (175ºF), it would not have been possible to include both set points within a ~~6.7ºC~~ 7ºC (12ºF) span. With these set points of 71.7ºC (161ºF) and 79.4ºC (175ºF) the Test would have to be ~~done~~ conducted separately for each set point.

~~**Corrective** **Action:**~~ If the response time exceeds four (4) seconds, the indicating thermometer ~~should~~ shall be repaired or replaced ~~or returned for repair~~ by milk plant personnel. If the thermometer fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

TEST 8.

TEMPERATURE ~~RECORDER/CONTROLLER~~ RECORDER-CONTROLLER THERMOMETERS - THERMOMETRIC RESPONSE

Reference: Item 16p.(B) and (D)
Application: To all HTST continuous-flow ~~pasteurizers~~ pasteurization systems, except for those in which the FDD is located ~~at the end of the cooler~~ downstream of the pasteurized regenerator section(s) and/or the final cooler section.
Frequency: Upon installation; ~~and~~ at least once each three (3) months thereafter; whenever the temperature recorder-controller thermometer has been repaired and/or replaced; or whenever the regulatory seal has been broken.
Criteria: Five (5) seconds~~, under specified conditions~~ or less.
Apparatus:
1. ~~Stopwatch~~ Accurate time measuring device;
2. The indicating thermometer, which was previously tested against a known accurate test thermometer;
3. Water, oil or other suitable media bath and agitator; and
4. Suitable means of heating the ~~water~~ media bath.

Method: Measure the time interval between the instant when the temperature ~~recording~~ recorder-controller thermometer reads 7ºC (12ºF) below the cut-in temperature and the moment of cut-in by the temperature ~~recorder/controller~~ recorder-controller. This time interval measurement is made when the temperature recorder-controller sensing element is immersed in a rapidly agitated ~~water~~ media bath maintained at 4ºC (7ºF) above the cut-in temperature.
Procedure:
1. Check and, if necessary, adjust the pen-arm setting of the ~~recording~~ temperature recorder-controller thermometer ~~in the proper reference~~ to ~~agree with~~ read the same as the indicating thermometer ~~reading~~ at ~~the~~ pasteurization temperature.
~~2. Determine the cut-in temperature of the recorder/controller, either while in normal operation or by using a water bath. (Refer to Test 10.)~~
~~3~~2. ~~Remove the~~ Allow the temperature recorder-controller sensing element ~~and allow it~~ to cool to room temperature.
~~4~~3. Heat the ~~water~~ media bath to 4ºC (7ºF) above the cut-in temperature, while continuously ~~vigorously~~ agitating the media bath to insure a uniform temperature.
~~5~~4. Immerse the temperature ~~recorder/controller~~ recorder-controller sensing element ~~bulb~~ in the media bath. Continue agitation during **Procedures** ~~6~~ 5 and ~~7~~ 6 below.

~~6~~5. Start the ~~stopwatch~~ accurate time measuring device when the temperature ~~recording~~ recorder-controller thermometer reaches a temperature of 7ºC (12ºF) below the cut-in temperature.
~~7~~6. Stop the ~~stopwatch~~ accurate time measuring device when the temperature ~~recorder/controller~~ recorder-controller cuts in.
~~8~~7. ~~Re-seal the regulatory controls as necessary and record the thermometric response time for office record.~~ Record the results of the Test on the appropriate Form.
8. Repeat **Procedures** 1 through 7 for each temperature cut-in set point.
~~Corrective~~ Action: If the response time exceeds five (5) seconds, the temperature ~~recorder/controller~~ recorder-controller ~~should~~ shall be repaired or replaced by milk plant personnel. If the temperature recorder-controller fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

TEST 9.

REGENERATOR PRESSURE CONTROLS

Reference: Item 16p.(C) and (D)

9.1 PRESSURE SWITCHES

~~Used to control the operation of the booster pump.~~

Application: To all pressure switches controlling the operation of a booster pump on HTST ~~pasteurizer~~ pasteurization systems ~~employing~~ ~~regenerators~~ with a regenerator section(s).
Frequency: Upon installation; at least once each three (3) months thereafter; ~~after~~ whenever there is any change ~~in~~ to the booster pump or the pressure switch circuit; ~~and/or~~ or whenever the ~~pressure switch~~ regulatory seal ~~is~~ has been broken.
Criteria: The booster pump shall not operate unless there is at least a 6.9 kPa (1 ~~pound~~ psi) pressure differential on the pasteurized milk and/or milk product side of the regenerator section.
Apparatus:
1. A ~~Sanitary~~ sanitary pressure gauge; ~~and~~
2. ~~pneumatic~~ Pneumatic testing device, for checking and adjusting the pressure switch settings~~.~~ ; and

NOTE: A simple pneumatic testing device may be made from a ~~discarded 50 millimeters (2 inches) 7BX~~ sanitary tee~~,~~ with a cap on one outlet of the tee that is ~~two (2) additional 13H nuts, one (1) of which is provided with a 16A cap,~~ drilled and tapped and fitted in sequence from the cap with an air bleeder valve, an air pressure reducing valve (suggested range 0-60 psi) and a quick disconnect fitting for attaching a pneumatic device to a milk plant air line. ~~for a 13 millimeters (0.5 of an inch) galvanized iron nipple for the air connection. A hose connection is~~

~~made to a compressed air source in the milk plant by means of a snap-on fitting. The air pressure can be controlled by pressure-reducing valve (range 0-60 psi) followed by a 13 millimeters (0.5 of an inch) globe-type bleeder valve connected into the side outlet of a 13 millimeters (0.5 of an inch) tee installed between the pressure-reducing valve and the testing device. The pressure switch to be tested is disconnected from the pasteurizer and connected to another of the outlets of the sanitary tee, and the pressure gauge is connected to the third outlet of the sanitary tee. By careful manipulation of the air pressure reducing valve and the air bleeder valve, the air pressure in the testing device may be regulated slowly and precisely. In operating the device, care should be taken to avoid exposing the pressure switch and the sanitary pressure gauge to excessive pressure that may cause damage. This may be done by first closing off the air pressure regulating valve and opening fully the bleeder valve; these may then be manipulated slowly to bring the air pressure in the testing device within the desired range.~~

3. A test light of proper voltage ~~should be~~ placed in-series with the pressure switch contact and in parallel with the ~~electrical load,~~ booster pump starter~~, so the actuation point may be readily determined~~.

Method: Check and make the adjustment of the pressure switch to prevent the operation of the booster pump, unless the pressure of the pasteurized milk and/or milk product side of the regenerator section is greater by at least 6.9 kPa (1 psi) than any pressure that may be generated by the booster pump ~~on the raw side~~.

Procedure:

1. Determine the maximum pressure of the booster pump.
   a. Install the sanitary pressure gauge in a tee at the discharge of the booster pump~~;~~.
   b. Operate the ~~pasteurizer~~ pasteurization system ~~with~~ on water; with the FDD in forward-flow; the timing pump operating at the minimum speed possible; and the booster pump operating at its ~~rated~~ maximum speed. If a separator and/or vacuum equipment is located between the raw outlet ~~from~~ of the regenerator section and the timing pump, ~~it~~ the separator and/or vacuum equipment ~~should~~ shall be ~~bypassed~~ effectively valved out of the pasteurization system ~~while this determination is made~~.
   c. ~~Note~~ Determine the maximum pressure indicated by the pressure gauge under these conditions.
2. Check and set the pressure switch.
   a. ~~Install a sanitary pressure gauge of known accuracy on the pneumatic testing device to which the pressure switch sensing element should also be connected~~. Disconnect the pressure switch to be tested from the pasteurization system and connect it to one (1) of the outlets of the pneumatic testing device sanitary tee.
   b. Connect the sanitary pressure gauge to the third outlet of the sanitary tee.
   c. Close the air pressure regulating valve and fully open the air bleeder valve. Slowly manipulate these valves to bring the air pressure in the pneumatic testing device within the desired range.

   NOTE: By careful manipulation of the air pressure reducing valve and the air bleeder valve, the air pressure in the pneumatic testing device may be regulated slowly and precisely. When operating the pneumatic testing device, care shall be taken to avoid

exposing the pressure switch and the sanitary pressure gauge to excessive pressure that might cause damage to the pressure switch.

~~b~~d. Remove the regulatory seal and cover to expose the adjustment mechanism on the pressure switch.

~~c~~e. Operate the pneumatic testing device and determine the pressure gauge reading at the ~~cut-in~~ booster pump start point ~~of~~ on the pressure switch, which will light the test ~~lamp~~ light. If the pressure switch is short circuited, the ~~lamp~~ test light will be ~~lighted~~ lit before the air pressure is applied.

~~d~~f. The ~~cut-in~~ booster pump start point ~~should~~ shall be adjusted, if necessary, so as to occur at a pressure gauge reading at least 6.9 kPa (1 psi) greater than the maximum booster pump operating pressure, as determined under ~~Section~~ Step 1 of this ~~procedure~~ **Procedure**. ~~Where~~ If an adjustment is necessary, refer to the manufacturer's instructions for the adjusting procedures. After adjustment, recheck the ~~actuation~~ booster pump start point ~~and readjust if necessary~~.

~~e~~g. Replace the cover, seal the pressure switch and ~~restore~~ put the pressure switch sensing element back ~~to~~ at its original location.

3. Identify the motor, casing and impeller of the booster pump.

~~f~~4. Record the maximum booster pump pressure ~~developed and~~, the pressure switch setting and the identity of the motor, casing and impeller of the booster pump ~~for the office record~~ on the appropriate Form.

Action: If the pressure switch fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

9.2 DIFFERENTIAL PRESSURE CONTROLLER

Application: Test 9.2.1 applies to all differential pressure controllers used to control the operation of booster pumps ~~on~~ within HTST pasteurization systems or used to control the operation of FDDs on HHST and HTST pasteurization systems with the FDD located downstream of the pasteurized regenerator section(s) and/or the final cooler section.

Test 9.2.2 applies only to HTST pasteurization systems with the FDD located immediately following the holding tube.

Test 9.2.3 applies to the testing of ~~continuous-flow~~ continuous-flow pasteurization systems in which the differential pressure controller is used to control the operation of the FDD.

Frequency: Upon installation; at least once each three (3) months thereafter; ~~and~~ whenever the differential pressure controller is adjusted or repaired; or whenever the regulatory seal has been broken.

Criteria: The booster pump shall not operate, or the ~~pasteurizer~~ pasteurization system shall not operate in forward-flow, unless the milk and/or milk product pressure in the pasteurized side of the regenerator section(s) is at least 6.9 kPa (1 psi) greater than the milk and/or milk product pressure in the raw side of the regenerator section(s). When the differential pressure controller is used to control the FDD on HHST pasteurization systems, and improper pressure

occurs in the regenerator section(s), the FDD shall move to the diverted-flow position and remain in diverted-flow until the proper pressures are re-established in the regenerator section(s) and all milk and/or milk product-contact surfaces between the holding tube and the FDD have been held at or above the ~~required~~ minimum legal pasteurization temperature, continuously and simultaneously for at least the required time.

Apparatus:

1. A sanitary pressure gauge; ~~and a~~
2. ~~pneumatic~~ Pneumatic testing device, described in Test **9.1 PRESSURE SWITCHES** can be used for checking and adjusting the differential pressure switch setting. ~~(Refer to Test 9.1.);~~
3. Water, oil or other suitable media bath and agitator;
4. Suitable means of heating the media bath. (Refer to Test 9.2.2); and
5. Test light. (Refer to Test 9.2.3)

Method: The differential pressure switch is checked and adjusted to prevent the operation of the booster pump, or prevent forward-flow, unless the milk and/or milk product pressure in the pasteurized side of the regenerator section(s) is at least 6.9 kPa (1 psi) greater than the pressure in the raw side of the regenerator section(s).

9.2.1 CALIBRATION OF THE DIFFERENTIAL PRESSURE CONTROLLER ~~PROBES~~ SENSING ELEMENTS

Procedure:

1. Loosen the ~~process~~ sanitary pipeline ~~connection~~ connections ~~at~~ to both differential pressure controller pressure ~~sensors~~ sensing elements and wait for any liquid to drain through the loose sanitary pipeline connections. Both pointers, or digital displays, ~~should~~ shall be within 3.5 kPa (0.5 psi) of 0 kPa (0 psi). If not, adjust the pointer(s), or the digital display(s), to read 0 kPa (0 psi).
2. Remove both differential pressure controller ~~sensors~~ sensing elements from the ~~processor~~ pasteurization system and mount them ~~in~~ on a testing tee~~,~~ which is connected either at the discharge of the booster pump~~;~~ or ~~connected~~ ~~to~~ at the pneumatic testing device. Note the separation between the two (2) pointers or digital displays. ~~The~~ A change in ~~elevations~~ elevation of the differential pressure controller ~~sensors~~ sensing elements ~~will~~ may cause ~~have caused~~ some change in the ~~zero~~ 0 kPa (0 psi) readings. Turn on the booster pump switch and ~~depress~~ activate the test ~~push button~~ switch/button to operate the booster pump~~.~~, or ~~If~~ if the pneumatic testing device is used in lieu of the booster pump, adjust the air pressure to the normal operating pressure of the booster pump. Note that the ~~pointer~~ pointers, or digital display reading separation is within 6.9 kPa (1 psi) of that observed before the pressure was applied. ~~If not, the instrument requires adjustment or returned for repair~~.
3. Record the results of the Test ~~results for the office record~~ on the appropriate Form.

Action: If the differential pressure controller fails to respond as indicated above, an immediate check of the differential pressure controller is required by milk plant personnel to correct the cause of the failure. If after adjustment and/or repair the differential pressure controller fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary

testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

9.2.2 HTST - INTERWIRING OF THE ~~PRESSURE~~ DIFFERENTIAL PRESSURE CONTROLLER WITH THE BOOSTER PUMP

Method: Determine if the booster pump stops running when the pressure differential is not properly maintained in the regenerator section(s).

Procedure:

1. Connect the pasteurized regenerator section differential pressure controller ~~sensor~~ sensing element to a testing tee with the other end of the testing tee capped.

NOTE: If there is water in the HTST pasteurization system, ensure that the ~~recorder/controller~~ recorder-controller ~~probe~~ sensing element and the pasteurized regenerator section differential pressure controller ~~sensor~~ sensing element ports are capped before the timing pump is turned on.

2. Turn on the timing pump and the booster pump.
3. Place the ~~recorder/controller~~ recorder-controller ~~probe~~ sensing element in a hot ~~water~~ media bath, which is above the cut-in temperature.
4. ~~Turn up~~ Increase the air supply on the testing tee to provide an adequate pressure differential to start the booster pump. The booster pump shall start running.
5. Decrease the air supply to the testing tee until the pasteurized milk and/or milk product differential pressure controller ~~sensor~~ sensing element pressure is less than 14 kPa (2 psi) greater than ~~of~~ the pressure on the raw milk and/or milk product side differential pressure controller ~~sensor~~ sensing element. The booster pump ~~should~~ shall ~~have stopped~~ stop running. Ensure that the FDD remains in the forward-flow position and the timing pump continues to operate.
6. ~~Reseal the regulatory controls as necessary and record~~ Record the results of the Test ~~results for the office record~~ on the appropriate Form.

~~Corrective~~ Action: If the booster pump fails to stop running when the pressure differential is not maintained, ~~have the~~ milk plant ~~maintenance~~ personnel shall determine and correct the ~~cause~~ problem. If after adjustment and/or repair the differential pressure controller fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

9.2.3 INTERWIRING OF THE ~~PRESSURE~~ DIFFERENTIAL PRESSURE CONTROLLER WITH THE FDD IN AN HHST ~~CONTINUOUS FLOW~~ CONTINUOUS-FLOW PASTEURIZATION SYSTEM

Application:

~~1.~~ To all differential pressure controllers used to control the operation of FDDs on HHST ~~continuous-flow~~ continuous-flow pasteurization systems with the FDD located downstream of the pasteurized regenerator section(s) and/or final cooler section.~~, and~~

~~2. To all differential pressure controllers used to control the operation of FDDs, milk or milk product divert systems, milk or milk product divert valve(s).~~

~~**Apparatus:** A sanitary pressure gauge and pneumatic testing device, described in **PRESSURE SWITCHES** can be used for checking and adjusting the differential pressure switch setting. (Refer to Test 9.1.)~~

Method: The differential pressure ~~switch~~ controller is checked and adjusted to prevent forward-flow, unless the milk and/or milk product pressure in the pasteurized side of the regenerator section(s) is at least 6.9 kPa (1 psi) greater than the pressure in the raw milk and/or milk product side of the regenerator section(s). In the case of milk and/or milk product-to-water-to-milk or milk product regenerators, protected on the pasteurized side of the regenerator section(s), the "water side" of the regenerator section(s) shall be considered to be the "raw product side" for purposes of this Test.

Procedure:

1. Wire the test ~~lamp~~ light in series with the signal from the ~~pressure~~ differential pressure ~~switch~~ controller to the FDD.
2. Calibrate the ~~pressure~~ differential pressure ~~switch~~ controller and ~~probes~~ sensing elements. (Use Test 9.2.1.)
3. Adjust the pressure on the differential pressure ~~switch~~ controller ~~sensors~~ sensing elements to their normal operating pressures, with the pasteurized milk and/or milk product pressure at least 14 kPa (2 psi) higher than the raw milk and/or milk product pressure.
   a. The test ~~lamp~~ light ~~should~~ shall be lit. If not, increase the pasteurized milk and/or milk product pressure, or lower the raw milk and/or milk product pressure, until the test light is lit.
   b. Gradually lower the pasteurized ~~side~~ milk and/or milk product pressure, or raise the raw milk and/or milk product pressure until the test light turns off.
   c. The test light ~~should~~ shall turn off when the pasteurized milk and/or milk product pressure is at least 14 kPa (2 psi) higher than the raw milk and/or milk product pressure.
   d. Note the ~~differential~~ pressure differential at the point the test light turns off.
   e. Gradually raise the pasteurized milk and/or milk product pressure, or lower the raw milk and/or milk product pressure, until the test light turns on.
   f. The test light ~~should~~ shall not turn on until the pasteurized milk and/or milk product pressure is at least 14 kPa (2 psi) higher than the raw milk and/or milk product pressure. Note the ~~differential~~ pressure differential at the point the test light turns off.

NOTE: This Test may be completed using a pneumatic testing device capable of producing ~~differential pressures~~ pressure differentials on the ~~probes~~ sensing elements~~. This device should be capable of being operated, and be operated, in a manner so as to duplicate~~ duplicating the conditions described above.

4. ~~Seal the instrument and record~~ Record the results of the Test~~ results for the office record~~ on the appropriate Forms.

Action: If the differential pressure controller fails to respond as indicated above, an immediate check of the differential pressure controller is required by milk plant personnel to locate and

correct the problem. If after adjustment and/or repair the differential pressure controller fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

9.3 ADDITIONAL HTST PASTEURIZATION SYSTEM TESTS FOR BOOSTER PUMPS - INTERWIRING

Application: To all booster pumps used for HTST pasteurization systems where the FDD is located immediately ~~after~~ downstream of the holding tube, except ~~for those systems which are magnetic flow meter based timing systems,~~ that Test 9.3.2 is not required to be performed on magnetic flow meter based timing systems.
Frequency: Upon installation; at least once each three (3) months thereafter; whenever there is any change to the booster pump or the booster pump interwiring; or when the regulatory seal has been broken.
Criteria: The booster pump shall be wired so it cannot operate if the FDD is in the ~~diverted~~ diverted-flow position or if the timing pump is not in operation.
Apparatus:
1. A sanitary pressure gauge; ~~and~~
2. ~~pneumatic~~ Pneumatic testing device, ~~as~~ described in Test 9.1 ~~Pressure Switches~~ **PRESSURE SWITCHES,** can be used for checking and adjusting the differential pressure controller setting. (Refer to Test 9.1);
3. Water, oil or other suitable media bath and agitator; and
4. Suitable means of heating the ~~water~~ media bath.

9.3.1 BOOSTER PUMPS -INTERWIRED WITH FDD

Method: Determine if the booster pump stops running by dropping the temperature and causing the FDD to divert.
Procedure:
1. Connect the pasteurized regenerator section(s) differential pressure controller ~~sensor~~ sensing element to a testing tee with the other end of the testing tee capped.

NOTE: If there is water in the HTST pasteurization system, ensure that the ~~recorder/controller~~ recorder-controller ~~probe~~ sensing element and the pasteurized regenerator section (s) differential pressure controller ~~sensor~~ sensing element ports are capped before the timing pump is turned on.

2. Turn on the timing pump and the booster pump.
3. Place the ~~recorder/controller~~ recorder-controller ~~probe~~ sensing element in a hot ~~water~~ media bath, which is above the cut-in temperature.
4. ~~Turn up~~ Increase the air supply on the testing tee to provide an adequate pressure differential to start the booster pump. The booster pump shall start running.

5. Remove the ~~recorder/controller~~ recorder-controller ~~probe~~ sensing element from the hot ~~water~~ media bath.
6. When the FDD moves to the diverted-flow position, the booster pump ~~must~~ shall stop running. Ensure that the pressure differential remains ~~adequate~~ greater than or equal to 6.9 kPa (1 psi) and the other flow-promoting devices, which are capable of causing flow through the FDD, in the timing ~~pump~~ system ~~continues~~ continue to operate.
7. ~~Reseal the regulatory controls as necessary and record~~ Record the results of the Test ~~results for the office record~~ on the appropriate Form.
~~Corrective~~ Action: If the booster pump fails to stop running when the FDD is in the diverted-flow position, ~~have the~~ milk plant ~~maintenance~~ personnel ~~check the wiring~~ shall determine and correct the cause. If after adjustment and/or repair the booster pump fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

9.3.2 BOOSTER PUMPS - INTERWIRED WITH THE TIMING PUMP

Method: Determine if the booster pump stops running when the timing pump is ~~off~~ not running.
Procedure:
1. Connect the pasteurized regenerator section(s) differential pressure controller ~~sensor~~ sensing element to a testing tee with the other end of the testing tee capped.

NOTE: If there is water in the HTST pasteurization system, ensure that the ~~recorder/controller~~ recorder-controller ~~probe~~ sensing element and the pasteurized regenerator section(s) differential pressure controller ~~sensor~~ sensing element ports are capped before the timing pump is turned on.

2. Turn on the timing pump and the booster pump.
3. Place the ~~recorder/controller~~ recorder-controller ~~probe~~ sensing element in a hot ~~water~~ media bath, which is above the cut-in temperature.
4. ~~Turn up~~ Increase the air supply on the testing tee to provide an adequate pressure differential to start the booster pump. The booster pump ~~should~~ shall start running.
5. Turn off the timing pump. The booster pump ~~must~~ shall stop running. Ensure that the pressure differential remains adequate and the FDD remains in the forward-flow position.
6. ~~Reseal the regulatory controls as necessary and record~~ Record the results of the Test ~~results for the office record~~ on the appropriate Form.
~~Corrective~~ Action: If the booster pump fails to stop running when the timing pump ~~has been turned off~~ is not running, ~~have the~~ milk plant ~~maintenance~~ personnel shall determine and correct the cause. If after adjustment and/or repair the booster pump fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency,

in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

TEST 10.

MILK OR MILK PRODUCT FLOW CONTROLS AND THE MILK OR MILK PRODUCT TEMPERATURE AT CUT-IN AND CUT-OUT

References: Item 16p.(B) and (D)
Frequency: Milk and/or milk product flow controls shall be tested for the milk and/or milk product temperature at cut-in and cut-out by one (1) of the following applicable Tests at the frequency prescribed:
Apparatus:
1. Water, oil or other suitable media bath and agitator;
2. Suitable means of heating the media bath; and
3. Test light for Tests 10.2 and 10.3.

10.1 HTST ~~PASTEURIZERS~~ PASTEURIZATION SYSTEMS

Application: To ~~All~~ all ~~recorder/controllers~~ recorder-controllers used in connection with HTST ~~pasteurizers~~ pasteurization systems, except those in which the FDD is located downstream from ~~at the end of~~ the pasteurized regenerator section(s) and/or final cooler section.
Frequency: Upon installation; at least once each three (3) months thereafter ~~by the Regulatory Agency, or HACCP qualified industry person, acceptable to the Regulatory Agency, qualified under Item 16p(D)2~~; ~~daily by the milk plant operator~~; whenever the recorder-controller and/or recorder-controller thermometer has been repaired and/or replaced; or ~~when~~ whenever ~~a~~ the regulatory seal has been broken; and daily by a milk plant's pasteurization system operator.
Criteria: ~~No forward-flow~~ Forward-flow cannot be achieved until at least the minimum legal pasteurization temperature has been reached. Flow shall be diverted before the temperature drops below the minimum legal pasteurization temperature.
~~**Apparatus:** No supplemental materials needed.~~
Method: By observing the actual temperature of the indicating thermometer at the instant forward-flow starts (cut-in) and forward-flow stops (cut-out).
Procedure:
1. **Cut-in temperature:**
   a. While milk, milk product or water is completely flooding the sensing ~~element~~ elements of the ~~recorder/controller~~ recorder-controller and the indicating thermometer, which was previously tested against a known accurate test thermometer, increase the heat gradually so as to raise the temperature of the milk, milk product or water at a rate not ~~exceeding~~ to exceed 0.5ºC (1ºF) ~~every~~ per thirty (30) seconds. If a water, oil or other suitable media bath is used in place of milk, milk product or water flowing through the pasteurization system, the water, oil or other suitable media bath shall be adequately and continuously agitated during this Test.

b. Observe the indicating thermometer reading at the moment forward-flow ~~starts~~ begins, i.e., the FDD moves. Observe that the recorder-controller ~~frequency~~ event pen reading is synchronized with the recording pen on the same reference arc as on the recording chart.

c. Immediately ~~Record~~ record and identify on the recording chart, the observed indicating thermometer temperature reading at cut-in ~~on the recording thermometer chart~~ and initial the recording chart. This may be accomplished by inscribing a line intersecting the recorded temperature arc at the pen location or any other method acceptable to the Regulatory Agency. ~~The Regulatory Agency shall record Test findings.~~

2. **Cut-out temperature:**

a. After the cut-in temperature has been determined, and while the milk, milk product or water is above the cut-in temperature, allow the milk, milk product or water to cool slowly at a rate not ~~exceeding~~ to exceed 0.5ºC (1ºF) per thirty (30) seconds. If a water, oil or other suitable media bath is used in place of milk, milk product or water flowing through the pasteurization system, the water, oil or other suitable media bath shall be adequately and continuously agitated during this Test. ~~Observe the indicating thermometer reading at the instant forward-flow stops.~~

b. Observe the indicating thermometer reading at the moment flow is diverted. Observe that the recorder-controller event pen reading is synchronized with the recording pen on the same reference arc as on the recording chart.

~~b~~c. ~~Re-seal the regulatory controls as necessary and~~ Immediately record and identify on the recording chart, the observed indicating thermometer temperature reading at cut-out ~~on the recording thermometer chart~~ and initial the recording chart. This may be accomplished by inscribing a line intersecting the recorded temperature arc at the pen location or any other method acceptable to the Regulatory Agency.

3. Record the results of both the cut-in and cut-out Tests on the appropriate Form.

~~Corrective~~ Action: ~~Should~~ If the cut-in and/or cut-out ~~reading~~ indicating thermometer reading ~~be~~ is below the minimum legal pasteurization temperature, the cut-in ~~and~~ and/or cut-out setting(s) ~~mechanism and/or the differential temperature mechanism~~ ~~should~~ shall be adjusted by milk plant personnel ~~to obtain proper cut-in and cut-out temperatures by repeated Tests~~. ~~When compliance is achieved, seal the recorder/controller mechanism.~~ If after adjustment the cut-in and/or cut-out temperature(s) fail this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

10.2 ~~PASTEURIZERS~~ PASTEURIZATION SYSTEMS USING INDIRECT HEATING

Application: To ~~All~~ all HHST and HTST continuous-flow pasteurization systems with the FDD located downstream of the pasteurized regenerator section(s) and/or the final cooler section using indirect heating.

Frequency: Upon installation; at least once every three (3) months thereafter; whenever the recorder-controller and/or recorder-controller thermometer has been repaired and/or replaced; ~~and~~ or whenever the ~~thermal~~ ~~controller~~ recorder-controller thermometer regulatory seal ~~is~~ has been broken.

Criteria: The ~~pasteurizer~~ pasteurization system shall not operate in forward-flow unless the minimum legal pasteurization temperature has been achieved in the holding tube and at the FDD. The milk and/or milk product flow shall be diverted ~~at a temperature lower than~~ before the temperature falls below the ~~chosen~~ minimum legal pasteurization ~~standard~~ temperature in the holding tube.

~~**Apparatus:** No supplemental materials needed.~~

Method: The cut-in and cut-out temperatures as read from the indicating thermometer located within the pasteurization system are determined ~~by observing~~ using a ~~the actual temperature in the constant temperature~~ media bath ~~at which~~ and the ~~two (2)~~ sensing elements from the holding tube and the FDD. ~~signal forward-flow (cut-in) and diverted-flow (cut-out).~~

Procedure:

1. **Cut-in temperature:**

   a. Wire the test ~~lamp~~ light in series with the control contacts of the holding tube recorder-controller sensing element. Immerse ~~this~~ the recorder-controller and holding tube indicating sensing ~~element~~ elements in the ~~constant temperature~~ media bath. Raise the media bath temperature at a rate not ~~exceeding~~ to exceed 0.5ºC (1ºF) ~~every~~ per thirty (30) seconds. Observe the temperature reading on the indicating thermometer when the test light comes on, which is ~~at~~ the cut-in temperature. ~~Record the temperature for the office record.~~

   b. Record the observed indicating thermometer cut-in reading on the appropriate Form.

2. **Cut-out temperature:**

   a. After the cut-in temperature has been determined and while the media bath is above the cut-in temperature, allow the media bath to cool slowly at a rate not ~~exceeding~~ to exceed 0.5ºC (1ºF) per thirty (30) seconds. Observe the temperature reading on the ~~thermal-limit-controller~~ recorder-controller when the test ~~lamp~~ light goes out, which is the cut-out temperature. Determine that the cut-out temperature, on the ~~thermal-limit-controller~~ recorder-controller is equivalent to or greater than the ~~chosen~~ minimum legal pasteurization ~~standard~~ temperature. ~~Where adjustment is necessary, refer to the manufacturer's instructions. After adjustment, repeat the procedure above, and when the results are satisfactory, record the results for the office records.~~

   b. Record the observed indicating thermometer cut-out reading on the appropriate Form.

3. Repeat the procedure for the FDD sensing element. Rewire the test light in series with the control contacts for the FDD sensing element. ~~When proper cut-out temperature has been verified for both sensing elements, seal the thermal-limit-controller system.~~

Action: Whenever adjustment is necessary, refer to the manufacturer's instructions. Retest the cut-in and cut-out temperatures after any adjustment, repair, replacement or whenever the regulatory seal has been broken. If after adjustment the cut-in and/or cut-out temperature(s) fail this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

10.3 ~~PASTEURIZERS~~ PASTEURIZATION SYSTEMS USING DIRECT HEATING

Application: To ~~All~~ all HHST and HTST continuous-flow pasteurization systems with the FDD located downstream of the pasteurized regenerator section(s) and/or the final cooler section using direct heating.

Frequency: Upon installation; at least once every three (3) months thereafter; whenever the recorder-controller and/or recorder-controller thermometer has been repaired and/or replaced; ~~and~~ or whenever the ~~thermal-limit-controller~~ recorder-controller thermometer regulatory seal ~~is~~ has been broken.

Criteria: The ~~pasteurizer~~ pasteurization system shall not operate in forward-flow unless the minimum legal pasteurization temperature has been achieved in the holding tube, at the vacuum chamber and at the FDD. The milk and/or milk product flow shall be diverted ~~at a temperature lower than~~ before the temperature falls below the ~~chosen~~ minimum legal pasteurization ~~standard~~ temperature in the holding tube.

~~**Apparatus:** No supplemental materials needed.~~

Method: The cut-in and cut-out temperatures as read from the indicating thermometer located within the pasteurization system are determined ~~by observing~~ using a ~~the actual temperature in the constant temperature~~ media bath ~~at which each of~~ and the ~~three (3)~~ sensing elements from the holding tube, vacuum chamber and the FDD ~~signals forward-flow (cut-in) and diverted-flow (cut-out)~~.

Procedure:

1. **Cut-in temperature:**
   a. Wire the test ~~lamp~~ light in series with the control contacts of the holding tube recorder-controller sensing element. Immerse ~~this~~ the recorder-controller and holding tube indicating sensing ~~element~~ elements in the ~~constant temperature~~ media bath. Raise the media bath temperature at a rate not ~~exceeding~~ to exceed 0.5ºC (1ºF) ~~every~~ per thirty (30) seconds. Observe the temperature reading on the ~~thermal-limit-controller~~ indicating thermometer when the test ~~lamp lights~~ light comes on, which is the cut-in temperature. ~~Record the temperature for the office record.~~
   b. Record the observed indicating thermometer cut-in reading on the appropriate Form.
2. **Cut-out temperature:**
   a. After the cut-in temperature has been determined and while the media bath is above the cut-in temperature, allow the media bath to cool slowly at a rate not ~~exceeding~~ to exceed 0.5ºC (1ºF) per thirty (30) seconds. Observe the temperature reading on the ~~thermal-limit-controller~~ recorder-controller when the test ~~lamp~~ light goes out, which is the cut-out temperature. Determine that the cut-out temperature, on the ~~thermal-limit-controller~~ recorder-controller is equivalent to or greater than the ~~chosen~~ minimum legal pasteurization ~~standard~~ temperature. ~~Where adjustment is necessary, refer to the manufacturer's instructions. After adjustment, repeat the procedure above, and when the results are satisfactory, record the results for the office records.~~
   b. Record the observed indicating thermometer cut-out reading on the appropriate Form.
3. Repeat the procedure for the other two (2) sensing elements, ~~i.e.,~~ from the vacuum chamber and the FDD. Rewire the test ~~lamp~~ light in series with the control contacts ~~from~~ for each sensing element, respectively. ~~When proper cut-out temperatures have been verified for all three (3) sensing elements, seal the thermal-limit-controller system.~~

Action: Whenever adjustment is necessary, refer to the manufacturer's instructions. Retest the cut-in and cut-out temperatures after any adjustment, repair, replacement or whenever the regulatory seal has been broken. If after adjustment the cut-in and/or cut-out temperature(s) fail this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

TEST 11.

CONTINUOUS-FLOW PASTEURIZATION SYSTEM HOLDING TUBES – PASTEURIZATION HOLDING TIME

(Continuous-flow pasteurization system holding tubes shall be tested for pasteurization holding times by one (1) of the following applicable Tests.)

Reference: Item 16p.(B) and (D)
~~Continuous-flow holding tubes shall be tested for holding times by one (1) of the following applicable Tests:~~

11.1 HTST ~~PASTEURIZERS~~ PASTEURIZATION SYSTEMS

(Except for magnetic flow meter based timing systems)

Application: To all HTST ~~pasteurizers~~ continuous-flow pasteurization systems employing a pasteurization holding time of fifteen (15) seconds or longer, except for magnetic flow meter based timing systems.
Frequency: Upon installation; ~~semi-annually~~ at least once every six (6) months thereafter; ~~whenever the seal on the speed setting is broken;~~ whenever any alteration is made affecting the pasteurization holding time, the velocity of the flow, such as the replacement of the timing pump, motor, belt, drive or driven pulleys, or a decrease in the number of HTST pasteurization system heat-exchange plates or the capacity of the holding tube; ~~or~~ whenever a check of the capacity of the holding tube indicates a speedup; or whenever the regulatory seal on the timing pump speed setting has been broken.
Criteria: Every particle of milk and/or milk product shall be held for at least ~~fifteen (15) seconds~~ a minimum legal pasteurization holding time of fifteen (15) seconds or twenty-five (25) seconds, respectively in both ~~the forward~~ forward-flow and diverted-flow ~~positions~~.
Apparatus:
1. An ~~Electrical~~ electrical conductivity measuring device, which is capable of detecting a change in conductivity, and is equipped with standard electrodes;
2. Table salt (sodium chloride) or other appropriate conductive solution;
3. A suitable apparatus for injecting the salt solution or other appropriate conductive solution ~~(50 ml syringe)~~ into the holding tube; and
4. An accurate ~~timing~~ time measuring device.

Method: The pasteurization holding time is determined by timing the interval for an ~~added~~ injected trace substance, such as sodium chloride, to pass through the entire length of the legal

holding tube. Although the time interval of the fastest particle of milk and/or milk product is desired, ~~the~~ this conductivity Test is ~~made~~ performed ~~with~~ using water. The results ~~found with~~ obtained when using water are converted to the milk and/or milk product flow pasteurization holding time, ~~by~~ using either the volume or weight formulation, as shown below, since a timing pump may not deliver the same amount of milk and/or milk product as it does water.

Procedure:

1. ~~Examine the entire~~ Operate the pasteurization system on water, ~~to insure that~~ with all flow-promoting ~~equipment is~~ devices, which are capable of causing flow through the FDD, operating at their maximum capacity and all flow-impeding ~~equipment is~~ devices ~~so~~ adjusted or bypassed ~~as~~ to provide the minimum amount of resistance to the flow through the pasteurization system. There shall not be ~~no~~ any leakage on the suction side of the timing pump.

   a. For a variable speed timing pump adjust the timing pump to its maximum capacity, preferably with a new belt and full size impellers.

   b. For a homogenizer used as the timing pump, check the homogenizer for its regulatory seal(s), and gears or pulley identification.

   c. For AC variable speed timing pump, check the timing pump's control box for its regulatory seal(s).

   NOTE: For pasteurization systems that employ a liquid ingredient injection (slurry) system as described in Appendix H., the slurry injection pump shall be energized and running at its maximum speed and the slurry supply tank shall be completely filled with water.

~~2. Adjust the variable speed pump to its maximum capacity, preferably with a new belt and full size impellers. Check the homogenizer for seals, and/or gears or pulley identification. Check the AC variable speed timing pump control box for seals. For systems that employ a liquid ingredient injection (slurry) system as described in Appendix H., the slurry pump must be energized and running at its maximum speed and the slurry supply tank must be completely filled with water.~~

~~3~~2. Install one (1) electrode at the ~~inlet to~~ beginning of the legal holding tube and the other electrode ~~in~~ at the end of the legal holding tube ~~outlet~~.

~~4~~3. Operate the ~~pasteurizer~~ pasteurization system~~,~~ using water at or above the minimum legal pasteurization temperature, with the FDD in the forward-flow position.

~~5~~4. Quickly inject a saturated sodium chloride or other appropriate conductive solution into the inlet at the beginning of the legal holding tube ~~inlet~~.

~~6~~5. The ~~timer~~ accurate time measuring device ~~should~~ shall start when it detects a change in conductivity ~~and~~ at the beginning of the legal holding tube.

~~7~~6. The ~~timer~~ accurate time measuring device ~~should~~ shall stop when it detects a change in conductivity ~~and~~ at the end of the legal holding tube.

~~8. Record the results.~~

~~9~~7. Repeat ~~the~~ this Test six (6) or more times, until six (6) ~~successive~~ consecutive results are within 0.5 seconds of each other. The average of these six (6) Tests is the pasteurization holding time for water in forward-flow. ~~When consistent readings cannot be obtained, purge the equipment, check instruments and connections and check for air leakage on the suction side. Repeat this Test. Should consistent readings not be obtained, use the fastest time as the holding time for water.~~

NOTE: When consistent Test readings cannot be obtained, purge the pasteurization system, check the Testing instruments and connections and check for any air leakage on the suction side of the timing pump. Repeat **Procedure** 7. When consistent readings cannot be obtained after repeating **Procedure** 7, use the fastest time obtained from any of these Tests as the pasteurization holding time for water in forward-flow.

8. Record all of the pasteurization holding time results for water in forward-flow as conducted in **Procedure** 7 above and the average of these six (6) Tests on the appropriate Form.

~~10~~9. Repeat **Procedures** ~~4~~ 3 through ~~9~~ 7 above for the pasteurization holding time ~~on~~ for water in diverted-flow.

~~For all gear driven timing pumps complete **Procedures** 11, 12 and 13. For those homogenizers used as timing pumps, when the measured holding time for water is less than 120% of the legal holding time, complete **Procedures** 11, 12 and 13. For those homogenizers used as timing pumps, when the measured holding time for water is 120% or more of the legal holding time, **Procedure** 11 is optional and **Procedure** 12 and 13 are not required.~~

10. Record all of the pasteurization holding time results for water in diverted-flow as conducted in **Procedure** 9 above on the appropriate Form.

11. Complete a., b. or c. below as appropriate:

a. For all gear driven timing pumps complete **Procedures** 12 through 16 below.

b. For those homogenizers used as timing pumps, when the measured pasteurization holding time for water is less than 120% of the minimum legal pasteurization holding time, complete **Procedures** 12 through 16 below.

c. For those homogenizers used as timing pumps, when the measured pasteurization holding time for water is 120% or more of the minimum legal pasteurization holding time, **Procedure** 12 is optional and **Procedure** 13 through 16 below are not required.

~~11~~12. With the timing pump at the same speed and all other ~~equipment~~ flow-promoting devices, which are capable of causing flow through the FDD, and flow-impeding devices adjusted as cited in **Procedure** 1, determine the time it takes to fill ~~the filling of~~ a 38 liter (10 gallon) can with a measured weight or volume of water, using the pasteurization system discharge outlet with the same head pressure as ~~in normal~~ is normally used during the operation of the pasteurization system. Average the ~~time~~ filling times ~~of~~ for several trials (minimum of three (3)). ~~Since flow rates of the large capacity units make it very difficult to check by filling a 38 liter (10 gallon) can, it is suggested, that a calibrated tank of considerable size be used.~~

NOTE: Since flow rates of a large capacity unit makes it very difficult to determine the time it takes to fill a 38 liter (10 gallon) can with a measured weight or volume of water, it is recommended that a calibrated tank of considerable size be used. It is also acceptable to use any other means to determine a measured weight or volume of water.

13. Record all of the can fill time results and the average time it takes to fill a 38 liter (10 gallon) can or other means as described in the **NOTE** above with a measured weight or volume of water for **Procedure** 12 above on the appropriate Form.

~~12~~14. Repeat **Procedure** ~~11~~ 12 above using milk.

15. Record the average time it takes to fill a 38 liter (10 gallon) can or other means used with a measured weight or volume of milk for **Procedure** 14 above on the appropriate Form.

~~13~~16. Compute the pasteurization holding time for milk from one (1) of the following formulas, either by volume or by weight. Compute separately for forward-flow and diverted-flow. ~~Re-seal the regulatory controls as necessary~~.

BY VOLUME:

The adjusted pasteurization holding time for milk is equal to: ~~the~~

The pasteurization holding time for water~~;~~, times the quotient of the time it takes to deliver a volume of milk~~;~~ divided by the time it takes to deliver the same volume of water.

Tm = Tw(Vm/Vw)

Where: Tm = Adjusted product pasteurization holding time for milk.
Tw = Pasteurization ~~Holding~~ holding time for water, the salt (sodium chloride or other appropriate conductive solution) ~~Test~~ test results.
Vm = Time, usually in seconds, that it takes to pump a known volume of milk.
Vw = Time, usually in seconds, that it takes to pump ~~a~~ the same volume of water.
~~Vm = Time, usually in seconds, that it takes to pump the same volume of milk.~~

BY WEIGHT (Using specific gravity):

The adjusted pasteurization holding time for milk is equal to:

~~the~~ The specific gravity of milk~~;~~, times the pasteurization holding time for water~~;~~, times the quotient of the time it takes to deliver a measured weight of milk~~;~~ divided by the time it takes to deliver the same weight of water.

Tm = 1.032xTw(Wm/Ww)

Where: Tm = Adjusted product pasteurization holding time for milk.
1.032 = The specific gravity of milk

NOTE: If another milk product is used, use the appropriate specific gravity.

~~Tm = Adjusted product holding time for milk.~~
Tw = Pasteurization ~~Holding~~ holding time for water, the salt (sodium chloride or other appropriate conductive solution) ~~Test~~ test results.
Wm = Time, usually in seconds, that it takes to pump a measured weight of milk.
Ww = Time, usually in seconds, that it takes to pump the same measured weight of water.

~~14~~17. Record the computed adjusted pasteurization holding time for forward-flow and divert-flow for milk, using either the formula for volume or weight as identified in **Procedure** 16 above, ~~results for the office record~~ on the appropriate Form.

~~**Corrective** **Action:**~~ When the computed adjusted pasteurization holding time for milk is less than ~~that required~~ the minimum legal pasteurization holding time, either in forward-flow or diverted-flow, the speed of the timing pump shall be reduced or an adjustment shall be made ~~in~~ to the length or diameter of the holding tube and ~~the timing~~ Test 11.1 shall be repeated until a satisfactory pasteurization holding time is achieved. ~~Should~~ If an orifice (restrictor) ~~be used~~ is required to be installed in the FDD divert line to ~~correct~~ comply with the minimum legal pasteurization ~~the~~ holding time in diverted-flow, there ~~should~~ shall not be ~~no~~ any excessive pressure exerted on the underside of the valve seat of the FDD. ~~Governors~~ Variable speed drives shall be sealed ~~on~~ for motors on timing pumps that do not provide a constant speed as provided for in Item ~~16p(B)5.b~~ 16p(B)2.f.(2). If after adjustment the pasteurization holding time fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

11.2A CONTINUOUS-FLOW PASTEURIZATION SYSTEMS UTILIZING A MAGNETIC FLOW METER BASED TIMING ~~SYSTEMS~~ SYSTEM ~~CONTINUOUS-FLOW~~ - PASTEURIZATION HOLDING TIME

Application: To all HTST ~~pasteurizers~~ continuous-flow pasteurization systems with a magnetic flow meter based timing system, used in lieu of a timing pump.
Frequency: Upon installation; ~~semiannually~~ at least once every six (6) months thereafter; ~~whenever a seal on the flow alarm is broken;~~ whenever any alteration is made affecting the pasteurization holding time, the velocity of the flow or the capacity of holding tube; or whenever a check of the capacity indicates a speed up; or whenever the regulatory seal on the flow alarm has been broken.
Criteria: Every particle of milk and/or milk product shall be held for at least a minimum legal pasteurization holding time of fifteen (15) seconds or twenty-five (25) seconds, respectively in both ~~the forward~~ forward-flow and diverted-flow ~~positions~~.
Apparatus:
1. An ~~Electrical~~ electrical conductivity measuring device, which is capable of detecting a change in conductivity, and is equipped with standard electrodes;
2. Table salt (sodium chloride) or other appropriate conductive solution;
3. A suitable apparatus for injecting the salt solution or other appropriate conductive solution ~~(50 ml syringe)~~ into the holding tube; ~~and~~
4. An accurate ~~timing~~ time measuring device.;
5. Water, oil or other suitable media bath and agitator; and
6. Suitable means of heating the media bath.

Method: The pasteurization holding time is determined by timing the interval for an ~~added~~ injected trace substance, such as sodium chloride, to pass through the entire length of the legal holding tube.
Procedure:
Utilize either **TEST OPTION I** or **TEST OPTION II**.

TEST OPTION I:

1. Adjust the set point on the high flow alarm above the estimated acceptable flow rate or bypass the high flow alarm.
2. Adjust the set point on the flow ~~recorder/controller~~ recorder-controller to a flow rate estimated to yield an acceptable pasteurization holding time.
3. Install one (1) electrode at the ~~inlet to~~ beginning of the legal holding tube and the other electrode at the end of the legal holding tube ~~outlet~~.
4. Operate the ~~pasteurizer~~ pasteurization system~~,~~ using water~~,~~ at or above the minimum legal pasteurization temperature, with the FDD in the forward-flow position.

NOTE: The appropriate temperature sensing elements may be placed in a water, ~~or~~ oil or other suitable media bath to simulate the ~~normal~~ minimum legal pasteurization temperature ~~of~~ in the holding tube as an alternative method to the heating of ~~the~~ water in the pasteurization system above the minimum legal pasteurization temperature.

5. Quickly inject ~~the~~ a saturated sodium chloride or other appropriate conductive solution into the inlet at the beginning of the legal holding tube ~~inlet~~.
6. The ~~timer~~ accurate time measuring device ~~should~~ shall start when it detects a change in conductivity at the beginning of the legal holding tube.
7. The ~~timer~~ accurate time measuring device ~~should~~ shall stop when it detects a change in conductivity at the end of the legal holding tube.
~~8. Record the results.~~
~~9~~8. Repeat ~~the~~ this Test six (6) or more times, until six (6) ~~successive~~ consecutive results are within 0.5 seconds of each other. The average of these six (6) Tests is the pasteurization holding time for water in forward-flow. ~~When consistent readings cannot be obtained, purge the equipment, check the instruments and connections; and check for air leakage on the suction side of the pump, located at the constant-level tank. Repeat this Test.~~ If six (6) consecutive ~~readings~~ Tests cannot be achieved within 0.5 seconds of each other, ~~the pasteurizing system is in need of repair~~ refer to the **Action** below.
9. Record all of the pasteurization holding time results for water in forward-flow as conducted in Procedure 8 above and the average of these six (6) Tests on the appropriate Form.
10. This procedure is not a required Test; it is at the option of the Regulatory Agency. With the flow ~~recorder/controller~~ rate recorder-controller at the same set point as in **Procedure** 2, determine the time ~~the~~ it takes to ~~filling of~~ fill a 38 liter (10 gallon) can with a measured weight or volume of water using the pasteurization system discharge outlet, with the same head pressure as ~~in normal~~ is normally used during the operation of the pasteurization system. Average the time of several trials (minimum of three (3)). Since ~~the~~ flow rates of ~~the~~ a large capacity ~~units~~ unit ~~make~~ makes it very difficult to ~~check by filling~~ determine the time it takes to fill a 38 liter (10 gallon) can with a measured weight or volume of water, it is suggested that a calibrated tank of considerable size be used. ~~This procedure is not a required Test; it is at the option of the Regulatory Agency.~~ It is also acceptable to use any other means to determine a measured weight or volume of water.
11. ~~Re-seal the regulatory controls as necessary and record this result for the office record.~~ If the Regulatory Agency chooses to conduct **Procedure** 10 above, record all of the can fill time

results and the average time it takes to fill a 38 liter (10 gallon) can or other means used with a measured weight or volume of milk for **Procedure** 10 above on the appropriate Form.

TEST OPTION II:

1. Install one (1) electrode at the ~~inlet to~~ beginning of the legal holding tube and the other electrode at the end of the legal holding tube ~~outlet~~.
2. Operate the ~~pasteurizer~~ pasteurization system~~,~~ using water~~,~~ with the FDD in the ~~diverted flow~~ divert-flow position at a flow rate just above the high flow alarm set point.
3. Quickly inject ~~the~~ a saturated sodium chloride or other appropriate conductive solution into the inlet at the beginning of the legal holding tube ~~inlet~~.
4. The ~~timer~~ accurate time measuring device ~~should~~ shall start when it detects a change in conductivity at the beginning of the legal holding tube.
5. The ~~timer~~ accurate time measuring device ~~should~~ shall stop when it detects a change in conductivity at the end of the legal holding tube.
~~6. Record the results.~~
~~7~~6. Repeat ~~the~~ this ~~test~~ Test six (6) or more times, until six (6) ~~successive~~ consecutive results are within 0.5 seconds of each other. The average of these six (6) Tests is the pasteurization holding time for water in diverted-flow. ~~When consistent readings cannot be obtained, purge the equipment, check the instruments and connections; and check for air leakage on the suction side of the pump, located at the constant-level tank. Repeat this Test.~~ If six (6) consecutive ~~readings~~ Tests cannot be achieved within 0.5 seconds of each other, ~~the pasteurizing system is in need of repair~~ refer to the **Action** below.
7. Record all of the pasteurization holding time results for water in diverted-flow as conducted in Procedure 6 above and the average of these six (6) Tests on the appropriate Form.
8. If the ~~required~~ minimum legal pasteurization holding time is achieved in diverted-flow ~~with this~~ when conducting **TEST OPTION II**, all flows through the pasteurization system below the high flow alarm set point will meet the required minimum legal pasteurization holding time in forward-flow. Proceed to ~~Procedure~~ **Procedure** 10 below.
9. If the Test results, when conducting **TEST OPTION II**, are not all above the required minimum legal pasteurization holding time in diverted-flow, **TEST OPTION I** ~~must~~ shall be conducted.
10. This procedure is not a required Test; it is at the option of the Regulatory Agency. With the flow ~~recorder/controller~~ rate recorder-controller at the same set point as in **Procedure** 2, determine the time ~~the~~ it takes to ~~filling of~~ fill a 38 liter (10 gallon) can with a measured weight or volume of water using the pasteurization system discharge outlet, with the same head pressure as ~~in normal~~ is normally used during the operation of the pasteurization system. Average the time of several trials (minimum of three (3). Since ~~the~~ flow rates of ~~the~~ a large capacity ~~units~~ unit ~~make~~ makes it very difficult to ~~check by filling~~ determine the time it takes to fill a 38 liter (10 gallon) can with a measured weight or volume of water, it is suggested that a calibrated tank of considerable size be used. ~~This procedure is not a required Test; it is at the option of the Regulatory Agency.~~ It is also acceptable to use any other means to determine a measured weight or volume of water.
11. ~~Record this result for the office record.~~

If the Regulatory Agency chooses to conduct **Procedure** 10 above, record all of the can fill time results and the average time it takes to fill a 38 liter (10 gallon) can or other means used with a measured weight or volume of milk for **Procedure** 10 above on the appropriate Form.
~~**Corrective** **Action:**~~ When the computed pasteurization holding time for milk is less than ~~that required~~ the minimum legal pasteurization holding time in diverted-flow, the set point on the flow rate ~~recorder/controller~~ recorder-controller shall be decreased, or an adjustment shall be made in the length or diameter of the legal holding tube by milk plant personnel to correct the pasteurization holding time, and ~~the timing~~ ~~Test~~ **TEST OPTION I** shall be repeated until a satisfactory pasteurization holding time is achieved. If after adjustment the pasteurization system fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

11.2B CONTINUOUS-FLOW PASTEURIZATION SYSTEMS UTILIZING A MAGNETIC FLOW METER BASED TIMING SYSTEM - HOLDING TUBES AND HIGH FLOW ALARM

Application: To all continuous-flow pasteurization systems using a magnetic flow meter based timing system ~~to replace~~, in lieu of a timing pump.
Frequency: Upon installation; ~~semiannually~~ at least once every six (6) months thereafter; ~~whenever a seal on the flow alarm is broken;~~ whenever any alteration is made affecting the pasteurization holding time, the velocity of the flow or the capacity of the holding tube; ~~or~~ whenever a check of the capacity of the holding tube indicates a speedup; or whenever the regulatory seal on the high flow alarm has been broken.
Criteria: ~~When~~ Whenever the high flow rate equals or exceeds the value at which the pasteurization holding time was measured, the high flow alarm shall cause the FDD to assume the ~~diverted~~ diverted-flow position, even though the temperature of the milk and/or milk product in the holding tube is above the minimum legal pasteurization temperature.
Apparatus: ~~None.~~ No supplementary materials required.
Method: The high flow alarm set point ~~must~~ shall be set so that flow is diverted when the flow rate equals or exceeds the value at which the pasteurization holding time was measured or calculated. ~~(Refer to **Procedure** 3 or 4 of this Test.)~~
Procedure:
1. Operate the ~~pasteurizer~~ pasteurization system, using water above the minimum legal pasteurization temperature, in forward-flow, at a flow rate below the high flow alarm set point~~, using water above the pasteurization temperature~~.

NOTE: The appropriate temperature sensing elements may be placed in a water, ~~or~~ oil or other suitable media bath to simulate the ~~normal~~ processing pasteurization temperature within ~~of~~ the holding tube as an alternative to heating ~~the~~ water in the pasteurization system above the minimum legal pasteurization temperature. ~~Observation and recording of this temperature should be done as described in **Procedures** 3 and 4 below.~~

2. Slowly raise the flow rate of the pasteurization system until the ~~frequency pen on the flow recorder/controller indicates that flow has been diverted~~ following occur:

a. The frequency pen(s) on the STLR and the flow rate recorder-controller(s) indicate that the FDD is in the diverted-flow position.

b. Observe that the FDD moved to the diverted-flow position.

~~**NOTE:** When performing this Test on systems that operate above the boiling point of water, be sure that the system is cooling to avoid the possibility of serious burns.~~

~~3. Observe that the FDD moved to the diverted position, while the temperature requirements are satisfied. Record the rate of flow where the FDD moved to the diverted position~~

4~~3~~. ~~Re-seal the regulatory controls as necessary.~~ Record the rate of flow; the set point of the high flow alarm ~~at the occurrence of flow diversion~~; and the temperature on the STLR ~~recording device during the flow alarm divert;~~ at the occurrence of flow-diversion for this Test ~~the official record~~ on the appropriate Form.

~~Corrective~~ Action: If the FDD does not move to the ~~diverted~~ diverted-flow position, when the frequency pen of the ~~recorder/controller~~ flow rate recorder-controller indicates a ~~diversion~~ flow-diversion, milk plant personnel shall make a modification ~~or repair of the control wiring~~ to the FDD or the STLR recorder-controller ~~is~~ as required. If after adjustment the pasteurization system fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

11.2C CONTINUOUS-FLOW PASTEURIZATION SYSTEMS UTILIZING A MAGNETIC FLOW METER BASED TIMING SYSTEM - HOLDING TUBES AND LOW FLOW/LOSS-OF-SIGNAL ALARM

Application: To all continuous-flow pasteurization systems using a magnetic flow meter based timing system ~~to replace~~, in lieu of a timing pump.

Frequency: Upon installation; ~~semiannually~~ at least once every six (6) months thereafter; ~~whenever a seal on the flow alarm is broken; or~~ whenever any alteration is made affecting the ~~holding time~~ flow rate in the holding tube; or whenever the regulatory seal on the low flow/loss-of-signal flow alarm has been broken.

Criteria: Forward-flow occurs only when flow rates are above the ~~loss-of-signal~~ low flow/loss-of-signal alarm set point.

Apparatus: ~~None.~~ No supplementary materials required.

Method: By observing the actions of the frequency ~~pens~~ pen on the ~~recorder/controller~~ flow rate recorder-controller and the position of the FDD.

Procedure:

1. Operate the ~~pasteurizer~~ pasteurization system, using water, in forward-flow~~,~~ at a flow rate below the high flow alarm set point and above the low flow/loss-of-signal alarm set point~~, using water~~.

NOTE: The appropriate temperature sensing elements may be placed in a water, oil or other suitable media bath to simulate the processing pasteurization temperature within the holding tube as an alternative to heating water in the pasteurization system above the minimum legal pasteurization temperature.

2. Disrupt the power to the magnetic flow meter to activate the loss-of-signal alarm or decrease the flow through the flow meter to a flow rate below the low flow~~/loss-of-signal~~ alarm set point. Observe that the FDD assumes the diverted-flow position and ~~both~~ that the ~~safety thermal limit recorder/controller~~ frequency ~~pen~~ pen(s) on the STLR and the flow rate recorder-controller(s) ~~frequency pen assume~~ assumed the diverted-flow position.
3. ~~Re-seal the regulatory controls as necessary and record the results for the office record.~~ Record the results of this Test and the low flow/loss-of-signal alarm set point, if applicable on the appropriate Form.
~~Corrective~~ Action: If the ~~valve~~ FDD does not divert or the frequency pens do not ~~move~~ assume the diverted-flow position, milk plant personnel shall make an adjustment ~~of~~ to the low flow/loss-of-signal alarm or a modification ~~or repair of the control wiring~~ to the FDD, the STLR or flow rate recorder-controller ~~is~~ as required. If after adjustment the pasteurization system fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

11.2D CONTINUOUS-FLOW PASTEURIZATION SYSTEMS UTILIZING A MAGNETIC FLOW METER BASED TIMING SYSTEM - HOLDING TUBES AND FLOW RATE CUT-IN AND CUT-OUT

Application: To all HTST ~~pasteurizers~~ continuous-flow pasteurization systems using a magnetic flow meter based timing system ~~to replace~~, in lieu of a timing pump.
Frequency: Upon installation; ~~semiannually~~ at least once every six (6) months thereafter; ~~whenever a seal on the flow alarm is broken;~~ whenever any alteration is made affecting the pasteurization holding time, the velocity of the flow or the capacity of the holding tube; ~~or~~ whenever a check of the capacity of the holding tube indicates a speedup; or whenever the regulatory seal on the high flow and/or low flow/loss-of-signal alarm(s) has been broken.
Criteria: Forward-flow occurs only when flow rates are below the high flow alarm set point and above the low flow/loss-of-signal alarm set point.
Apparatus: ~~None.~~ No supplementary materials required.
Method: By observing the ~~recorder/controller~~ flow rate recorder-controller's readings along with the action of the frequency pen on the ~~recorder/controller~~ flow rate recorder-controller and the position of the FDD.
Procedure:
1. Operate the ~~pasteurizer~~ pasteurization system, using water above the minimum legal pasteurization temperature, in forward-flow~~,~~ at a flow rate below the high flow alarm set point and above the low flow/loss-of-signal alarm set point~~, using water above the pasteurization temperature~~.

NOTE: The appropriate temperature sensing elements may be placed in a water, oil or other suitable media bath to simulate the processing pasteurization temperature within the holding tube as an alternative to heating water in the pasteurization system above the minimum legal pasteurization temperature.

2. Using the flow rate ~~recorder/controller~~ recorder-controller, slowly increase the flow rate ~~slowly~~ until the frequency pen on the flow rate ~~recorder/controller~~ recorder-controller indicates a ~~flow diversion~~ flow-diversion, because the high flow ~~cut-out~~ alarm set point had been exceeded. The FDD ~~will~~ shall ~~also~~ assume the ~~diverted~~ diverted-flow position. Observe the flow rate reading ~~of flow rate~~ from the flow rate ~~recorder/controller~~ recorder-controller ~~at~~ the instant ~~flow~~ forward-flow cut-out occurs, as indicated by the flow rate recorder-controller's frequency pen.
3. With the ~~pasteurizer~~ pasteurization system operating on water, above the minimum legal pasteurization temperature~~,~~ and with the FDD in the ~~diverted~~ diverted-flow position ~~because of excessive~~ due to exceeding the high flow ~~rate~~ alarm set point, slowly decrease the flow rate until the frequency pen on the flow rate ~~recorder/controller~~ recorder-controller indicates the start of ~~a~~ the FDD's forward-flow movement, which indicates the flow rate cut-in point. Because of the time delay ~~relay~~ described in Test ~~11.2~~ 11.2E, the FDD will not move immediately to the forward-flow position. Observe the flow rate reading from the flow rate ~~recorder/controller~~ recorder-controller ~~at~~ the instant flow rate cut-in occurs, as indicated by the flow rate recorder-controller's frequency pen.
4. ~~Re-seal the regulatory controls as necessary and record the results for the office record.~~ Record the flow rate cut-in and cut-out results of this Test on the appropriate Form.
~~**Corrective** **Action:** If the flow rate cut-in or cut-out ~~point~~ point(s) occurs at a flow rate equal to or greater than the value at which the pasteurization holding time was measured, milk plant personnel shall adjust the high flow alarm to a lower set point, and ~~repeat~~ ~~the~~ this Test shall be repeated. If after adjustment the pasteurization system fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

11.2E CONTINUOUS-FLOW PASTEURIZATION SYSTEMS UTILIZING A MAGNETIC FLOW METER BASED TIMING SYSTEM - HOLDING TUBES AND TIME DELAY ~~RELAY~~

Application: To all HTST ~~pasteurizers~~ continuous-flow pasteurization systems with a FDD located at the end of the holding tube that use a magnetic flow meter based timing system ~~to replace~~, in lieu of a timing pump.
Frequency: Upon installation; ~~semiannually~~ at least once every six (6) months thereafter; ~~whenever the seal on the flow alarm is broken;~~ whenever any alteration is made affecting the pasteurization holding time, the velocity of the flow or the capacity of the holding tube; ~~or~~ whenever a check of the capacity of the holding tube indicates a speedup; or whenever the regulatory seal on the flow alarm has been broken.

Criteria: Following the determination of the flow rate cut-in, as described in Test 11.2D, forward-flow shall not occur until all milk and/or milk product in the holding tube has been held at or above the minimum legal pasteurization temperature for at least the minimum legal pasteurization holding time.
Apparatus: ~~Stopwatch~~ An accurate time measuring device.
Method: Set the time delay equal to or greater than the minimum legal pasteurization holding time.
Procedure:
1. Operate the ~~pasteurizer~~ pasteurization system, using water above the minimum legal pasteurization temperature, in forward-flow~~,~~ at a flow rate below the high flow alarm set point and above the low flow/loss-of-signal alarm set point~~, using water above the pasteurization temperature~~.

NOTE: The appropriate temperature sensing elements may be placed in a water, oil or other suitable media bath to simulate the processing pasteurization temperature within the holding tube as an alternative to heating water in the pasteurization system above the minimum legal pasteurization temperature.

2. Using the flow rate ~~recorder/controller~~ recorder-controller, slowly increase the flow rate ~~slowly~~ until the frequency pen on the flow rate ~~recorder/controller~~ recorder-controller indicates a ~~diversion~~ flow-diversion ~~movement~~ and the FDD moves to the ~~diverted~~ diverted-flow position. There shall not be ~~no~~ any time delay between the movements of the flow rate recorder-controller's frequency pen and the FDD.
3. With the ~~pasteurizer~~ pasteurization system operating on water, above the minimum legal pasteurization temperature~~,~~ and with the FDD in the ~~diverted~~ diverted-flow position, ~~because of excessive~~ due to exceeding the high flow ~~rate~~ alarm set point, slowly decrease the flow rate.
4. Start the ~~stopwatch~~ accurate device the instant the flow rate recorder-controller's frequency pen ~~on the flow recorder/controller~~ indicates ~~the start of a forward-flow movement~~ flow rate cut-in.
5. Stop the ~~stopwatch~~ accurate time measuring device the instant the FDD starts to move to the forward-flow position.
6. Record the results of this Test on the appropriate ~~for the office record~~ Form.
~~7. Install and seal the enclosure over the time delay relay.~~
~~**Corrective**~~ **Action:** If the time delay is less than the minimum pasteurization holding time, milk plant personnel shall increase the time setting on the time delay and ~~repeat~~ Test 11.2E shall be repeated. If after adjustment the pasteurization system fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

11.2F CONTINUOUS-FLOW PASTEURIZATION SYSTEMS UTILIZING A MAGNETIC FLOW METER BASED TIMING SYSTEM - HIGH FLOW ALARM RESPONSE TIME

Application: To all continuous-flow pasteurization systems using a magnetic flow meter based timing system ~~to replace~~, in lieu of a timing pump.
Frequency: Upon installation; ~~semiannually~~ at least once every six (6) months thereafter; ~~whenever the seal on the flow alarm is broken;~~ whenever any alteration is made affecting the pasteurization holding time, the velocity of the flow or the capacity of the holding tube; ~~or~~ whenever a check of the capacity of the holding tube indicates a speedup; or whenever the regulatory seal on the flow alarm has been broken.
Criteria: When the flow rate equals or exceeds the value at which the pasteurization holding time was measured, the high flow alarm shall cause the FDD to assume the ~~diverted~~ diverted-flow position within one (1) second.
Apparatus: ~~Stopwatch~~ An accurate time measuring device.
Method: Rapidly increase the flow rate to exceed the high flow alarm and verify that the FDD ~~shifts~~ moves to the ~~diverted~~ diverted-flow position within one (1) second.
Procedure:
1. Operate the ~~pasteurizer~~ pasteurization system, using water above the minimum legal pasteurization temperature, in forward-flow~~,~~ at a flow rate 25% below the high flow alarm set point as determined in Test 11.2B (**Procedure** 2).

NOTE: The appropriate temperature sensing elements may be placed in a water~~,~~ ~~or~~ oil or other suitable media bath to simulate the ~~normal~~ processing pasteurization temperature within ~~of~~ the holding tube as an alternative to heating ~~the~~ water in the pasteurization system above the minimum legal pasteurization temperature. The ~~Observation~~ observation and recording of ~~this~~ the ~~temperature~~ high flow alarm response time ~~should~~ shall be ~~done~~ conducted as described in **Procedures** 3 ~~and 4~~ through 6 below.

2. ~~Mark~~ Identify the high flow alarm set point on the flow rate ~~recorder~~ recorder-controller chart ~~with the high flow alarm set point~~. This may be accomplished by inscribing a line intersecting the recorded flow arc at the pen location or any other method acceptable to the Regulatory Agency.
3. Increase the pasteurization system flow rate as rapidly as practical to a point above the high flow alarm set point.

~~**NOTE:** When performing this Test on systems that operate above the boiling point of water, be sure that the system is cooling to avoid the possibility of serious burns.~~

4. Start the ~~stopwatch~~ accurate time measuring device when the flow rate ~~recorder~~ recorder-controller's recording pen exceeds the high flow alarm set point.
5. Stop the ~~stopwatch~~ accurate time measuring device when the FDD has moved to the ~~diverted~~ diverted-flow position.
6. Record the ~~elapsed~~ high flow alarm response time on the appropriate Form ~~for the office record~~.
~~**Corrective**~~ **Action:** If the response time exceeds one (1) second, immediate ~~corrective~~ action ~~must~~ shall be taken by milk plant personnel to correct this FDD deficiency. If after adjustment the pasteurization system fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry

personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

11.3 CALCULATED ~~HOLD~~ PASTEURIZATION HOLDING TIME FOR HHST PASTEURIZATION SYSTEMS USING INDIRECT HEATING

Application: To all HHST ~~pasteurizers~~ pasteurization systems using indirect heating.
Frequency: ~~When installed~~ Upon installation; ~~semiannually~~ at least once every six (6) months thereafter; ~~whenever the seal on the speed setting is broken;~~ whenever any alteration is made affecting the pasteurization holding time, the velocity of the flow, ~~i.e.,~~ such as the replacement of the timing pump, motor, belt, ~~driver~~ drive or driven pulley, decrease in the number of HHST pasteurization system heat-exchange plates, or the capacity of the holding tube; ~~and~~ whenever a check of the capacity of the holding tube indicates a speedup; or whenever the regulatory seal on the timing pump speed setting has been broken.
Criteria: Every particle of milk and/or milk product shall be held for the applicable minimum pasteurization holding time in both the ~~forward~~ forward-flow and diverted-flow positions.
Apparatus: No supplemental materials ~~needed~~ required.
Method: For this Test, ~~Fully~~ fully developed laminar flow is assumed and the required holding tube length ~~is~~ shall be calculated from an experimental determination of the pumping rate. An experimental determination of the pumping rate ~~is required; this is~~ can be accomplished by determining the time required for the ~~pasteurizer~~ pasteurization system to fill a vessel of a known volume; converting these data by division to obtain the flow rate in gallons per second; and then multiplying this value, by the proper value referenced in Table 14 to determine the required holding tube length. ~~Holding tube lengths for HHST pasteurizers with indirect heating for a pumping rate of 1 gallon/second are:~~

Table 14. Holding Tube Length - HHST ~~Pasteurizers~~ Pasteurization System- Indirect Heating - at a Pumping Rate of 1 gallon/second

	Tubing Size (inches)		
Pasteurization Holding Time (sec.)	2	2-1/2	3
	Holding Tube Length (inches)		
1.0	168.0	105.0	71.4
0.5	84.0	52.4	35.7
0.1	16.8	10.5	7.14
0.05	8.4	5.24	3.57
0.01	1.68	1.05	.714

Procedure:
1. ~~Examine the entire~~ Operate the pasteurization system on water, in forward-flow, with ~~to ensure that~~ all flow-promoting ~~equipment is~~ devices, which are capable of causing flow through the FDD, operating at their maximum capacity and all flow-impeding ~~equipment is so~~ devices adjusted or bypassed to provide the minimum amount of resistance to the flow through the pasteurization system. ~~Remove in-line filters; make sure the booster pump is operating; and that vacuum equipment in the system is operating at the maximum vacuum.~~ ~~Also, before~~

~~the Tests are begun, operate~~ ~~the~~ ~~pasteurizer~~ ~~at maximum flow for~~ ~~a sufficient time~~ ~~to purge~~ ~~the air from the system, about fifteen (15) minutes~~, ~~and tighten the pipe connections on the suction side of the timing pump, tight enough to exclude the entrance of air~~. ~~With the pasteurizer operating on water, adjust the timing pump to its maximum capacity, preferably with a new belt and full-size impellers~~.

There shall not be any leakage on the suction side of the timing pump.

a. For a variable speed timing pump adjust the timing pump to its maximum capacity, preferably with a new belt and full size impellers.

b. For a homogenizer used as the timing pump, check the homogenizer for its regulatory seal(s), and gears or pulley identification.

c. For AC variable speed timing pump, check the timing pump's control box for its regulatory seal(s).

NOTE: For pasteurization systems that employ a liquid ingredient injection (slurry) system as described in Appendix H., the slurry injection pump shall be energized and running at its maximum speed and the slurry supply tank shall be completely filled with water.

2. ~~Determine that no flow exists in the diverted line, and measure~~ Measure the time required to deliver a known volume of water at the discharge outlet of the ~~pasteurizer~~ pasteurization system ~~in forward-flow~~. Repeat the Test ~~determine that~~ until the measurements are consistent.

3. Repeat **Procedures** 1 and 2 in diverted-flow by collecting the ~~effluent~~ water at the pasteurization system's diverted-flow discharge ~~of the divert line~~.

NOTE: Procedure 3 is not required for HHST pasteurization systems with magnetic flow meter based timing systems.

4. Select the ~~greatest~~ highest flow rate, the shortest delivery time for the known volume; and calculate the flow rate in gallons per second by dividing the known volume by the time required to collect the known volume. Multiply this value with the appropriate value referenced in Table 14 to determine the required holding tube length for the pasteurization system.

5. The holding tube may include fittings. The centerline length of the fitting is treated as an equivalent length of straight pipe. The centerline distance may be measured by forming a flexible steel tape along the centerline of the fitting. Determine the total length of the holding tube by adding the equivalent lengths of the fittings to the measured lengths of straight pipe. ~~Record the number and type of fittings, the number and length of straight pipe and the holding tube configuration for the office record.~~ ~~If the temperature sensor is located at the beginning of the holding tube, the holding tube shall be protected against heat loss by material that is impervious to water.~~

NOTE: The holding tube shall be arranged to have a continuously upward slope in the direction of flow of not less than 2.1 centimeters (0.25 of an inch) per foot. If the indicating temperature sensing element is located at the beginning of the holding tube, the entire length of the holding tube shall be protected against heat loss by a material that is impervious to water.

6. ~~Re-seal the regulatory controls as necessary.~~ When the actual holding tube length is equivalent to or greater than the calculated minimum holding tube length, record the number and type of fittings, the number and length of straight pipe, the holding tube configuration and the results on the appropriate Form. If the actual holding tube length is not equivalent or greater than the calculated minimum holding tube length, refer to the **Action** noted below.

Alternate Procedure for Measuring the Flow Rate: ~~For pasteurizers of large capacity, the method of measuring flow rate at the discharge of the pasteurizer is inconvenient. The following alternate Test procedure may be used. Remove the divert line from the constant-level tank and turn off the milk or milk product pump feeding the constant-level tank.~~ Suspend a sanitary dipstick in the constant-level tank and operate the ~~pasteurizer~~ pasteurization system at its maximum flow capacity. Record the time that is required for the water level in the constant-level tank to ~~move~~ drop between two (2) identified graduations on the dipstick. The volume of water is calculated from the dimensions of the constant-level tank and the drop in water level. The ~~Flow~~ flow rate is determined as follows:

1. Divide the volume of water, in gallons, removed from the constant-level tank by the time, in seconds, required to remove ~~it~~ the volume of water.
2. Then use this flow rate to calculate the required holding tube length as provided in **Procedures** 3 and 4 above. ~~Table 14 to calculate the required holding tube length.~~

Alternate Procedures for the Determination of the Holding Tube Length for Non-Standard Pipe Size: The holding tube length may be accurately calculated from the following equation:

$$\mathbf{L = 588\ Qt/D^2}$$

Where: L = Holding tube length (inches)
Q = Pumping rate (gallons per second)
t = Pasteurization ~~Holding~~ holding time standard (seconds)
D = Internal diameter of the holding tube (inches)

~~Table 15 provides internal pipe diameters for piping in HHST holding tubes with nominal external diameters of 2.0, 2.5, 3.0 and 4.0 inches.~~

NOTE: Table 15 provides the internal pipe diameters for piping in a HHST pasteurization system's holding tube with nominal external diameters of 2.0, 2.5, 3.0 and 4.0 inches. Internal diameters, for pasteurization system's holding tubes designed for high pressure and for holding tubes with external piping sizes not listed in Table 15, ~~must~~ shall be individually determined and the minimum holding tube length calculated using the above formula.

Table 15. Dimension for Standard Stainless Steel Sanitary Tubing[1]	
Nominal External Diameter[2]	**Internal Diameter[2]**
2.0	1.870
2.5	2.370
3.0	2.870
4.0	3.834

[1] Abstracted from Table 6.1 "Pipe and Heat Exchanger Tube Dimensions", Fundamentals of Food Process Engineering, 1979, R. T. Toledo, AVI Press
[2] Measurements are in inches.

After the minimum required holding tube length is obtained from the calculation above, the length of the holding tube is measured to determine that it is at least as long as the calculated length. ~~The holding tube may include fittings or, for the shorter holding times, may be a fitting. The centerline length of the fitting is treated as an equivalent length of straight pipe. The centerline distance may be measured by forming a flexible steel tape along the centerline of the fitting.~~ Record the number and type of fittings, the number and length of straight pipe and the holding tube configuration results on the appropriate Form.

~~**Corrective** **Action:**~~ If the length of the holding tube is shorter than the calculated required minimum length, reseal the timing ~~pump~~ system at a slower maximum speed, based on new calculations with this slower maximum speed, or have milk plant personnel lengthen the holding tube, or both, and repeat ~~this~~ the Test ~~Procedure~~ **Procedure** previously used. If after adjustment the pasteurization system fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

11.4 CALCULATED ~~HOLD~~ PASTEURIZATION HOLDING TIME FOR HHST PASTEURIZATION SYSTEMS USING DIRECT HEATING

Application: To all HHST ~~pasteurizers~~ pasteurization systems using direct ~~contact~~ heating.
Frequency: ~~When installed~~ Upon installation; ~~semiannually~~ at least once every six (6) months thereafter; ~~whenever the seal on the speed setting is broken;~~ whenever any alteration is made affecting the pasteurization holding time, the velocity of the flow, ~~i.e.,~~ such as replacement of the timing pump, motor, belt, ~~driver~~ drive or driven pulley, ~~or a~~ decrease in number of heat-exchange plates~~;~~, or the capacity of the holding tube; ~~and~~ whenever a check of the capacity of the holding tube indicates a speedup; or whenever the regulatory seal on the timing pump speed setting has been broken.
Criteria: Every particle of milk and/or milk product shall be held for the appropriate minimum pasteurization holding time in both the ~~forward~~ forward-flow and diverted-flow positions.
Apparatus: No supplemental materials ~~needed~~ required.

Method: For this Test, ~~Fully~~ fully developed laminar flow and a temperature increase by the steam injection of 67ºC (120ºF) are assumed~~,~~ and the processor chooses the temperature-time standard and the required holding tube length is calculated from an experimental determination of the pumping rate.

Procedure:

1. ~~Examine the entire~~ Operate the pasteurization system on water, in forward-flow, with ~~to ensure that~~ all flow-promoting ~~equipment is~~ devices, which are capable of causing flow through the FDD, operating at their maximum capacity and all flow-impeding ~~equipment is so~~ devices adjusted or bypassed to provide the minimum amount of resistance to the flow through the pasteurization system. ~~Remove in-line filters; make sure the booster pump is operating; and that vacuum equipment in the system is operating at the maximum vacuum. Also, before the Tests are begun, operate the pasteurizer at maximum flow for a sufficient time to purge the air from the system, about fifteen (15) minutes, and tighten the pipe connections on the suction side of the timing pump, tight enough to exclude the entrance of air. With the pasteurizer operating on water, adjust the timing pump to its maximum capacity, preferably with a new belt and full-size impellers.~~

There shall not be any leakage on the suction side of the timing pump.

a. For a variable speed timing pump adjust the timing pump to its maximum capacity, preferably with a new belt and full size impellers.

b. For a homogenizer used as the timing pump, check the homogenizer for its regulatory seal(s), and gears or pulley identification.

c. For AC variable speed timing pump, check the timing pump's control box for its regulatory seal(s).

d. When vacuum equipment is present, operate the vacuum equipment at maximum vacuum rate.

NOTE: For pasteurization systems that employ a liquid ingredient injection (slurry) system as described in Appendix H., the slurry injection pump shall be energized and running at its maximum speed and the slurry supply tank shall be completely filled with water.

2. ~~Determine that no flow exists in the diverted line, and measure~~ Measure the time required to deliver a known volume of water at the discharge outlet of the ~~pasteurizer~~ pasteurization system ~~in forward-flow~~. Repeat the Test ~~to determine that~~ until the measurements are consistent.

3. Repeat **Procedures** 1 and 2 in diverted-flow by collecting the ~~effluent~~ water at the pasteurization system's diverted-flow discharge ~~of the divert line~~.

NOTE: Procedure 3 is not required for HHST pasteurization systems with magnetic flow meter based timing systems.

4. Select the ~~greatest~~ highest flow rate, the shortest delivery time for the known volume~~,~~; and calculate the flow rate in gallons per second by dividing the known volume by the time required to collect the known volume. Multiply this value with the appropriate value referenced in Table 16 to determine the required holding tube length for the pasteurization system. ~~Holding tube lengths for direct contact heating pasteurizers with a pumping rate of 1 gallon/second are~~:

Table 16. Holding Tube Length, HHST ~~Pasteurizers~~ ~~Pasteurizer~~ Pasteurization System, Direct Heating - at a Pumping Rate of 1 gallon/second			
Tubing Size (inches)			
Pasteurization Holding ~~time~~ Time (sec.)	2	2-1/2	3
		Holding tube length (inches)	
1	188.0	118.0	80.0
0.5	94.0	59.0	40.0
0.1	18.8	11.8	8.0
0.05	9.40	5.90	4.0
0.01	1.88	1.18	0.8

5. The holding tube may include fittings. The centerline length of the fitting is treated as an equivalent length of straight pipe. The centerline distance may be measured by forming a flexible steel tape along the centerline of the fitting. Determine the total length of the holding tube by adding the equivalent lengths of the fittings to the measured lengths of straight pipe. ~~If the actual holding tube length is equivalent to or greater than the required holding tube length, record the number and type of fittings, the number and length of straight pipes and the holding tube configuration, for the office record. Make sure that the holding tube slopes upward at least 6.35 millimeters (0.25 of an inch) per foot. If the temperature sensor is located at the beginning of the holding tube, the holding tube shall also be protected against heat loss by material that is impervious to water.~~

NOTE: The holding tube shall be arranged to have a continuously upward slope in the direction of flow of not less than 2.1 centimeters (0.25 of an inch) per foot. If the indicating temperature sensing element is located at the beginning of the holding tube, the entire length of the holding tube shall be protected against heat loss by a material that is impervious to water.

6. ~~Re-seal the regulatory controls as necessary.~~ When the actual holding tube length is equivalent to or greater than the calculated minimum holding tube length, record the number and type of fittings, the number and length of straight pipe, the holding tube configuration and the results on the appropriate Form. If the actual holding tube length is not equivalent or greater than the calculated minimum holding tube length, refer to the **Action** noted below.

Alternate Procedure for Measuring the Flow Rate: ~~For pasteurizers of large capacity, the method of measuring flow rate at the discharge of the pasteurizer is inconvenient. The following alternate Test procedure may be used. Remove the divert line from the constant-level tank and turn off the milk or milk product pump feeding the constant-level tank.~~ Suspend a sanitary dipstick in the constant-level tank and operate the ~~pasteurizer~~ pasteurization system at its maximum flow capacity. Record the time that is required for the water level in the constant-level tank to ~~move~~ drop between two (2) identified graduations on the dipstick. The volume of water is calculated from the dimensions of the constant-level tank and the drop in water level. The ~~Flow~~ flow rate is determined as follows:

1. Divide the volume of water, in gallons, removed from the constant-level tank by the time, in seconds, required to remove ~~it~~ the volume of water.
2. Then use this flow rate to calculate the required holding tube length as provided in **Procedures** 3 and 4 above. ~~Table 16 to calculate the required holding tube length.~~

Alternate Procedures for the Determination of the Holding Tube Length for Non-Standard Pipe Size: The holding tube length may also be accurately calculated from the following equation:

$$L = (588\ Qt \times 1.12)/D^2$$

Where: L = Holding tube length (inches)
Q = Pumping rate (gallons per second)
t = Pasteurization ~~Holding~~ holding time standard (seconds)
1.12 = 12% expansion for steam
D = Internal diameter of the holding tube (inches).
~~1.12 = 12% expansion for steam~~

~~Table 15 provides internal pipe diameters for piping in a HHST holding tubes with nominal external diameters of 2.0, 2.5, 3.0 and 4.0 inches.~~

NOTE: Table 15 provides the internal pipe diameters for piping in a HHST pasteurization system's holding tube with nominal external diameters of 2.0, 2.5, 3.0 and 4.0 inches. Internal diameters, for pasteurization system's holding tubes designed for high pressure and for holding tubes with external piping sizes not listed in Table 15, ~~must~~ shall be individually determined and the minimum holding tube length calculated using the above formula.

After the minimum required holding tube length is obtained from the calculation above, the length of the holding tube is measured to determine that it is at least as long as the calculated length. ~~The holding tube may include fittings or, for the shorter holding times, may be a fitting. The centerline length of the fitting is treated as an equivalent length of straight pipe. The centerline distance may be measured by forming a flexible steel tape along the centerline of the fitting.~~ Record the number and type of fittings, the number and length of straight pipe and the holding tube configuration results on the appropriate Form.
~~**Corrective**~~ **Action:** If the length of the holding tube is shorter than the calculated required minimum length, reseal the timing ~~pump~~ system at a slower maximum speed, based on new calculations with this slower maximum speed, or have milk plant personnel lengthen the holding tube, or both, and repeat the ~~Procedure~~ Test **Procedure** previously used. If after adjustment the pasteurization system fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

11.5 HHST PASTEURIZATION SYSTEMS HOLDING TIME—USING DIRECT STEAM ~~INFUSERS~~ INFUSION HEATING WITH A STEAM PRESSURE RELIEF POP-OFF VALVE AND A VACUUM CHAMBER ORIFICE ~~USED~~ IN PLACE OF A TIMING PUMP

Application: To all HHST ~~pasteurizers~~ pasteurization systems using direct steam infusion heating and using a steam pressure relief pop-off valve and a vacuum chamber orifice in place of a timing pump.

Frequency: Upon installation; at least once ~~every~~ each three (3) months thereafter; whenever the steam infusion shell or feed line, pressure relief pop-off valve or vacuum chamber orifice has been repaired or replaced; or ~~when a~~ whenever the regulatory seal has been broken.

Criteria: Every particle of milk and/or milk product shall be held for the applicable minimum pasteurization holding time in both the ~~forward~~ forward-flow and diverted-flow positions.

Apparatus: No supplemental materials ~~needed~~ required.

Method:

1. The steam ~~infuser~~ infusion shell or feed line shall be equipped with a pressure relief pop-off valve. This pressure relief pop-off valve shall be located and sized so that the total pressure inside the steam ~~infuser~~ infusion shell or feed line can never exceed the set point on this pressure relief pop-off valve.
2. An orifice or restriction, which is permanently installed in a noticeable fitting, shall be placed in the holding tube just prior to the vacuum chamber. The opening in the orifice or restriction, shall be sized to ensure a minimum milk and/or milk product residence pasteurization holding time at least as long as that specified in the chosen HHST pasteurization standard.
3. The size of the opening in the orifice or restriction and the setting of the pressure relief valve shall be determined by trial and error. Once an appropriate maximum flow rate has been determined and a ~~legal~~ minimum legal pasteurization holding time has been calculated, both the ~~restriction or~~ orifice or restriction and the steam pressure setting on the pressure relief pop-off valve shall be sealed by the Regulatory Agency so that neither can be changed or altered.

~~4. The Regulatory Agency shall keep records of the orifice or restriction size. They shall also keep records of the location, size, setting and manufacturer of the pressure relief valve.~~

Procedure:

1. Operate the pasteurization system on water, in forward-flow, with ~~to ensure that~~ all flow-promoting ~~equipment is~~ devices, which are capable of causing flow through the FDD, operating at their maximum capacity and all flow-impeding ~~equipment is so~~ devices adjusted or bypassed to provide the minimum amount of resistance to the flow through the pasteurization system.

There shall not be any leakage on the suction side of the timing pump.

a. For a variable speed timing pump adjust the timing pump to its maximum capacity, preferably with a new belt and full size impellers.

b. For a homogenizer used as the timing pump, check the homogenizer for its regulatory seal(s), and gears or pulley identification.

c. For AC variable speed timing pump, check the timing pump's control box for its regulatory seal(s).

NOTE: For pasteurization systems that employ a liquid ingredient injection (slurry) system as described in Appendix H., the slurry injection pump shall be energized and running at its maximum speed and the slurry supply tank shall be completely filled with water.

2. The steam pressure in the steam ~~infuser~~ infusion shell or feed line shall be raised to a level just below the pressure relief pop-off point ~~on~~ of the pressure relief pop-off valve.
3. Any back-pressure valves or other variable restrictions in the holding tube shall be ~~normally~~ placed into the fully open position.
4. All air bleeds to the vacuum chamber shall be closed so that the vacuum chamber will be operating under maximum vacuum.
5. ~~Before the Tests are begun, operate~~ Operate the ~~pasteurizer~~ pasteurization system at its maximum flow for ~~a sufficient time~~ approximately fifteen (15) minutes to purge ~~the~~ air from the pasteurization system~~, about fifteen (15) minutes, and tighten the pipe connections to exclude the entrance of air~~.
6. ~~Determine that no flow exists in the diverted line, and measure~~ Measure the time required to deliver a known volume of water at the discharge outlet of the ~~pasteurizer~~ pasteurization system ~~in forward flow~~. Repeat the Test until the measurements are consistent.
~~7. Repeat the Test to determine that the measurements are consistent.~~
~~8~~7. Repeat **Procedures** 1 through 5 in diverted-flow by collecting the ~~effluent~~ water at the pasteurization system's diverted-flow discharge ~~of the divert line~~.

NOTE: Procedure 7 is not required for HHST pasteurization systems with magnetic flow meter based timing systems.

~~9~~8. Select the ~~greatest~~ highest flow rate, the shortest delivery time for the known volume; and calculate the flow rate in gallons per second by dividing the known volume by the time required to collect the known volume. Multiply this value with the appropriate value referenced in Table 16 to determine the required holding tube length for the pasteurization system.
~~10. Multiply this value, gallons per second, with the appropriate value in Table 16 to determine the required holding tube length.~~
~~11. Holding tube lengths for direct contact heating pasteurizers with a pumping rate of 1 gallon/second are specified in Table 16.~~
~~12~~9. The holding tube may include fittings. The centerline length of the fitting is treated as an equivalent length of straight pipe. The centerline distance may be measured by forming a flexible steel tape along the centerline of the fitting. Determine the total length of the holding tube by adding the equivalent lengths of the fittings to the measured lengths of straight pipe.
~~13.Make sure that the holding tube slopes upward at least 6.35 millimeters (0.25 of an inch) per foot.~~

NOTE: The holding tube shall be arranged to have a continuously upward slope in the direction of flow of not less than 2.1 centimeters (0.25 of an inch) per foot. ~~14.~~ If the indicating temperature ~~sensor~~ sensing element is located at the beginning of the holding tube, the entire length of the holding tube shall ~~also~~ be protected against heat loss by a material that is impervious to water.

~~15~~10. If the actual holding tube length is equivalent to or greater than the ~~required~~ calculated minimum holding tube length, record the number and type of fittings, the number and length of straight pipes and the holding tube configuration and results ~~for the office record~~ on the appropriate Form.

~~16. Re-seal the regulatory controls as necessary.~~

~~**Corrective** **Action:**~~ If the length of the holding tube is shorter than the calculated required minimum length, reseal the timing ~~pump~~ system at a slower maximum speed, based on new calculations with this slower maximum speed, or have milk plant personnel lengthen the holding tube, or both, and repeat the Test **Procedure** previously used. If after adjustment the pasteurization system fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

TEST 12.

THERMAL-LIMIT-CONTROLLER FOR CONTROL - SEQUENCE LOGIC

References: Items 16p.(B) and (D)

Thermal-limit-controllers used with ~~HHST~~ HTST and ~~HTST~~ HHST pasteurization systems that have the FDD located downstream ~~from~~ of the pasteurized regenerator section(s) and/or cooler section shall be tested by one (1) of the following applicable Tests at the frequency prescribed:

12.1 PASTEURIZATION - INDIRECT HEATING

Application: To all ~~HHST~~ HTST and ~~HTST~~ HHST pasteurization systems that have the FDD located downstream ~~from~~ of the pasteurized regenerator section(s) and/or cooler section and using indirect heating.

Frequency: Upon installation; at least once ~~every~~ each three (3) months thereafter; whenever the thermal-limit-controller has been repaired or replaced; or ~~when~~ whenever the ~~a~~ regulatory seal has been broken.

Criteria: The ~~pasteurizer~~ pasteurization system shall not operate in forward-flow until the milk and/or milk ~~product~~ product-contact surfaces downstream from the holding tube have been sanitized. Upon start-up, milk and/or milk product-contact surfaces shall be exposed to fluid at the applicable required pasteurization temperature for at least the applicable required pasteurization or sterilization time. If any public health control causes the FDD to assume the diverted-flow position due to incorrect temperature, pressure or flow, forward-flow shall not be re-achieved until the milk and/or milk product-contact surfaces downstream from the holding tube have been re-sanitized or re-sterilized as appropriate.

Apparatus: A constant temperature bath of water, ~~or~~ oil, or other suitable media and the test ~~lamp~~ light from the pneumatic testing device described in Test 9.1 may be used to check the control-sequence logic of the thermal-limit-controller.

Method: The control-sequence logic of the thermal-limit-controller is determined by monitoring the electric signal from the thermal-limit-controller during a series of immersions and removals of the two (2) sensing elements, located at the FDD and in the holding tube, from a media bath heated above the cut-in temperature.

Procedure:

1. Heat the ~~water or oil~~ media bath to a constant temperature, a few degrees above the cut-in temperature ~~on~~ of the thermal-limit-controller. Wire the test ~~lamp~~ light in series with the signal from the thermal-limit-controller to the FDD.

NOTE: Some processors may have time delays built into their control logic in excess of that required for public health reasons. If so equipped, by-pass these ~~timers~~ time delays or account for their effect in delaying forward-flow.

2. Immerse the sensing element ~~of~~ from the FDD ~~in~~ into the media bath, which is above the cut-in temperature. The test ~~lamp~~ light ~~should~~ shall remain ~~unlighted~~ unlit, ~~i.e.,~~ indicating diverted-flow. Leave ~~the~~ this sensing element in the media bath.
3. Immerse the sensing element from the holding tube ~~in~~ into the media bath. The test ~~lamp~~ light ~~should~~ shall light up, ~~i.e.,~~ indicating forward-flow after a minimum time delay of one (1) second for continuous-flow pasteurization systems.
4. Remove the sensing element ~~of~~ from the FDD from the media bath. The test ~~lamp~~ light ~~should~~ shall remain ~~lighted~~ lit, ~~i.e.,~~ indicating forward-flow.
5. Remove the ~~holding tube~~ sensing element from the holding tube from the media bath. The test ~~lamp~~ light ~~should~~ shall turn off immediately, ~~i.e.,~~ indicating diverted-flow.
6. Re-immerse the sensing element ~~of~~ from the holding tube ~~in~~ into the media bath. The test ~~lamp~~ light ~~should~~ shall remain ~~unlighted~~ unlit, ~~i.e.,~~ indicating diverted-flow.
7. ~~Re-seal the regulatory controls as necessary.~~ Record the results of the Test on the appropriate Form.

~~**Corrective** **Action:**~~ If the control-sequence logic of the thermal-limit-controller does not follow these **Procedures**, the instrument shall be reconfigured to conform to this logic. If after reconfiguration, the pasteurization system fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

12.2 PASTEURIZATION - DIRECT HEATING

Application: To all ~~HHST~~ HTST and ~~HTST~~ HHST pasteurization systems that have the FDD located downstream ~~from~~ of the pasteurized regenerator section(s) and/or cooler section and using direct ~~contact~~ heating.

Frequency: Upon installation; at least once ~~every~~ each three (3) months thereafter; whenever the thermal-limit-controller has been repaired or replaced; or ~~when~~ whenever the ~~a~~ regulatory seal has been broken.

Criteria: The ~~pasteurizer~~ pasteurization system shall not operate in forward-flow until the milk and/or milk ~~product~~ product-contact surfaces downstream from the holding tube have

been sanitized. Upon start-up, milk and/or milk product-contact surfaces shall be exposed to fluid at the applicable required pasteurization temperature for at least the applicable required pasteurization or sterilization time. If the milk and/or milk product temperature falls below the applicable pasteurization standard in the holding tube, forward-flow shall not be re-achieved until the milk and/or milk product-contact surfaces downstream from the holding tube have been re-sanitized or re-sterilized as appropriate.

Apparatus: A constant temperature bath of water, ~~or~~ oil~~,~~ or other suitable media and the test ~~lamp~~ light from the pneumatic testing device described in Test 9.1 can be used to check the control-sequence logic of the thermal-limit-controller.

Method: The control-sequence logic of the thermal-limit-controller is determined by monitoring the electric signal from the thermal-limit-controller during a series of immersions and removals of the three (3) sensing elements, located at the FDD, vacuum chamber and in the holding tube, from a media bath heated above the cut-in temperature.

Procedure:

1. Heat a ~~water or oil~~ media bath to a constant temperature, a few degrees above the cut-in temperature on the thermal-limit-controller. Wire the test ~~lamp~~ light in series with the signal from the thermal- limit-controller to the FDD.

NOTE: Some processors have time delays built into their control logic, in excess of that required for public health reasons. If so equipped, bypass these ~~timers~~ time delays or account for their effect in delaying forward-flow. Before performing this Test, make sure the pressure switches, which ~~must~~ shall be closed to achieve forward-flow, have also been bypassed.

2. Immerse the sensing element from the FDD ~~in~~ into the media bath ~~that~~, which is above the cut-in temperature. The test ~~lamp~~ light ~~should~~ shall remain ~~unlighted~~ unlit, ~~i.e.,~~ indicating diverted-flow. Remove this sensing element from the media bath.
3. Immerse the sensing element~~,~~ from the vacuum chamber~~,~~ ~~in~~ into the media bath. The test ~~lamp~~ light ~~should~~ shall remain ~~unlighted~~ unlit, ~~i.e.,~~ indicating diverted-flow. Remove ~~the~~ this sensing element from the media bath.
4. Immerse the two (2) sensing elements ~~located at~~ from the vacuum chamber and the FDD, into the media bath. The test ~~lamp~~ light ~~should~~ shall remain ~~unlighted~~ unlit, ~~i.e.,~~ indicating diverted-flow. Leave ~~the~~ these two (2) sensing elements in the media bath.
5. Immerse the third sensing element ~~located at~~ from the holding tube, into the media bath. The test ~~lamp~~ light ~~should~~ shall light up, ~~i.e.,~~ indicating forward-flow, after a minimum time delay of one (1) second for continuous-flow pasteurization systems.
6. Remove the ~~FDD~~ sensing element from the FDD from the media bath. The test ~~lamp~~ light ~~should~~ shall remain ~~lighted~~ lit, ~~i.e.,~~ indicating forward-flow.
7. Remove the ~~vacuum chamber~~ sensing element from the vacuum chamber from the media bath. The test ~~lamp~~ light ~~should~~ shall remain ~~lighted~~ lit, ~~i.e.,~~ indicating forward-flow.
8. Remove the remaining~~, holding tube,~~ sensing element from the holding tube from the media bath. The test ~~lamp~~ light ~~should~~ shall immediately turn off, ~~i.e.,~~ indicating diverted-flow~~, immediately~~.
9. Re-immerse the ~~holding tube~~ sensing element from the holding tube into the media bath. The test ~~lamp~~ light ~~should~~ shall remain ~~unlighted~~ unlit, ~~i.e.,~~ indicating diverted-flow.
10. ~~Re-seal the regulatory controls as necessary.~~ Record the results of the Test on the appropriate Form.

~~**Corrective** **Action:**~~ If the control-sequence logic of the thermal-limit-controller does not follow these **Procedures**, the instrument shall be reconfigured to conform to this logic. If after reconfiguration the pasteurization system fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

TEST 13.

SETTING OF CONTROL SWITCHES FOR MILK AND/OR MILK PRODUCT PRESSURE IN THE HOLDING TUBE

Reference: Item 16p.(B) and (D)
Application: To all HHST pasteurization systems, which are capable of operating with milk and/or milk product in forward-flow mode, with less than 518 kPa (75 psig) pressure in the holding tube.
Frequency: Upon installation; at least once ~~every~~ each three (3) months thereafter; whenever the pressure switch has been repaired or replaced; whenever the pressure switch regulatory seal is broken; ~~and~~ or whenever the operating temperature is changed.
Criteria: The ~~pasteurizer~~ pasteurization system shall not operate in forward-flow unless the product pressure in the holding tube is at least 69 kPa (10 psi) above the boiling pressure of the milk and/or milk product.
Apparatus: ~~A~~ The sanitary pressure gauge and ~~a~~ the pneumatic testing device described in Test 9.1 can be used for checking and adjusting the pressure switch setting.
Method: The pressure switch is checked and adjusted so as to prevent forward-flow unless the milk and/or milk product pressure in the holding tube is at least 69 kPa (10 psi) above the boiling pressure of the milk and/or milk product.
Procedure:
1. ~~From~~ Using Figure 57 determine the pressure switch setting necessary for the operating temperature being used in the pasteurization system, do not use the diversion temperature~~, being used in the process~~. Install the sanitary pressure gauge~~, of known accuracy,~~ and the pressure switch sensing element on the pneumatic testing device.
2. Remove the regulatory seal and cover to expose the adjustment mechanism on the pressure switch. Place the test ~~lamp~~ light in series with the pressure switch contacts or use some other method to monitor the cut-in signal.
3. Apply air pressure to the pressure switch sensing element and determine the pressure gauge reading at the cut-in point of the pressure switch, which ~~should~~ shall turn on the test ~~lamp~~ light. If the pressure switch is short circuited, the ~~lamp~~ light will ~~be lit~~ light up before the air pressure is applied.
4. Determine that the cut-in pressure on the pressure switch is equivalent to or greater than the required pressure from Figure 57. If adjustment is necessary, refer to the manufacturer's instructions.
5. After the necessary adjustment is made, repeat the Test.

6. ~~When the results are satisfactory, seal the pressure switch setting and record the results for the office record.~~ Record the results of the Test on the appropriate Form.
Action: If forward-flow is achieved with less than 69 kPa (10 psi) above the boiling point of the milk and/or milk product in the holding tube, adjust the pressure setting and retest. If after adjustment the pasteurization system fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

For each HHST ~~pasteurizer~~ pasteurization system temperature, the milk and/or milk product pressure switch setting is as follows:

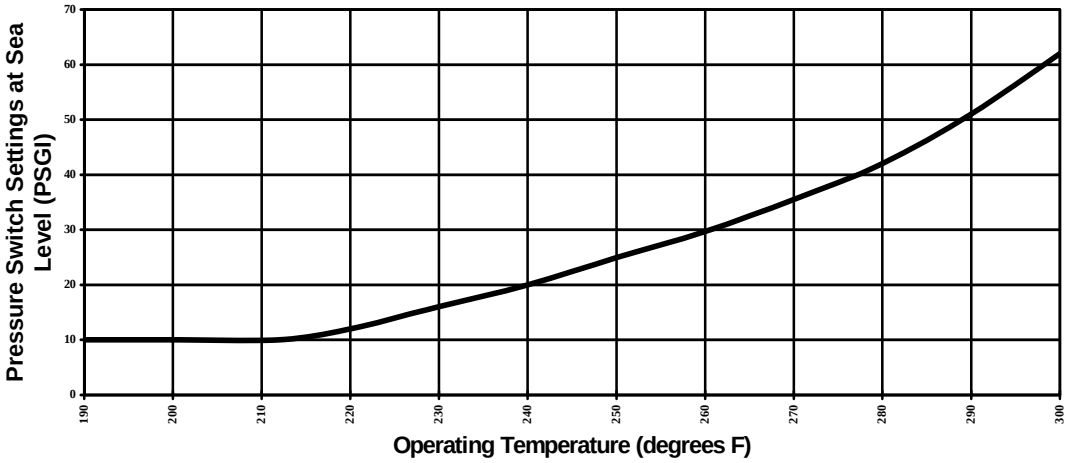

Figure 57. Pressure Switch Setting

This pressure switch setting shall be adjusted upward by the difference between the routine local ~~normal~~ atmospheric pressure and the atmospheric pressure at sea level.

TEST 14.

SETTING ~~OF~~ THE CONTROL FOR THE DIFFERENTIAL PRESSURE ~~SWITCHES~~ CONTROLLER ~~FOR DIFFERENTIAL PRESSURE~~ ACROSS THE STEAM INJECTOR

Reference: Item 16p.(B) and (D)
Application: To all HTST and HHST continuous-flow pasteurization systems using direct steam injection heating.
Frequency: : Upon installation; at least once ~~every~~ each three (3) months thereafter; whenever the differential pressure controller has been repaired or replaced; ~~and~~ or whenever the differential pressure ~~controller~~ controller's regulatory seal is broken.

Criteria: The ~~pasteurizer~~ pasteurization system shall not operate in forward-flow unless the milk and/or milk product pressure drop across the steam injector is at least 69 kPa (10 psi).
Apparatus: ~~A~~ The sanitary pressure gauge and ~~a~~ the pneumatic testing device described in Test 9.1 can be used for checking and adjusting the differential pressure controller.
Method: Adjust the differential pressure ~~switch~~ controller to prevent forward-flow, unless the pressure differential ~~pressure~~ across the steam injector is at least 69 kPa (10 psi).
Procedure:
1. **Calibration of the Steam Injector Differential Pressure Controller ~~Probes~~ Sensing Elements:**

a. Loosen the connection at both pressure ~~sensors~~ sensing elements and allow for any liquid to drain through the loose connections. While the sensing elements are still in their original positions, ~~Both~~ both pointers~~,~~ or the digital ~~displays~~ display(s), shall be within 3.5 kPa (0.5 psi) of 0 kPa (0 psi). If not, adjust the pointer(s)~~,~~ or the digital display(s), to read 0 kPa (0 psi).

b. Remove both ~~sensors~~ sensing elements and ~~mount~~ install them ~~in~~ onto a tee~~,~~ or connect them to ~~a~~ the pneumatic testing device. Record any difference ~~in~~ from the zero (0 kPa (0 psi)) readings in **Procedure** 1.a. that may have occurred ~~because of this change in elevation~~ when installing the ~~sensors~~ sensing elements onto the tee. Attach the tee and both ~~sensors~~ sensing elements to ~~a~~ the pneumatic testing device described in Test 9.1 and adjust the air pressure to the ~~normal~~ operating pressure used at the steam injector. Make sure that the ~~pointer~~ pointer(s) or digital ~~display~~ display(s) reading separation is within 6.9 kPa (1 psi) of that observed before the pressure was applied. If not, the ~~instrument~~ differential pressure controller requires adjustment or repair.

~~c. When the results are satisfactory, record the Test results for the office record and proceed as directed below.~~

2. **Setting of the Steam Injector Differential Pressure Controller ~~Switch~~:**

a. Disconnect the sanitary pressure sensing element that is ~~normally~~ located after the steam injector from the pneumatic testing device and cap the ~~resulting~~ opening. Leave the pressure sensing element, which is installed prior to the steam ~~injection~~ injector, on the pneumatic testing device.

b. Leave the other pressure sensing element open to the atmosphere, but at the same height as the pressure sensing element connected to the pneumatic testing device.

c. Wire the test ~~lamp~~ light in series with the differential pressure controller microswitch or use the method provided by the instrument manufacturer to monitor the cut-in signal.

d. Apply air pressure to the pressure sensing element and determine, from the test ~~lamp~~ light, the pressure gauge reading at the cut-in point of the differential pressure ~~switch~~ controller.

e. The differential pressure cut-in on the differential pressure controller shall be at least 69 kPa (10 psi). If adjustment is necessary, refer to the manufacturer's instructions.

f. After adjustment, repeat ~~the~~ this Test.

~~g. When the results are satisfactory, seal the instrument and record the results for the office record.~~

3. Record the results of the Test on the appropriate Form.

Action: If after adjustment the pasteurization system fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants,

qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

TEST 15.

ELECTRO-MAGNETIC INTERFERENCE FROM HAND-HELD COMMUNICATION DEVICES

Application: To all electronic control devices used to assure compliance with public health safeguards on HTST and HHST continuous-flow pasteurization equipment that are installed in milk plants.

Frequency: Upon installation; ~~any alteration of the electronic control devices;~~ at least once ~~every~~ each three (3) months thereafter; whenever any alteration of the electronic control devices occur; ~~and~~ or whenever the type or wattage of the hand-held communication device(s) used in that milk plant is changed. Once a hand-held communication device has been shown to cause a given electronic control device to react adversely, the electronic control device ~~must~~ shall be repaired and re-tested using the same type hand-held communication device. (Refer to the **NOTE:** below.) If any electronic control device is altered or there is a change in the hand-held communication device(s) used, the electronic control device(s) ~~would be required to~~ shall be tested.

Criteria: The use of hand-held communication devices shall not have any adverse effect on the electronic control device's public health safeguards.

Apparatus: One (1) hand-held communication device representing each make and model used in the milk plant. The hand-held communication ~~device~~ device(s) ~~must~~ shall be operating at maximum output and be fully charged.

Method: By observing the actual effect of the hand-held communication device on an electronic control device, it can be determined if that hand-held communication device can be used near that equipment without compromising any of the electronic control device's public health ~~safeguard~~ safeguards.

Procedure:

1. Position the hand-held communication device 30.5 centimeters (12 inches) in front of the electronic control device where the public health safeguard(s) resides.
2. Place the hand-held communication device in the "send" mode for five (5) seconds and observe the effect on the electronic control device's public health safeguard(s). There ~~should~~ shall not be any adverse effect with the electronic control device. An adverse effect is any change that may adversely affect an electronic control device's public health safeguard(s).
3. If applicable, repeat the Test with the operator access door open
4. Repeat the above Test for each hand-held communication device identified ~~in the~~ under **Apparatus** ~~Section~~.
5. Repeat the above Test for each electronic control device used to regulate a pasteurization system's public health safeguard(s).
6. Record the make and model of each hand-held communication device tested and the Test results on the appropriate Form.

For Example: For the temperature set point, operate the pasteurization equipment on water in diverted-flow in the "Product" mode, at a steady temperature within 3ºC (5ºF) of the lowest cut-in temperature. In this example, an adverse effect is defined as the forward-flow movement of the FDD or any artificial increase in temperature.

~~**Corrective**~~ **Action:** Have the milk plant check for shielding, grounding and other installation concerns with the electronic control device and retest. Until a solution, acceptable to the Regulatory Agency, can be found that does not adversely affect the electronic control device's public health safeguard(s), the hand-held communication device cannot be used in the area of the electronic control device's public health safeguard(s).

NOTE: Continuous "Hand-Held Communication Device Free" or "Radio Free" zones, etc., are not acceptable permanent solutions to hand-held communication devices which cause adverse affects to an electronic control device's public health safeguards.

Proposal: 117
Document: 2011 PMO (Appendixes H and I)
Pages: 222, 223, 296, 297 and 299

Make the following changes to ***APPENDIX H. PASTEURIZATION EGUIPMENT AND PROCEDURES AND OTHER EQUIPMENT*** *on Pages 222 and 223:*

Page 222:

PRESSURE RELIEF VALVES LOCATED ~~WITHIN~~ <u>DOWNSTREAM FROM THE HOLDING TUBE WITHIN</u> HTST PASTEURIZATION SYSTEMS

~~**Between the Timing Pump and the Beginning of the Holding Tube:** Placement of a pressure relief valve between the timing pump and the beginning of the holding tube is acceptable provided it meets either OPTION I or II below:~~

Page 223:

~~**OPTION I:**~~

~~a. Provisions are made for the cleaning of the valve vent and any return piping to the constant-level tank whenever the system is cleaned.~~

~~b. The pasteurizer shall not be timed if the valve is leaking. Leakage may be determined by observation at the pressure relief valve vent opening to the floor or at the opening of the return piping from the pressure relief valve vent into the constant-level tank.~~

~~c. The system is designed and operated so that loss of pressure from the pasteurized side of the regenerator cannot occur if the system flow-promoting devices stop while the FDD is in the forward-flow position. A system not protected against this potential pressure loss is considered a violation of Item 16p(C) of this *Ordinance*.~~

~~**OPTION II.** The pressure relief valve is spring-loaded and plumbed so that it cannot be opened or forced open in any mode, "Product", "CIP" or "Inspect", without the assistance of pressure from the liquid flowing through the system. In this case, a leaking pressure relief valve can cause an unacceptable loss of pressure in the pasteurized side of the regenerator if the system flow-promoting devices stop while the FDD is in the forward-flow position. This is considered a violation of Item 16p(C) of this *Ordinance*. Any leakage from this pressure relief valve must be readily visible. This may be accomplished by opening the pressure relief valve vent directly to the floor or by providing sanitary piping from the pressure relief valve vent to the constant-level tank. If the later option is utilized, the piping shall be properly sloped to assure drainage to the constant-level tank and shall be provided with a properly located and installed sight-glass.~~

~~2.~~ **~~Downstream from the Holding Tube:~~** The pressures in the pasteurized side of the regenerator ~~must~~ shall be protected from falling within 6.9 kPa (1 psi) of the pressures in the raw side of the regenerator at all times, including during shut down. A pressure relief valve ~~and line~~ on the pasteurized side of the FDD ~~can~~ will meet this criterion if~~:~~

~~a. After the relief valve and before the entrance to the pasteurized side of a regenerator, all milk or milk product rises at least 30.5 centimeters (12 inches) higher than the highest raw milk or milk product in the system, and is open to the atmosphere at that point; or~~

~~b. After exiting the pasteurized regenerator, and before the pressure relief valve, all milk or milk product must rise at least 30.5 centimeters (12 inches) higher than the highest raw milk or milk product in the system, and be open to the atmosphere at that point; or~~

~~c. The pressure relief valve is spring-loaded and plumbed so that it cannot be opened or forced open in any mode, "Product", "CIP" or "Inspect", without the assistance of pressure from the liquid flowing through the system.~~ the pressure relief valve is fail-safe. ~~In this case, a~~ A leaking pressure relief valve can cause an unacceptable loss of pressure in the pasteurized side of the regenerator during a shut down and is considered a violation of Item 16p(C) of this *Ordinance*. Any leakage from this pressure relief valve ~~must~~ shall be readily visible. This may be accomplished by opening the pressure relief valve vent directly to the floor or by providing sanitary piping from the pressure relief valve vent to the constant-level tank. If the later option is utilized, the piping shall be properly sloped to assure drainage to the constant-level tank and shall be provided with a properly located and installed sight-glass.

Make the following changes to ***APPENDIX I. PASTEURIZATION EQUIPMENT AND CONTROLS - TESTS*** *on Pages 296, 297 and 299:*

Page 296:

TEST 11.

CONTINUOUS-FLOW HOLDING TUBES – HOLDING TIME …

11.1 HTST ~~PASTEURIZERS~~ PASTEURIZATION SYSTEMS …

Page 297:

Procedure:
1. ~~Examine the entire~~ Operate the pasteurization system on water ~~to insure that~~ with all flow-promoting ~~equipment is~~ devices, which are capable of causing flow through the FDD, operating at their maximum capacity and all flow-impeding ~~equipment is so~~ devices adjusted or bypassed ~~as~~ to provide the minimum amount of resistance to the flow through the pasteurization system. There shall not be ~~no~~ any leakage on the suction side of the timing pump.

NOTE: In pasteurization systems equipped with a pressure relief valve located between the timing pump and the beginning of the holding tube, this Test shall not be performed if the pressure relief valve is observed to be leaking. …

Page 299:

11.2A CONTINUOUS-FLOW PASTEURIZATION SYSTEMS UTILIZING A MAGNETIC FLOW METER BASED TIMING ~~SYSTEMS~~ SYSTEM ~~CONTINUOUS FLOW~~ – PASTEURIZATION HOLDING TIME …

Procedure:
Utilize either **TEST OPTION I** or **TEST OPTION II**.

NOTE: In pasteurization systems equipped with a pressure relief valve located between the timing pump and the beginning of the holding tube, this Test shall not be performed if the pressure relief valve is observed to be leaking. …

Proposal: 119
Document: 2011 PMO (Appendix H)
Pages: 232-234

Make the following changes to ***Appendix H. PASTEURIZATION RQUIPMENT AND PROCEDURES AND OTHER EQUIPMENT*** *on Pages 232, 233 and 234:*

HTST AND HHST FLOW DIAGRAMS

Page 232:

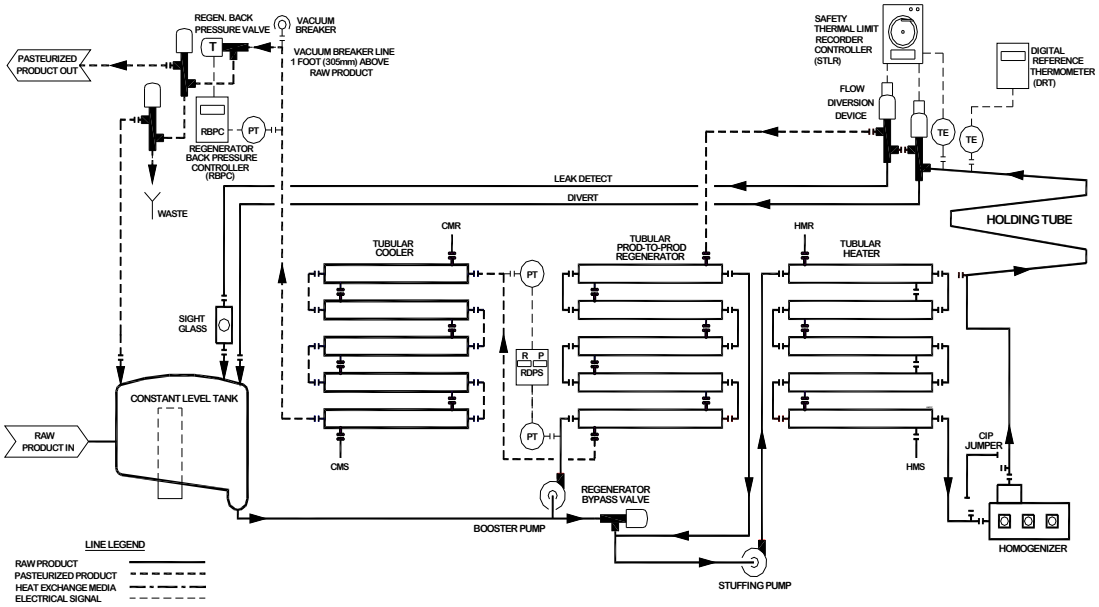

Figure 37. HTST Pasteurizer Utilizing Tubular Type Heat Exchangers and A Homogenizer as the Timing Pump

Page 233:

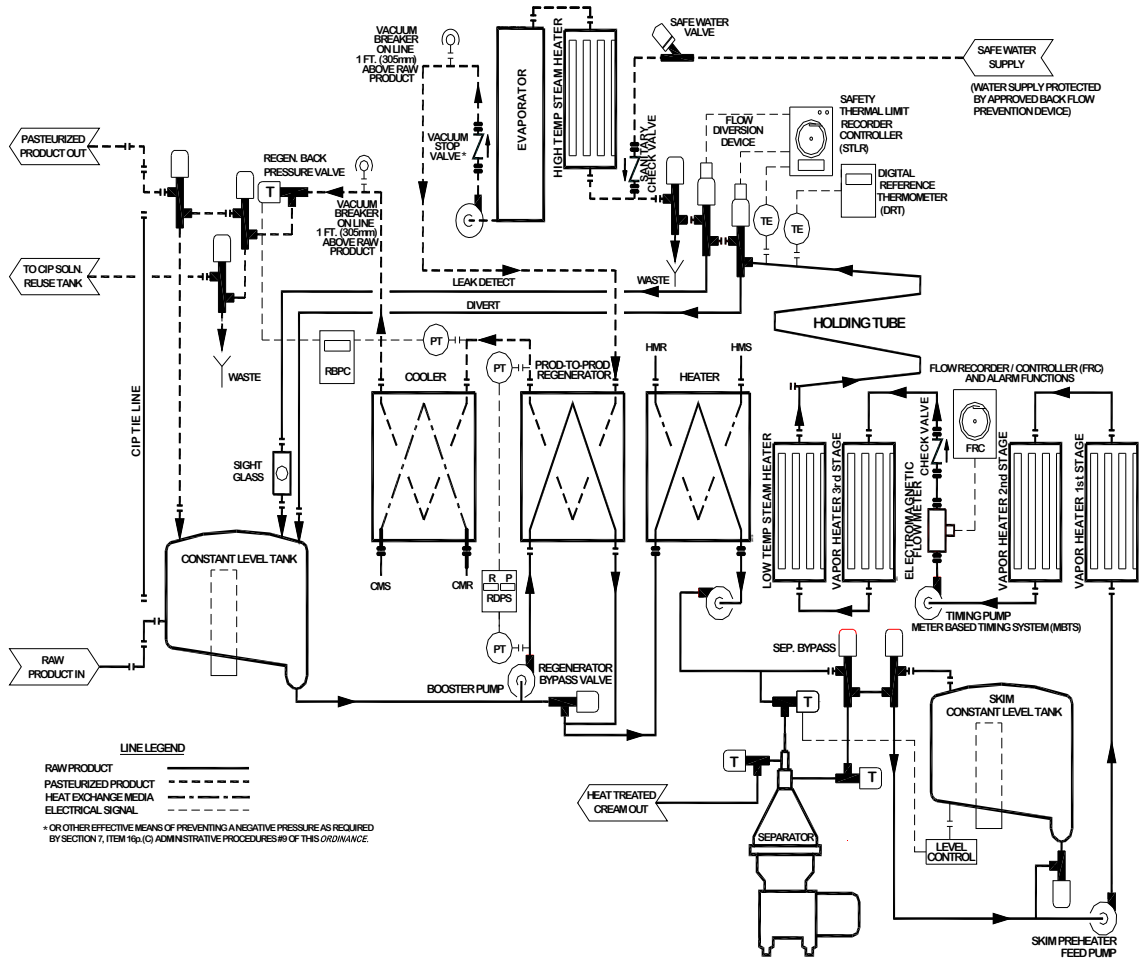

Figure 39. HTST Pasteurizer with a Regenerator, Separator, Skim Surge Tank and a Meter Based Timing System Located Upstream from an Evaporator

Page 234:

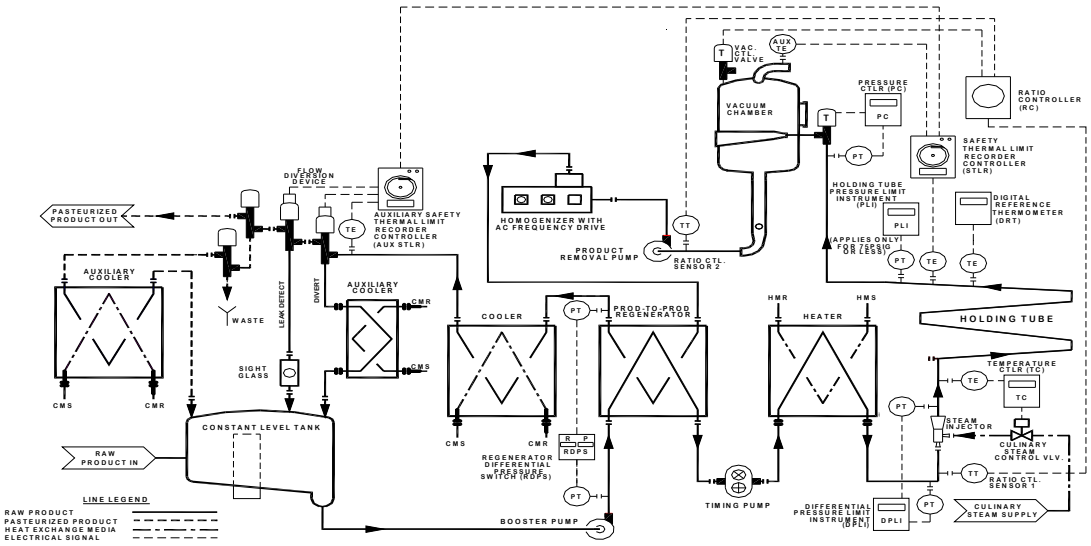

Figure 41. HHST Pasteurizer Utilizing Steam Injection Heating, Vacuum Flash Cooling and a Flow-Diversion Device Located Downstream of the Cooler Section

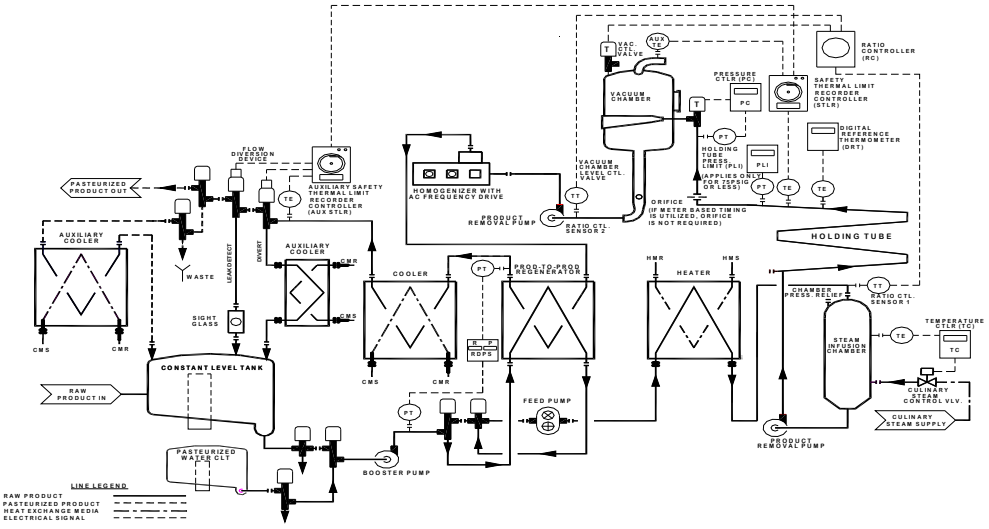

Figure 42. HHST Pasteurizer Utilizing Direct Culinary Steam Infusion and Vacuum Flash Cooling with a Homogenizer Located Downstream

Proposal: 301
Document: 2011 PROCEDURES (Section IV)
Pages: 11-14, 16 and 17

NEW PROCEDURE

Make the following changes to ***SECTION IV. OVERSIGHT AND RESPONSIBILITIES*** *on Pages 11-14, 16 and 17:*

Page 11:

B. **STATE RESPONSIBILITIES**

1. State Ratings and Single-Service Containers and Closures Manufacturer Listings

Page 12:

j. The Rating Agency shall certify U.S. manufacturers of single-service containers and closures in accordance with Appendix J. STANDARDS FOR THE FABRICATION OF SINGLE-SERVICE CONTAINERS AND CLOSURES FOR MILK AND MILK PRODUCTS ~~in~~ of the *Grade "A" PMO* for inclusion ~~in~~ on the *IMS List*.

k. When a certified manufacturer of Single-Service Containers and Closures for Milk and Milk Products changes status because of permit suspension and/or revocation or the withdrawal of their listing based upon observed violations that cannot ensure the sanitary quality of their single-service containers and/or closures that may lead to a potential public health concern involving the contamination of milk and/or milk products packaged within them, the shipping State shall immediately notify all known receiving States and the appropriate PHS/FDA Regional Offices.

When an existing listing is no longer valid because a listed single-service containers and closures manufacturer's permit is revoked, the State shall within five (5) days request PHS/FDA to withdraw the shipper from the *IMS List*.

Receiving States shall notify shipping States of any irregularities in the single-service container and closure supply received. (Refer to Section IV., B., 7.)

The Rating Agency shall keep current the listings of all certified single-service containers and closures shippers within its State. …

Page 13:

7. Challenges and Remedies

a. Complaints from Receiving States and Municipalities

1.) Complaints as to the sanitary quality of milk and/or milk products and/or single-service containers and closures being received and challenges ~~of~~ related to the validity of certified ratings and/or single-service containers and closures listings shall be made in writing by the receiving State or municipality to the Rating Agency of the shipping State, with a copy to the appropriate PHS/FDA Regional Office. …

Page 14:

4.) After an investigation, and based on the facts disclosed, the shipping State shall: …

C.) Make a new rating or listing for single-service containers and closures manufacturers within sixty (60) days, and with the written permission of the shipper, forward the new rating or listing, respectively, and a copy of the shipper's written permission to the appropriate PHS/FDA Regional Office for listing ~~in~~ on the *IMS List*. The receiving State(s) shall also be notified of the action being taken by the shipping State. …

c. Action to be Taken if the PHS/FDA Check Rating or Single-Service Containers and Closures Manufacturer's Audit Indicates the Listed Rating is Not Justified: …

Page 16:

3.) Single-Service Containers and Closures For Milk and Milk Products

A. Withdrawal of Certification

When PHS/FDA audit data indicates violations that cannot ensure the sanitary quality of single-service containers and/or closures that may lead to a potential public health concern involving the contamination of milk and/or milk products packaged within them requires a withdrawal of certification, the Rating Agency upon written recommendation of PHS/FDA, shall immediately withdraw the current certification of the shipper and notify such shipper, PHS/FDA, and all known receiving States thereof, in accordance with Section IV., B., 1k. In case of withdrawal, a new certification shall be made in not less than thirty (30) days and not to exceed sixty (60) days, unless the Rating Agency has reason to believe a new certification within a lesser time period, would result in an acceptable listing. The effective date for action shall be determined from the date of the letter of notification by the Rating Agency. Such letter shall be dated within five (5) working days following the date of the official notification.

~~3~~4.) If a Rating Agency fails to take the required action outlined in Section IV., B., 7.c.1.), ~~and~~ 7.c.2.) and 7c.3.), calling for immediate notification of all known receiving States when the current certification of a listed shipper is to be withdrawn

as recommended by PHS/FDA, PHS/FDA after a reasonable lapse of time (not to exceed five (5) days), shall provide all participating States with the check rating scores or audit findings for single-service containers and closures listings. The State which failed to take the required action shall be identified in the next listing of the *IMS List* as not being in compliance with Section IV., B., 7.c.1.), ~~and~~ 7.c.2.) and 7c.3.).

Page 17:

~~4~~5.) ~~Should the~~ If a Rating Agency ~~indicate~~ indicates that it is not in a position to make a new rating or listing within ~~a~~ the sixty (60) day period or a reinspection within thirty (30) days, PHS/FDA shall identify those States in the next listing of the *IMS List* as not being in compliance with the provisions of this paragraph.

~~5~~6.) If ~~the~~ a Rating Agency informs PHS/FDA that it is unable to make arrangements for PHS/FDA to check rate the sanitation compliance status of listed shippers or audit single-service containers and closures listed shippers, PHS/FDA shall identify those States in the next listing of the *IMS List* as not being in compliance with the provisions of this paragraph.

~~6~~7.) If a Rating Agency fails to request the removal of a milk plant, receiving station and/or transfer station or single-service containers and closures manufacturer from the *IMS List* as provided for in Section IV., B., 1.f. and B., 1.k, respectively, PHS/FDA shall, after five (5) days, provide this information to all receiving states.
…

The following text is a part of the Proposal but will not be placed in an NCIMS document.

FDA requests the NCIMS Chair to assign the following charges to the identified NCIMS standing committee(s) and to report back to the 2015 NCIMS Conference:

- SSCC and Methods Committees Jointly: To develop listing and withdrawal of listing criteria for SSCC manufacturers. Consultants that currently have SSCC listings on the IMS List shall participate on these Committees.

- SSCC Committee: To develop qualifications, authorization, certification/recertification procedures, etc. for consultants that currently certify or wish to certify SSCC manufacturers located outside the geographical boundaries of NCIMS Member States. Consultants that currently have SSCC listings on the IMS List shall participate on this Committee.

Proposal: 215
Document: 2011 EML (Entire Document)
Pages: Entire Document

*Make the following changes to the **2011 EML**:*

Page i:

PREFACE

In 1941 the United States Public Health Service began evaluations of the facilities, procedures and techniques of analysts in state and local milk laboratories doing official analysis. In 1977, the Food and Drug Administration (FDA) and 46 States had programs for measuring analyst performance in official and officially designated milk laboratories, by on-site ~~evaluations~~ surveys of techniques and proficiency testing. Today all 50 States, Puerto Rico and the Virgin Islands participate in the National Conference on Interstate Milk Shipments (NCIMS) Milk Laboratory Program. These evaluations have resulted in greater uniformity, accuracy and precision of microbiological and chemical analysis.

The material in this publication provides the procedures for the evaluation of milk laboratories required to meet the sanitation standards of the current ~~in use~~ edition of the ~~Grade 'A'~~ Grade "A" Pasteurized Milk Ordinance (PMO).

The information in this booklet was revised by the ~~Food and Drug Administration~~ FDA Laboratory Proficiency Evaluation Team (FDA/LPET) in conjunction with the NCIMS and its Laboratory Committee. The basic responsibility for preparation of this revision was assumed by the ~~Food and Drug Administration~~ FDA, Center for Food Safety and Applied Nutrition, Office of Food Safety, Division of Food Processing Science and Technology, Laboratory Proficiency and Evaluation Team, HFH-450, 6502 South Archer Road, Bedford Park, IL 60501, USA (Telephone (708) 728-4114; Fax (708) 728-4179), hereafter referred to as the FDA/LPET.

Page 1:

EVALUATION OF MILK LABORATORIES
2011 Revision

INTRODUCTION

Official accreditation of milk laboratories and Certified Industry Supervisors (~~CIS~~ CISs) requires that the appropriate ~~Federal~~ FDA/LPET or State milk laboratory control agency conduct an on-site survey to determine satisfactory performance of analysis in milk laboratories and performance of analysis by ~~CIS~~ CISs in facilities where the examinations, required by the ~~*Grade 'A'*~~ *Grade "A" Pasteurized Milk Ordinance* (PMO), are performed. In addition, satisfactory performance in the analysis of annual proficiency test samples ~~must~~ shall be demonstrated. An accredited milk laboratory may be an approved official or officially designated milk laboratory under the administrative control of a federal, state or local regulatory authority. Approval of Industry Supervisors (~~IS~~ ISs) and Industry Analysts (~~IA~~ IAs) requires verification of proficiency in performing drug residue analysis at least biennially, through ~~on-site performance~~ laboratory evaluations and/or performance evaluations by analysis of split samples or by other means as noted in SECTION 1 below.

~~The~~ State Laboratory Evaluation Officers (State LEOs) certified by the FDA/LPET ~~will~~ shall use the appropriate FDA-2400 Series Forms when evaluating official laboratories, officially designated laboratories, ~~CIS~~ CISs, ~~IS~~ ISs and ~~IA~~ IAs. The ~~Federal~~ FDA/LPET Laboratory Evaluation Officers (~~Federal~~ FDA/LPET LEOs) ~~will~~ shall use the appropriate FDA-2400 Series Forms when evaluating State Central Milk Laboratories and State LEOs. Appropriate FDA-2400 Series Forms are those forms that have been approved by the NCIMS Laboratory Committee working cooperatively with the ~~Food and Drug Administration (FDA)~~ FDA and the NCIMS Executive Board, and are effective 90 days after executive board approval. Approved forms shall be issued within 90 days of NCIMS Executive Board approval. If the FDA is unable to release the approved forms within the 90 day time frame, the FDA/LPET shall issue a draft version of the 2400 series forms 90 days after NCIMS Executive Board approval. …

State Central Milk Laboratory: A State owned and operated Official Laboratory with analysts employed by the State working in conjunction with the State Regulatory Agency designated as the primary State laboratory for the examination of producer samples of ~~Grade 'A'~~ Grade "A" raw and commingled raw milk for pasteurization, pasteurized milk and milk products, and dairy waters, as necessary.

Officially Designated Laboratory: An officially designated laboratory is a commercial laboratory authorized to do official work by the regulatory agency, or a milk industry laboratory officially designated by the regulatory agency for the examination of producer samples of ~~Grade 'A'~~ Grade "A" raw milk for pasteurization and commingled milk tank truck samples of raw milk for drug residues. …

Page 2:

~~Food and Drug Administration (FDA)~~ The FDA laboratory accreditation procedures provide a national base for the uniform collection and examination of milk, in compliance with the sanitation standards of the PMO.

Uniform accreditation of milk laboratories is maintained by the following two functions:

1. FDA accreditation of state central milk laboratories and certification of analysts is based on (a) satisfactory triennial on-site ~~evaluations~~ survey of laboratory facilities, equipment, records, and analyst performance of techniques, and (b) satisfactory annual proficiency testing (the examination of split milk samples) to continuously appraise analyst performance.

2. FDA certification of State LEOs who (1) accredit local laboratories and certify analysts and ~~CIS~~ CISs based on (a) satisfactory biennial on-site ~~evaluations~~ survey of laboratory facilities, equipment, records and analyses and (b) satisfactory annual proficiency testing which meets established national standards and (2) approve ~~IS~~ ISs and ~~IA~~ IAs (who only screen for drugs) based on (a) verification that each IS has been trained (by conducting required workshops for all industry supervisors) and has established a program that ensures the proficiency of the ~~IA~~ IAs they supervise, (b) verification that each IS and IA has demonstrated proficiency in performing drug residue analysis at least biennially. Verification of proficiency may include an analysis of split samples and/or an on-site

performance evaluation or another proficiency determination that the State LEO and the FDA/LPET agree is appropriate. (PMO, Appendix N)

Page 3:

SECTION 1: LABORATORY EVALUATION PROGRAMS

An evaluation of a milk laboratory ~~must~~ shall include an on-site ~~visit~~ survey ~~to~~ of the laboratory, a review of the records, including training records of IAs, records of split sample performance, facilities, equipment, materials and procedures. The evaluation shall be made using the most recent approved Official Milk Laboratory Evaluation Forms (FDA-2400 Series Forms). The ~~Federal~~ FDA/LPET or State LEO shall determine if the laboratory facilities, equipment, records and techniques of analysts are in compliance with the FDA-2400 Series Forms.

A copy of the ~~Grade 'A'~~ "Grade "A" Milk Laboratory Evaluation Request and Agreement Form" (see page 20) ~~must~~ shall be signed by a representative of the facility prior to the initiation of the on-site survey. This document ~~must~~ shall be maintained on file by the ~~Federal~~ FDA/LPET or State LEO.

A set of completed evaluation forms may accompany the narrative report ~~which~~ that describes the degree of suitability of the laboratory facilities, equipment, records, the analysts' procedures, and a statement as to whether the results of the analyst or CIS examinations are acceptable for use in rating milk for interstate shipments. The narrative report ~~must~~ shall be sufficiently detailed to allow readers to determine what is being cited without having to refer to the FDA-2400 Series Forms.

~~Survey reports of on-site evaluations~~ Reports of on-site surveys of Official Milk Laboratories and CISs shall be sent within 60 days of the initial, biennial/triennial anniversary or supplemental date of the laboratory evaluation to the Official Milk Laboratory/CIS, the appropriate ~~Food and Drug Administration~~ FDA Regional Office and the FDA/LPET. Reports can be submitted by traditional fashion (mail, common courier) or electronically. Reports to the Official Milk Laboratories/CIS ~~must~~ shall include the narrative report and may include copies of the completed FDA-2400 Series Forms. Reports to an FDA Regional Office and the FDA/LPET shall be sent electronically and shall include the narrative report and appropriate, completed FDA summary template only (see page 37 – 40).

~~Survey reports~~ Reports of on-site ~~evaluations~~ surveys of screening sites shall be sent to the facility within 60 days of the initial, biennial anniversary, or supplemental date of the laboratory ~~evaluation~~ survey.

CERTIFICATION/APPROVAL OF MILK LABORATORY ANALYSTS

Certification of milk laboratory analysts by the FDA/LPET ~~Federal~~ or State LEO shall be based on the following criteria:

1. Evaluations of State central milk ~~laboratories' evaluations~~ laboratories shall be scheduled and performed by their triennial expiration date. State central milk laboratories shall submit requests, in writing, for an on-site ~~evaluation~~ survey of a new analyst(s) performance of techniques, new methods and/or new facilities to the FDA/LPET. The ~~Federal~~ FDA/LPET LEO shall schedule a mutually agreeable date within 30 days of the request for an evaluation.

2. Evaluations of other milk laboratories within a state shall be scheduled and performed by their biennial expiration date. Milk laboratories within a state shall submit requests, in writing, for on-site ~~evaluation~~ surveys of new analyst(s) performance of techniques, new methods and/or new

Page 4:

facilities to the State LEO. The State LEO shall schedule a mutually agreeable date within 30 days of the receipt of the request for an evaluation.

3. The laboratory facilities, equipment and records shall meet the requirements stated on the FDA-2400 Series Forms, as determined by an on-site ~~evaluation~~ survey.

4. Analyst performance is in compliance during an on-site ~~evaluation~~ survey, with procedures required by the FDA-2400 Series Forms and the PMO. …

Analysts seeking certification or approval who are employed in laboratories not previously approved, or laboratories that have lost accreditation or approval and are seeking Recertification, may be approved to conduct official examinations only if criteria 3 and 4 above are met. When such analysts successfully complete the next official proficiency tests administered by the State LEO, a certificate of approval may be issued to such analyst. If such analyst does not successfully meet the performance levels of the proficiency testing program, the approval to conduct official examinations shall be withdrawn.

When a new analyst is assigned to an accredited laboratory between on-site ~~evaluations~~ surveys, conditional approval status ~~will~~ shall be provided to the new analyst upon satisfactory completion of criteria 4 or 5 above. Full certification ~~will~~ shall follow after acceptable completion of both criteria 4 and 5 above. Conditionally approved analysts failing to meet the established applicable criteria of laboratory performance during an on-site laboratory ~~evaluation~~ survey ~~will~~ shall have their conditionally approved status revoked.

The ~~CIS~~ CISs and certified analysts ~~must~~ shall participate, at least annually, in proficiency testing (the examination of milk split samples) for those specific procedures for which they are certified. Failure without cause to participate in the annual split samples ~~evaluation~~ or failure to meet established satisfactory performance criteria ~~will~~ shall result in the ~~CIS~~ CIS(s) or certified analyst(s) having their certification status downgraded from full to provisional. Failure of a provisionally certified analyst or CIS to participate in the examination of or to meet established satisfactory performance levels on the next set of split samples ~~will~~ shall result in withdrawal of their certification.

A CIS or certified analyst that loses their certification for one or more tests cannot examine official samples using a test for which their certification was withdrawn. Recertification procedures are shown in "SECTION 2: PROFICIENCY TESTING PROGRAMS". …

Page 5:

ACCREDITATION/APPROVAL OF MILK LABORATORIES

Accreditation or approval of milk laboratories by ~~Federal~~ the FDA/LPET or State milk laboratory control agencies shall be based on meeting the following requirements:

1. The laboratory facilities, equipment, procedures and records ~~must~~ shall meet the requirements stated on the appropriate FDA-2400 Series Forms and for ~~CIS~~ CISs, appropriate Appendix N 2400 Series Forms, as determined by an on-site ~~evaluation~~ survey.

2. All official examinations required by the PMO ~~must~~ shall only be performed by certified analysts or ~~CIS~~ CISs. …

When an accredited laboratory changes location or undergoes substantial remodeling, ~~an evaluation~~ a survey of the new laboratory or screening facility is required within 3 months. ~~No evaluation~~ A survey of personnel or procedures is not required at this time.

For initial accreditation, milk laboratories shall have a minimum of 15 days of required records available at the time of the on-site ~~evaluation~~ survey. The laboratory has records to show that all necessary quality control requirements have been performed and are satisfactory, and that there are 15 days of records to demonstrate that critical equipment is functional.

When a certified analyst or CIS leaves an accredited laboratory, the laboratory/facility manager ~~must~~ shall notify the ~~Federal~~ FDA/LPET or State LEO immediately since the loss of a certified analyst may result in the loss of certification for one or more procedures, or may result in the loss of the laboratory's accreditation. For example, a laboratory having only one certified analyst ~~will~~ shall lose accreditation. Official examinations cannot be conducted at non-accredited laboratories. When a laboratory or CIS facility loses its accreditation because of lack of certified analysts, or for some other reason,

Page 6:

the ~~Federal~~ FDA/LPET or State LEO shall immediately notify the milk laboratory involved, the state milk regulatory agency, the state milk sanitation rating agency, any out-of-state milk regulatory agencies where known customers are located, the appropriate FDA Regional Office and the FDA/LPET, by a letter of notification to be dated within five (5) working days of the loss of accreditation. For any FDA/LPET notification, changes in accreditation shall be indicated on the appropriate, completed FDA summary template and shall be submitted electronically. …

State Central Milk Laboratories requesting withdrawal of accreditation shall notify the FDA/LPET in writing and shall notify the appropriate FDA Regional Office in writing within 5 working days of the FDA/LPET's receipt of the written request.

Additionally, the laboratory shall notify its customers in writing, that it has withdrawn or been decertified and shall not represent itself as an official laboratory or officially designated laboratory, for those decertified or unapproved procedures under the agreements of the NCIMS. A copy of the generic notification ~~must~~ shall be sent to the State LEO. Decertification ~~will~~ shall remain in effect until measures are taken by the laboratory to attain compliance and another on-site survey is completed successfully.

APPROVAL OF INDUSTRY ANALYSTS/INDUSTRY SUPERVISORS

Approval of Industry Supervisors (~~IS~~ ISs) and Industry Analysts (~~IA~~ IAs) by the State LEOs shall be based on meeting all of the following requirements: …

2. All screening tests required by the PMO, Appendix N ~~must~~ shall only be performed by approved ~~IS~~ ISs, ~~IA~~ IAs or by a certified entity. …

Page 7:

5. Approval of ~~IS~~ ISs and ~~IA~~ IAs require verification of proficiency in performing drug residue analyses at least biennially, through an on-site ~~performance evaluation~~ survey and/or analysis of split samples, or ~~another proficiency determination~~ by other means of determining proficiency that the State LEO and the FDA/LPET agree is appropriate. (PMO, Appendix N)

6. The IS has attended and received training by the State LEO. This training ~~must~~ shall be documented.

The IS shall report to the State LEO the result of all competency evaluations performed by ~~IA~~ IAs. The name of each IS and IA (as well as their training and ~~evaluation~~ approval status) shall be maintained by the State LEO and updated as replacement, additions and/or removals occur. The State LEO shall verify (document) that each IS has established a program that ensures the proficiency of the ~~IA~~ IAs they supervise. The State LEO shall also verify that each IS and IA has demonstrated proficiency in performing drug residue analysis at least biennially. Verification may include an analysis of split samples and/or an on-site ~~performance evaluation~~ survey or ~~another proficiency determination~~ by other means of determining proficiency that the State LEO and the FDA/LPET agree is appropriate.

When a new analyst is assigned to an approved laboratory, conditional approval status ~~will~~ shall be provided to the new analyst upon satisfactory demonstration of competency to the IS. Full approval status ~~will~~ shall follow after verification of proficiency (see criteria #5, above). Conditionally approved analysts failing to meet the established applicable criteria of laboratory performance during an on-site ~~laboratory evaluation~~ survey or analysis of split samples ~~will~~ shall have their conditionally approved status revoked.

Fully approved analysts failing to meet the established applicable criteria of laboratory performance during an on-site ~~laboratory evaluation~~ survey or analysis of split samples ~~will~~ shall have their fully approved status downgraded to "provisional". Provisionally approved analysts failing to meet the established applicable criteria of laboratory performance during an on-site ~~laboratory evaluation~~ survey or analysis of split samples ~~will~~ shall have their provisionally approved status revoked.

Failure by the ~~IS~~ ISs or the ~~IA~~ IAs to demonstrate adequate proficiency to the State LEO shall lead to their removal from the State LEO list of approved ~~IS~~ ISs /~~IA~~ IAs. Re-instatement of their testing status shall only be possible by completing retraining and/or successfully analyzing split samples and/or passing an on-site ~~evaluation~~ survey or otherwise demonstrating proficiency to the State LEO. Analysts not on the State LEO list of ~~A~~approved ~~IS~~ ISs/~~IA~~ IAs are not approved to test bulk milk in the Appendix N program.

When a screening facility loses its approval because of the lack of approved ~~IS~~ ISs or ~~IA~~ IAs, or for some other reason, the State LEO shall immediately notify the screening facility involved, the state milk regulatory agency, the state milk sanitation rating agency, any out-of-state milk regulatory agencies where known customers are located, the appropriate FDA Regional Office and the FDA/LPET, by a letter of notification to be dated within five (5) working days of receipt of the loss of their approval. For FDA/LPET notification, changes in approval shall be indicated on the appropriate, completed FDA summary template and shall be submitted by email. …

Page 8:

Additionally, the screening facility shall notify its customers in writing that it has been withdrawn or has lost its approval and shall not represent itself as an approved screening facility under the agreements of the NCIMS. A copy of the generic notification ~~must~~ shall be sent to the State LEO. Loss of approval ~~will~~ shall remain in effect until measures are taken by the screening facility to attain compliance and another on-site survey is completed successfully.

APPROVAL OF BACTOSCAN INDUSTRY OPERATORS

Approval of BactoScan Industry Operators (~~BIO~~ BIOs) shall be based on meeting the following requirements:

1. The industry operator ~~must~~ shall complete the BIO operating protocols, training and oversight specified in the training procedure document.

2. The laboratory ~~must~~ shall maintain one (1) certified BactoScan analyst (see current FDA 2400 series form) for training and ongoing oversight of the BIO. …

Page 9:

SECTION 2: PROFICIENCY TESTING PROGRAMS

SPLIT SAMPLES – MICROBIOLOGY

The ~~Food and Drug Administration~~ FDA/LPET shall split samples annually with all ~~federally~~ FDA certified analysts of each State/Territory (hereafter noted as State) central accredited milk laboratory. State milk laboratory control agencies shall split samples at least annually with all state certified analysts of each official, officially designated accredited milk laboratory, and all ~~CIS~~ CISs. State milk laboratory control agencies shall verify that each IS and IA has demonstrated proficiency in performing drug residue analysis at least biennially through ~~on-site performance~~ laboratory evaluation and/or ~~analysis of split samples~~ annual performance evaluation, or ~~another proficiency determination~~ by other means of determining proficiency that the State LEO and the FDA/LPET agree is appropriate.

State milk laboratory control agencies having less than 10 analysts (total) in their milk laboratory program are to develop joint state proficiency testing programs with other states which can meet the criteria for certification of analysts and accreditation of laboratories. In cases where a minimum number of analysts (≥ 10) are not available, evaluation of proficiency ~~will~~ shall be made by a determination that the State LEO and the FDA/LPET agree is appropriate.

An acceptable annual proficiency testing program shall meet the following applicable criteria:
…

4. When a CIS examines bulk milk tanker milk or its equivalent for Appendix N purposes, a minimum of eight (8) samples shall be analyzed utilizing the test kit(s) for which that CIS is certified or approved, or for which the CIS is seeking certification. In general, the milk samples shall consist of the members of the beta-lactam family, at the safe/tolerance levels, which the test kit(s) is designed to detect as well as milk samples that do not contain ~~containing no~~ animal drug residues. The CIS may misidentify one of the samples and maintain and/or gain certification. If more than one (1) sample is misidentified, the CIS falls one (1) level of certification. If this occurs twice consecutively, the CIS is ~~no longer~~ not certified or approved (rules for Recertification of laboratories apply).

Page 10:

5. When an IS or an IA examines bulk milk tanker milk or its equivalent for Appendix N purposes, a minimum of eight (8) samples shall be analyzed utilizing the test kits for which that IS or IA is approved or for which the IS or IA is seeking approval. In general, the milk samples shall consist of members of beta-lactam family, at the safe/tolerance levels, which the test kits are designed to detect as well as milk samples ~~containing no~~ that do not contain animal drug residues. The IS or IA may misidentify one (1) of the samples and maintain and/or gain approval. If more than one (1) sample is misidentified, the IS or IA falls one (1) level of approval. If this occurs twice consecutively, the IS or IA is ~~no longer~~ not approved. Re-instatement of their testing status shall only be possible by completing retraining and/or successfully analyzing split samples and/or passing an on-site ~~evaluation~~ survey or otherwise demonstrating proficiency to the State LEO.

6. Each analyst certified to perform visual drug residue tests ~~will~~ shall participate in annual proficiency tests to demonstrate their ability to detect the beta-lactams at safe/tolerance level per kit label claim (Penicillin G, Cloxacillin, Ceftiofur, and Cephapirin) using blind samples with duplicate negatives. A minimum of six (6) samples may be used. However, with six (6) samples ALL results ~~must~~ shall be correct. If eight (8) samples are used, an analyst/CIS may miss one (1) and still pass the proficiency test. …

SPLIT SAMPLE ANALYSIS …

The steps for statistical analysis of split sample results are as follows: …

2. Calculate the logarithmic mean for the ~~Standard Plate Count~~ SPC, ~~Petrifilm Aerobic Count~~ PAC, ~~Plate Loop Count~~ PLC, ~~BactoScan FC Count (BSC)~~ BSC, ~~Spiral Plate Count Method (SPLC)~~ SPLC, ~~Direct Microscopic Somatic Cell Count~~ DMSCC, ~~Electronic Somatic Cell Count~~ ESCC, Electronic Phosphatase

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Count and Vitamin A and D_3 results of each test sample; using a table of common logarithms, list the logarithms of all analyst counts for a given sample. Calculate the mean of the logarithms for the sample. …

ANALYST PERFORMANCE LEVEL

Analysts certified to perform the examinations required by the ~~Grade 'A'~~ "Grade "A" PMO" shall meet the following performance levels on an annual basis.

1. Analysts certified to perform the ~~Standard Plate Count~~ SPC, ~~Petrifilm Aerobic Count~~ PAC, ~~Plate Loop Count~~ PLC, ~~BactoScan FC~~ BSC, ~~Spiral Plate Count Method~~ SPLC, ~~Direct Microscopic Somatic Cell Count~~ DMSCC, ~~Electronic Somatic Cell Count~~ ESCC, Electronic Phosphatase Count and Vitamin A and D_3 analysis, and BIOs approved to operate a BactoScan FC shall meet the acceptance limits and performance levels shown in Tables 2 and 3, page 28.

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2. Analysts certified to perform inhibitor tests shall detect samples that contain beta-lactam or other animal drug residues detectable by the appropriate official test for the drug and product. If using a drug other than beta-lactam, samples ~~must~~ shall be spiked in duplicate. See Table 3, page 28. …

5. ~~Certified Industry Supervisors~~ CISs certified to perform Appendix N test(s) for beta-lactam drugs shall detect members of the beta-lactam family, at the safe/tolerance levels, which the test kit(s) is designed to detect. See Table 3, page 28.

Fully certified analysts not meeting the described performance levels shall be provisionally certified for the test procedure(s) in which they exceed the maximum number of unacceptable results on samples. Provisionally certified analysts can regain full certification status by meeting satisfactory performance levels on the next set of split samples. If a provisionally certified analyst does not meet satisfactory performance levels on the next set of split samples, certification to perform the specific test(s) ~~will~~ shall be withdrawn. An analyst who has lost certification may be required to participate in a training program acceptable to the milk laboratory certifying authority before requesting recertification. Recertification after training shall be based on the analyst meeting the certification criteria described in SECTION 1: LABORATORY EVALUATION PROGRAMS. A certified analyst may only become conditionally approved again by the route by which he/she lost certification, i.e. if the analyst lost certification due to failure on milk split samples then he/she can only become conditionally certified by passing the next set of milk split samples. If the analyst failed an on-site survey ~~evaluation~~ that leads to his/her loss of certification then he/she ~~must~~ shall pass the next on-site certification to become conditionally certified.

~~BactoScan Industry Operators~~ BIOs performance levels shall follow the performance procedures indicated above for fully certified analysts. …

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SPLIT SAMPLES – CHEMISTRY

VITAMINS

The Grade "A" Vitamin Proficiency Test Program is operated by the FDA/LPET. In order to be accredited and be listed, laboratories ~~must~~ shall have analysts who have satisfactorily participated in at least two (2) consecutive split sample analyses and ~~must~~ shall have submitted satisfactory method validation and quality control/quality assurance (QC/QA) information. Participation in proficiency testing alone does not satisfy the criteria for analyst certification and laboratory accreditation.

The Grade ~~A~~ "A" Vitamin Proficiency Testing Program involves the analysis of sets of four (4) samples sent to participating laboratories every four (4) months, i.e., three (3) times a year with a total of twelve (12) samples. Certification status is based in part on the ability of analysts to analyze samples and have their results fall within limits (L_1=0.300 and L_2=0.200, based on the statistical parameters set at the 1995 NCIMS Conference in St. Louis, MO). Conditional certification is granted to an analyst (not to a laboratory) when the analyst has satisfactorily analyzed two (2) sets of samples (eight (8) samples in two (2) consecutive shipments). Analysts may have one (1) unsatisfactory result, i.e., miss (out of limits) one (1) sample, and still be considered as having satisfactory performance. After analyzing the next consecutive set of samples, the analyst is considered fully certified if not more than ~~2~~ two (2) samples have been missed over the course of a one (1) year period (twelve (12) consecutive samples analyzed).

Once fully certified, analysts maintain certification by satisfactorily analyzing all three (3) sets of split samples each year. During the course of the year full certification is maintained if ~~no~~ not more than two (2) samples (of ~~12~~ twelve (12)) are missed. Failure without cause to analyze all twelve (12) samples during the course of the year ~~will~~ shall result in the down grading of an analyst's status. It is imperative that laboratory schedules be set up to allow for the analysis of these samples. If a fully certified analyst misses more than two (2) samples (of ~~12~~ twelve (12)) then that analyst ~~will~~ shall be ~~down graded~~ downgraded to provisional certification. Full certification ~~will~~ shall be regained if that analyst misses ~~no~~ not more than one (1) sample of the next eight (8) that he/she analyzes. Provisionally or conditionally certified analysts that miss more than one (1) sample in the next eight (8) samples analyzed after receiving the respective status ~~will~~ shall have their certification/approval removed.

Once certification/approval is removed an analyst may only regain conditional certification by satisfactory performance on the next eight (8) samples, i.e., miss ~~no~~ not more than one (1) sample. Full certification requires that the analyst meet the criteria described above.

For split sample purposes each analyst ~~must~~ shall independently analyze the samples. Routine analysis may be performed by multiple analysts working together or by partitioning duties. Certified analysts are responsible for conducting official analysis. Non certified analysts may assist in analysis, but may not solely perform official analyses or report official results.

Re-entry of laboratories that have voluntarily withdrawn or laboratories that have had their accreditation removed ~~is~~ are subject to meeting all of the requirements needed from a new laboratory, including all quality control (QC) information. It is the responsibility of the laboratory to inform the FDA/LPET when a certified analyst is ~~no longer~~ not employed at that laboratory. A laboratory

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that loses all of their certified analysts is ~~no longer~~ not accredited to do official work and ~~must~~ shall seek new laboratory entry prior to resuming official analysis. …

LABORATORY PERFORMANCE LEVEL …

Fully accredited laboratories not meeting the described performance levels shall be provisionally accredited for the test procedure(s) in which they exceed the maximum number of unacceptable results on samples. Provisionally accredited laboratories can regain full accreditation status by meeting satisfactory performance levels on the next set of split samples. If a provisionally accredited laboratory does not meet satisfactory performance levels on the next set of split samples, accreditation to perform the specific test(s) ~~will~~ shall be withdrawn. A laboratory that has lost their accreditation ~~must~~ shall participate in a training program acceptable to the milk laboratory certifying authority before requesting ~~reaccreditation~~ re-accreditation. Re-accreditation after training shall be based on the laboratory meeting the accreditation criteria described in SECTION 1: LABORATORY EVALUATION PROGRAMS.

Copies of the proficiency testing report, including tabulation of laboratory results, shall be sent within four (4) months of the split sample examination date to the participating laboratory, the appropriate ~~Food and Drug Administration~~ FDA Regional Office, and the FDA/LPET.

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SECTION 3: CERTIFICATION OF LABORATORY EVALUATION OFFICERS

Initial certification of a State LEO shall be based on meeting the following criteria:

1. The individual ~~must~~ shall be a State government employee and demonstrate competence in evaluating milk testing laboratories and analysts' performance of milk laboratory test methods or Appendix N procedures as stated on the FDA-2400 Series Forms when accompanied by a representative of the FDA/-LPET on ~~an~~ the initial check ~~laboratory~~ on-site survey(s). The ~~Federal~~ FDA/LPET LEO shall accompany the State LEO to not more than two (2) laboratories/facilities during ~~an~~ the initial check on-site survey(s) for initial certification purposes. Initial check on-site surveys (for certification) should not be conducted at sites that have been evaluated within the past 90 days.

2. The individual ~~must~~ shall submit an acceptable written report of the milk laboratory initial check on-site survey to the FDA/LPET within ~~60~~ sixty (60) days of the ~~evaluation~~ survey. Reports to the appropriate FDA Regional Office and the FDA/LPET shall be sent by email and shall include the narrative report and appropriate, completed FDA summary template only (see pages 37 - 40).

3. The individual ~~must~~ shall attend the Milk Laboratory Evaluation Officers Workshop (FDA Course #FD373) conducted by the FDA/LPET ~~in conjunction with the Food and Drug Administration, State Training Team~~. If the individual does not have experience in the examination of dairy products, they ~~must~~ shall attend Course #FD374 "Laboratory Examination of Dairy Products" prior to or within the year of attending the Milk Laboratory Evaluation Officers Workshop.

   NOTE: It is recommended that the individual attend the Milk Laboratory Evaluation Officers Workshop prior to step 1 above.

Laboratory evaluations conducted by conditionally approved State LEOs ~~will~~ shall be considered official.

Conditional certification of a new State LEO can occur following the initial check on-site survey(s) described above. Full certification ~~will~~ shall be granted after the State LEO attends the next scheduled Milk Laboratory Evaluation Officers Workshop. Failure of a conditionally certified State LEO to attend the next scheduled Milk Laboratory Evaluation Officers Workshop, unless excused with cause by the FDA/LPET, ~~will~~ shall require that the State LEO ~~must~~ restart the process. The State LEO candidate would then be required to participate in ~~another~~ a new check on-site survey(s) with a representative of the FDA/LPET, and then attend the next scheduled Milk Laboratory Evaluation Officers Workshop.

Recertification of the State LEO ~~will~~ shall occur triennially, and ~~will~~ shall be based on satisfactorily meeting the following criteria:

1. The individual ~~must~~ shall be a State government employee and demonstrate continued competence in evaluating milk testing laboratories and analysts' performance of milk laboratory test methods or Appendix N procedures as stated on the FDA-2400 Series Forms when accompanied by a representative of the FDA/LPET on a check ~~laboratory~~ on-site survey. The

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~~Federal~~ FDA/LPET LEO shall accompany the State LEO to not more than two (2) laboratories/facilities during a check on-site survey for recertification purposes.

2. The individual ~~must~~ shall submit ~~an~~ acceptable written reports of the milk laboratory check on-site survey(s) to the FDA/LPET within ~~60~~ sixty (60) days of the ~~evaluation~~ survey. Reports to the appropriate FDA Regional Office and the FDA/LPET shall be sent by email and shall include the narrative report and appropriate, completed FDA summary template only (see pages 37 – 40).

3. The individual ~~must~~ shall have all laboratory evaluations, proficiency test examinations, and reports current (in particular, biennial on-site surveys ~~must~~ shall be performed within the month of their anniversary date).

4. The individual ~~must~~ shall have prepared and transmitted, at least annually, a summary list of certified and approved analysts and procedures by laboratory to the state milk sanitation rating agency and the FDA/LPET.

5. The individual has met the responsibilities for the training of ~~Industry Supervisors~~ ISs.

6. The individual ~~must~~ shall attend the Milk Laboratory Evaluation Officers Workshop once every three (3) years.

7. The individual ~~must~~ shall not fail, without cause, to attend an FDA Regional Milk Seminar. If a region holds a FDA Regional Milk Seminar, then State LEOs in that region are obligated to attend. If another region holds their regional milk seminar in the same year the State LEO may opt to attend that regional milk seminar in lieu of attending the regional milk seminar held in their region and still meet the requirement.

Once an individual has become a State LEO and is therefore considered fully certified, if he/she fails to submit acceptable written reports of milk laboratory ~~evaluations~~ on-site surveys within ~~60~~ sixty (60) days to the FDA/LPET or fails to comply with item 2 above for Recertification (or continued certification), the State LEO ~~will~~ shall have ~~their~~ his/her certification status downgraded from full to provisional. In addition, an action plan ~~will~~ shall be established that is mutually agreeable to the FDA/LPET and the state. The State LEO

~~would~~ shall have to meet the action plan criteria in addition to continuing to meet all the criteria specified in items 1-7 above, to maintain provisional certification status.

Laboratory evaluations conducted by provisionally approved State LEOs ~~will~~ shall be considered official.

Should a provisionally certified State LEO meet the criteria specified by their action plan and EML, SECTION 3, their certification ~~will~~ shall be returned to full certification once they have successfully undergone their next State LEO check evaluation with the FDA/LPET.

Should a provisionally certified State LEO fail to meet the criteria specified in EML, SECTION 3 and/or follow the action plan, then their certification would be revoked.

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The procedures for revocation ~~must~~ shall follow SECTION V. QUALIFICATIONS AND CERTIFICATIONS, Part H. of the *Procedures* Document.

State LEOs who lose certification cannot be re-certified for a period of 60 days from the date of loss of certification. Recertification ~~will~~ shall require meeting the requirements for initial certification.

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SECTION 4: EQUIPMENT AND APPARATUS OF AID TO EVALUATION OFFICERS

While conducting ~~laboratory evaluations~~ on-site surveys, the ~~Federal~~ FDA/LPET or State LEO may find it extremely useful to have in his/her possession different types of equipment which ~~will~~ shall enable them to examine the apparatus in use and judge the proficiency of laboratory procedures in use for the examination of milk products. Some ~~evaluation officers~~ LEOs currently use a large percentage of the equipment and apparatus listed below. Equipment should be maintained in proper working conditions to assure accuracy. …

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SECTION 5: GUIDELINES FOR CONDUCTING LABORATORY EVALUATIONS

The evaluations of laboratories by a ~~Federal~~ FDA/LPET or State LEO should be systematic. These guidelines are recommended to enable a complete ~~evaluation~~ survey of the laboratory facilities, equipment and records and of analyst technique.

Upon initial evaluation and/or renewal, the laboratory~~,~~ ~~must~~ shall make application for an evaluation upon a form provided by the ~~Federal~~ FDA/LPET or State LEO. The application ~~will~~ shall include the statement:

"I AGREE TO THE PROVISIONS OF THE NCIMS AND THE PROCEDURES FOR THE EVALUATION OF MILK LABORATORIES."

In preparation for the ~~laboratory evaluation~~ on-site survey, normally the laboratory director or supervisor should be notified in advance to insure the presence of analysts and the availability of samples for laboratory examination. In arranging for an initial ~~evaluation~~ on-site survey, laboratory officials should be told that all tests ~~must~~ shall be set up and that during the ~~evaluation~~ on-site survey the work of all analysts, who may perform any official methods ~~must~~ shall be observed. If ~~laboratory evaluation~~ on-site surveys are conducted on days when procedures, e.g. the SPC, are not normally performed, advance arrangements should be made to have samples on hand in order to observe the SPC procedure and the laboratory personnel should be requested to save countable plates from the previous day. Where the latter is not feasible, previously prepared and incubated plates may be brought to the laboratory by the ~~Federal~~ FDA/LPET or State LEO to permit observations of counting procedures.

On the designated ~~laboratory evaluation day~~ day of the on-site survey, delay arrival at the laboratory/facility until 10 - 15 minutes after the opening of the laboratory, to allow all personnel to start their day's activities normally. A visit to the laboratory director and/or supervisor's office should be made prior to entering the laboratory. At this time, the purpose of the ~~evaluation~~ on-site survey should be reviewed, and arrangements made to discuss the completed ~~laboratory evaluation~~ on-site survey informally with the laboratory director and/or supervisors on completion of the ~~evaluation~~ on-site survey . Assure that the ~~"Grade 'A'~~ Grade "A" Milk Laboratory Evaluation Request and Agreement Form" has been signed by a representative of the facility.

After entering the laboratory, the ~~Federal~~ FDA/LPET or State LEO should note the names of all analysts in the laboratory as/or after they are introduced and record the procedures performed by each.

Before beginning the on-site survey, the ~~Federal~~ FDA/LPET or State LEO should discuss the "ground rules" for the survey. Rules should be established for ~~procedural evaluations~~ the observation of the analysts' technique (e.g. whether an analyst can restart a procedure if the analyst notices that he/she make an error, how many times ~~may~~ an analyst may restart...).

During an ~~evaluation~~ on-site survey of a large laboratory, various analysts may be performing different examinations which may make a comprehensive ~~evaluation~~ survey difficult, particularly since all analysts are to be observed for each bacteriological and chemical procedure for which certification is requested. It is recommended that the ~~officer~~ FDA/LPET or State LEO establish a schedule so as to be in a position to evaluate apparatus and procedures used in the laboratory without disrupting, as far as

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possible, the routine examination of samples. Since it is expected that various portions of the evaluation forms ~~will~~ shall be used at separate times, it is advisable to note observed items of the various procedures on the left hand margins of the evaluation forms. By frequent referral

to the noted items, the ~~Federal~~ FDA/LPET or State LEO ~~will~~ shall be reminded to observe all laboratory procedures in use and avoid misuse of the phrase "undetermined" (U) when procedures were actually in use but were not observed.

While observations of procedures are being made and the evaluation forms completed, certain precautions should be taken by the ~~Federal~~ FDA/LPET or State LEO: …

2. Try to keep the ~~evaluation on an~~ on-site survey informal ~~basis and~~ to minimize nervousness on the part of analysts, ~~e.g., do not over emphasize the evaluation of procedures by unusually close physical observation;~~ and …

During the ~~evaluation~~ on-site survey it is probable that some items pertinent to receiving samples will not be observed. However, the ~~Federal~~ FDA/LPET or State LEO should determine from consultation with the laboratory supervisor the procedures used in receiving samples from the sample collectors: …

Deviations are to be discussed with the analysts at some time after it has been observed and properly recorded. This discussion should include the nature of the deviation, any effect on

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the validity of the results, remedial action suggested and reasons justifying the change. All interested personnel should have an opportunity to look over the completed evaluation form and each major deviation should be discussed by the ~~officer~~ FDA/LPET or State LEO with interested staff. At that time comments should be invited from the staff concerning the ~~evaluation~~ survey. The ~~Federal~~ FDA/LPET or State LEO should make suggestions concerning any needed improvement of laboratory techniques. Following the discussion of procedures and competence of analysts, past split sample results of the laboratory should be discussed, suggestions made for improvement, and/or commendations made for superior performance.

In addition to a regularly scheduled visit, some ~~Federal~~ FDA/LPET or State LEOs find that an occasional unannounced visit to an accredited laboratory provides them with supporting information concerning laboratory practices. Information generated on all surveys (unannounced, scheduled, check on-site surveys) ~~must~~ shall be evaluated by the ~~Federal~~ FDA/LPET or State LEO and used to determine compliance with the NCIMS Milk Laboratory Program.

If at any time during an on-site survey there is interference with or willful refusal to permit the survey, the ~~Federal~~ FDA/LPET or State LEO ~~will~~ shall serve notice that the laboratory ~~will~~ shall not be certified or ~~will~~ shall be decertified until such time as the laboratory agrees to abide by the voluntary certification program. The laboratory may make reapplication by completing the application form and stipulating that future interference or refusals ~~will~~ shall result in non-certification or decertification for thirty days (30). Or, if at any time before or during any on-site survey the ~~Federal~~ FDA/LPET or State LEO feels their safety is in jeopardy or determines extensive non-compliance, they may terminate the survey. The ~~Federal~~ FDA/LPET or State LEO ~~must~~ shall indicate to the laboratory management ~~why~~ the reason the

survey was terminated and ~~must~~ shall indicate what steps ~~must~~ shall be taken before a ~~resurvey~~ re-survey ~~will~~ shall be scheduled. The laboratory may make ~~reapplication~~ re-application by addressing the concerns that led to the termination of the survey and by completing the application form stipulating that the safety concerns and/or non compliance issues have been addressed.

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SECTION 6: LABORATORY EVALUATION REPORTS

EVALUATION FORMS …

Copies of the ~~survey~~ completed evaluation forms may be prepared for the laboratory evaluated. The ~~Federal~~ FDA/LPET or State LEO ~~must~~ shall maintain a complete copy of the on-site survey report, including forms. The laboratory/facility and ~~Federal~~ FDA/LPET or State LEO ~~must~~ shall maintain, at a minimum, copies of the last two (2) biennial/triennial surveys~~s~~ reports, subject to verification by the State LEO and the FDA/LPET. In marking the official copies of the completed ~~survey~~ evaluation forms, leave items in compliance blank. When typing copies for transmittal to others, do not include check marks in the margin which were made at the time of the actual on-site survey for the convenience of the evaluating official.

NARRATIVE REPORT

The set of completed ~~survey~~ evaluation forms for the laboratory may accompany the narrative report which states the conclusions of the ~~Federal~~ FDA/LPET or State LEO as to whether or not the laboratory is doing acceptable work. If the completed evaluation forms do not accompany the narrative report, the report ~~must~~ shall be sufficiently detailed to allow readers to determine what is being cited without having to refer to the FDA-2400 Series Forms. Each form used shall have the revision date noted. Additional narrative reports, without FDA-2400 Series Forms, are to be sent to others that need to be informed as to the outcome of the laboratory ~~survey~~ evaluation. The copy of the narrative report submitted by email to the FDA/LPET ~~must~~ shall be accompanied by the appropriate, completed FDA summary template, both attached to the same email. The State LEO ~~must~~ shall receive verification of receipt by return email and ~~must~~ shall maintain a copy of the verification in their records. The narrative report ~~must~~ shall identify the laboratory, give the laboratory number, show the date of the on-site survey, ~~who made the~~ name of the LEO that conducted the survey, list the prior status, list the date of the last on-site survey, indicate the present status, ~~what recommendations were made to correct any deviations,~~ what test(s) were approved, and ~~who was certified to do them~~ necessary changes to the IMS List.

Formats suitable for narrative reports appear on pages 29 - 36.

If choosing the option to send the narrative only via electronic submission, it ~~will~~ shall be necessary to summarize what each item is. Grouped under the title of each method observed (e.g., Standard Plate Count), list each major and/or minor deviation or omission numbered

identically with the item number on the evaluation form and the corrective action necessary for compliance with standard procedures or good laboratory practices.

A paragraph headed "Remarks" or "Recommendations" may be included if the ~~officer~~ FDA/LPET or State LEO wishes to comment on an item, e.g., one which could be improved by a change in procedure or by new equipment, or for any comment which is not appropriately covered in other Sections of the report. …

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After "Personnel and Procedures Certified" list the full name of all laboratory personnel qualified to make each individual test for which certification or approval is given. Include information on the analysts' last split sample performance. Also include a statement requiring participation in the Proficiency Testing Program to maintain certification (e.g., "To maintain certification, analysts ~~must~~ shall successfully participate in the Annual Proficiency Testing Program for all procedures for which certification has been granted"). …

Under "Conclusion" give a descriptive statement of the degree of acceptability or rejection of the procedures used by the laboratory, including recommendations for approval or rejection of the results of the laboratory. Some typical conclusions are given in the following text, and except in special circumstances, one of the conclusions listed ~~must~~ shall be used to indicate whether the results are (or are not) acceptable to State authorities for use in rating milk for interstate shipment, where this is the purpose of the evaluation.

CONCLUSIONS

1. This laboratory is accredited/approved as the procedures, records, facilities and equipment in use at the time of the on-site survey were in compliance with the requirements of the ~~*Grade 'A'*~~ *Grade "A" PMO.*

   Explanation: Unqualified acceptance of the laboratory.

2. Although the procedures, records, facilities and/or equipment in use at the time of the ~~evaluation~~ on-site survey were in substantial compliance with the requirements of the ~~*Grade 'A'*~~ *Grade "A" PMO* the analyst/facility/equipment/records deviations noted ~~must~~ shall be corrected. This laboratory is accredited/approved for 30 - 60 days pending correction of the deviations and receipt of a letter by the ~~evaluation officer~~ FDA/LPET or State LEO detailing the corrections made. Upon receipt of such letter, full accreditation/approval ~~will~~ shall be given.

   Explanation: A qualified acceptance where the ~~Federal~~ FDA/LPET or State LEO believes that the deviations noted do not seriously affect the analytical results and that a letter explaining the corrective actions taken ~~will~~ shall be sufficient to ensure compliance.

3. Although the procedures, records, facilities and/or equipment in use at the time of the ~~evaluation~~ on-site survey did not substantially comply with the requirements of the ~~*Grade*~~

~~'A'~~ *Grade "A" PMO*, the analyst/facility/equipment/records deviations noted are readily correctable. This laboratory is accredited/approved for (___) days pending correction of the deviations. Corrections ~~must~~ shall be made and detailed in writing to the ~~evaluation officer~~ FDA/LPET or State LEO during this period. A new on-site survey ~~will~~ shall be scheduled upon receipt of the letter to assure full compliance.

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Explanation: A qualified acceptance where procedural or technical errors or facilities which could have an effect on analytical results are noted but which are readily correctable by the analysts or management. Depending on the judgment of the FDA/LPET and State LEO, a period of ~~no~~ not more than ~~60~~ sixty (60) days usually is given to make the required adjustments before another survey is made or specified criteria are met, record, new equipment, etc. (some things may not require a return visit) to fully accredit (or approve) the laboratory.

4. This laboratory is not accredited/approved as the procedures, records, facilities and/or equipment in use at the time of the on-site survey did not comply with the requirements of the *Grade ~~'A' PMO"~~ "A" PMO*.

   Explanation: Severe deficiencies in facilities, records, staff and/or procedural techniques exist which would result in unacceptable results. A new on-site survey shall be made when the ~~Federal~~ FDA/LPET or State LEO has reason to believe that a rating would result in an acceptable rating. A new on-site survey would not be required for certified milk laboratories, CIS facility or screening facilities if the withdrawal was for facility deficiencies only. The laboratory, CIS facility or screening facility would be required to submit pictures, invoices, etc. to show compliance with the facility requirements noted in the last on-site ~~evaluation~~ survey.

FDA SUMMARY TEMPLATES

The narrative report sent to the FDA/LPET ~~must~~ shall be accompanied by the appropriate, completed FDA summary template for the laboratory, specifically representing the information required for verifying and updating the IMS List of accredited laboratories and CISs along with other useful information to be used by the FDA/LPET. Only the current revision of the FDA summary template~~s~~, authored by the FDA/LPET, may be used. ~~There are two FDA summary templates: one for full service laboratories and one for Appendix N Screening Only facilities (CIS and IS).~~ There is one (1) FDA summary template used by full service laboratories, and Appendix N and Screening Only facilities (CISs and ISs). The information captured on the FDA summary template ~~must~~ shall match the information provided in the narrative report (i.e., IMS number, facility identification, accreditation and certification status, dates, procedures, conclusion, etc.). The information captured may also lend itself to analyst/laboratory tracking and filing by the State LEO.

The appropriate FDA summary template form ~~must~~ shall also be used for the notification of changes in accreditation and certification status, and ~~must~~ shall be submitted by email to the FDA/LPET.

Directions for completing the FDA summary template, authored by LPET, ~~will~~ shall be updated with each revision of the FDA summary template, as necessary, and provided to the LEOs by email.

An example of a completed FDA summary template for each application appears on pages 37-40.

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REFERENCES

1. Copies of the FDA-2400 Series Forms can be obtained from the FDA/LPET ~~Federal~~ or State LEO(s).

   A list of the FDA/LPET ~~Federal~~ and State LEOs can be found at the website: http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/MilkSafety/FederalStatePrograms/InterstateMilkShippersList/default.htm.

   Once at that website:

   For the FDA/LPET ~~Federal~~ LEOs click on the link ~~FDA CFSAN Personnel~~ "FDA CFSAN Personnel" and scroll down to the Laboratory Proficiency and Evaluation Team.

   For State LEOs click on the link ~~State Grade A Milk Regulatory, Rating and Laboratory Personnel~~ "State Grade A Milk Regulatory, Rating and Laboratory Personnel" and then click on your state. The table is organized by listing Regulatory personnel first, then Rating personnel, and finally Laboratory personnel. Scroll down to the laboratory section to find the contact information for your state's LEO(s). …

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~~**EXAMPLE REPORT #1**~~

~~Report of a Biennial On-Site Evaluation~~

~~of~~

~~City Health Department Milk Laboratory~~

~~Accredited Laboratory~~
~~NCIMS LAB #####~~

100 South Main Street
City, State 78000

On

March 1, 2010

By

LEO Name
Laboratory Evaluation Officer
State Department of [Health, Agriculture}
100 Healthy Way
City, State 78000

Last Full Evaluation Date: March 19, 2008
Next Evaluation Due By: March 31, 2012

A copy of the "Grade "A" Grade 'A' Milk Laboratory Evaluation Request and Agreement Form" is signed and is on file.

Previous Laboratory Status: Fully certified for [5, 9C13, 9C14, 9D3, 12, 20, 22, 24, 28]

Present Laboratory Status: Fully certified for [5, 9C13, 9D3, 12, 16, 20 22, 24, 28] pending receipt within 60 days of correction of deviations resulting from on - site evaluation of March 1, 2010.

Other changes that need to be made to IMS list, etc: Update Anniversary Date, drop procedure 9C14, add procedure 16.

The following is a summary of the recent evaluation of your milk laboratory in accordance with the requirements of the *Grade "A" Grade 'A' PMO*. If forms accompany the narrative then deviated items are marked with an "X" on the evaluation forms. Items marked "U" are undetermined because of local conditions at the time of the evaluation. Laboratory procedures and/or

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procedures equipment marked "O" are not used. Items marked "NA" are optional procedural techniques and/or equipment not applicable to designated laboratory procedures. Repeat deviations are marked by an asterisk "*". Noted items are not considered deviations. The phrase "Note" as used in these narrative reports is to suggest or remark upon items which

would improve laboratory functions. These are usually considered to be good laboratory practices but are not listed in the FDA 2400 Series Forms and are not debitable items.

DEVIATIONS AND CORRECTIVE ACTIONS

ITEM **METHOD**

CULTURAL PROCEDURES - GENERAL REQUIREMENTS (rev. 2/10)

2. Records

2c Corrections to all records follow appropriate requirements

During the review of the autoclave records it was noticed that there were a number a items written over.

Analysts are to be reminded of the proper protocol for correcting mistakes. Cross out the error with one line, initial, date and write the correct information next to it.

Send copies of the March and April autoclave records.

3. Thermometers

3a NIST Thermometer

#NOTE: The graduations on the lower end of the NIST thermometer are so worn that it is difficult to read. It is suggested that a new thermometer be purchased.

The other option is to use the new NIST traceable unit that is available for use in the rest of the laboratory.

3c3 No tag was found on the freezer thermometer

Although the accuracy check was documented the unit was not tagged.

Tag the thermometer with the following: identification/location, date of check, temperature checked and the correction factor.

Send a copy of the tag.

5. Freezer

5b Maintains -15C or below

Over the past four months at least 50% of the days noted with the unit out of temperature range with no corrective action noted.

This is a serious violation and no controls or samples may be kept in the unit until it is proven that that the unit holds the proper temperature.

Send copies of the freezer temperature records for the next 4 months. If the unit cannot be maintained then a new one shall will need to be purchased.

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13. Autoclave

13i Performance check

There were no thermometers for the incubation units for the spore check. There shall must be a way to check the appropriate temperature range for the test.
Please purchase thermometers for these units and send a copy of the purchase order, the temperature calibrations when received and the temperature records for the two months following.

TECHNIQUES

PETRIFILM AEROBIC AND COLIFORM COUNTS (IMS# 5,20 rev. 1/09)

No deviations noted. The analysts showed marked improvement over the last biennial on-site.

PASTEURIZED MILK CONTAINERS (IMS# 22 rev. 1/09)

10. Collection of Surface Rinse Samples

10b2 While adding the rinse solution to the container, do not touch the bottle of rinse solution to the container.
One analyst held the bottle against the container while adding the rinse solution.
Use aseptic technique when adding the rinse solution.

DELVOTEST P 5 PACK (IMS# 9D3 rev. 2/10)

No deviations noted.

DMSCC (IMS# 12 rev. 2/10)

21. Sample Measurement

21e Touch the slide with the tip and expel the test portion.
One analyst held the syringe above the slide and dripped the milk.
Take the syringe and hold it vertically against the slide, depress the plunger slowly allowing the milk to be expelled. Then touch off to a dry spot.

ESCC - BENTLEY 150 (IMS# 16 rev. 10/07)

No deviations noted.

FLUOROPHOS ALP (IMS# 28 rev. 6/05)

15. Instrument and Reagent Checks

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15g2b Reconstituted Substrate / Buffer Stability Check A/D Value Recorded

The A/D value for this check was missing on several days of testing records during the period evaluated. While this may be from having to reconstitute a new bottle of substrate because the A/D value was greater than 1200, the corrective action shall must be noted with both the old *AND* new values recorded.

DAIRY WATERS (IMS# 24 rev. 1/09)

No deviations noted.

CHARM SL BETA LACTAM (IMS# 9C13 rev. 1/10)

No deviations noted.

PERSONNEL & PROCEDURES OBSERVED

Analyst	5	9C13	9D3	12	16	20	22	24	28	ON-SITE Last 2	SPLITS Last 2
Analyst 1	X	X	X	X	X	X	X	X	X	3/10, 3/08	10/09, 10/08
Analyst 2	X	X	X	X	X	X	X	X	X	3/10, 3/08	10/09, 10/08
Analyst 3	X	X	X	X	X	X	X	X	X	3/10, 3/08	10/09, 10/08
Analyst 4	X	X	X	X		X	X	X	X	3/10	10/09
Analyst 5*	X	X	X	X	X	X	X	X	X	3/08, 3/06	10/09, 10/08

X = Fully Certified
* = Analyst excused - on medical leave.
5 = Petrifilm Aerobic Count
9C13 = Charm SL Beta Lactam
9D3 = Delvotest 5 Pack
12 = DMSCC
16 = ESCC (Bentley 150)
20 = Petrifilm Coliform Count
22 = Pasteurized Milk Containers
24 = Dairy Waters
28 = Advanced Fluorometer

CONCLUSION

Although the procedures, records, facilities and equipment in use at the time of the evaluation were in substantial compliance with the requirements of the *Grade "A" Grade 'A' PMO* the analyst, equipment and record deviations noted shall must be corrected. This laboratory is accredited until May 1, 2010 pending correction of the deviations and receipt of a letter by the evaluation officer detailing the corrections made. Upon receipt of such letter, full accreditation shall will be given.

Sincerely,
LEO

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~~EXAMPLE REPORT #2~~

~~REPORT Of an Biennial On-Site/~~
~~Supplemental (analyst, procedure, walk-through)/~~
~~Unofficial/Check~~

~~Certified Laboratory~~
~~NCIMS Lab #####~~

~~Certified Industry Supervisor~~
~~CIS #####~~

~~Appendix N Screening Site~~

~~NAME OF SITE~~
~~Address~~
~~Date of Evaluation~~
~~By LEO's name~~

~~Previous Laboratory Status: Fully/provisionally/conditionally Certified until [date]~~
~~Previous Procedures: X, X, X~~

~~Present Laboratory Status: Fully/provisionally/conditionally Certified until [date], pending acceptable response to this report~~
~~Procedures evaluated: X, X~~

~~A copy of the "Grade 'A' Milk Laboratory Evaluation Request and Agreement Form" is signed and is on file with LEO.~~

~~Other changes that need to be made to IMS list, etc: None or addition of analysts, change in procedures, etc.~~

~~The following is a summary of the recent evaluation of your milk laboratory in accordance with the requirements of the Grade "A" Grade 'A' PMO. If forms accompany the narrative then deviated items are marked with an "X" on the evaluation forms. Items marked "U" are undetermined because of local conditions at the time of the evaluation. Laboratory procedures and/or equipment marked "O" are not used. Items marked "NA" are optional procedural techniques and/or equipment not applicable to designated laboratory procedures. Repeat deviations are marked by an asterisk "*". Noted items are not considered deviations. The phrase "Note" as used in these narrative reports is to suggest or remark upon items which would improve laboratory functions. These are usually considered to be good laboratory practices but are not listed in the FDA-2400 Series Forms and are not debitable items.~~

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DEVIATIONS AND CORRECTIVE ACTIONS

ITEM **METHOD**

CULTURAL PROCEDURES FOR CERTIFIED LAB [rev. 2/10] / GENERAL REQUIREMENTS FOR APPENDIX N [rev. 2/10]

CERTIFIED LAB

3. Thermometers

3c2 All test temperature measuring devices are checked at temperature of use.
The thermometers in the media section were checked for accuracy but were not always done at the temperature of use as required. The hot air oven was checked at 65C vs. 170C. Re-check the thermometer and send with the response.

3c3a Tags include correction factors on temperature measuring devices.
The tags did not include correction factors in media area.
Send copies of the tags.

APPENDIX N LAB

1c Adequate lighting, [NCIMS Certified Laboratories, and Certified Industry Supervisors >50 foot candles at the working surface (pref. 100)].

During the technique demonstration, the wall light was not used. The lighting measured 14-24 foot candles in the confirmation testing area. The confirmation testing area had 83-105 foot candles when the wall light was utilized. Whenever testing is being conducted the wall light shall must be utilized.

It was determined during the survey that the screening test area had 20-25 foot candles of light. Add additional lighting to the area to increase to >50 ft-candles and send verification.

TESTS-LIST ALL TESTS OBSERVED and DEVIATIONS OF TECHNIQUES.

CERTIFIED LAB

Standard Plate Count, Coliform, and Simplified Count Methods (IMS#2 rev. 1/09)

5. Sample Agitation

5b1 Shake samples raw samples 25 times in 7 sec with 1 ft movement
All analysts did not shake quickly enough. Raw samples need to be shaken more vigorously.

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5b2. Invert filled retail container 25 times, each inversion a complete down and up motion
All analysts did not complete the inversions.

6d. Avoid foam if possible when pipet is inserted into sample.
All analysts did not avoid the foam. The raw milk container may be tapped on the container on counter and tilted as to show clear spot on surface of milk. The pipet is not inserted more than 2.5 cm. Analysts may use the cap of retail containers or sterile Petri dish to adjust the pipet volume and not adjust pipet volume while pipet is still in liquid portion of sample.

APPENDIX N LAB

CHARM SL BETA LACTAM (IMS# 9C13 rev 2/10)

3a1. Incubator level. Temperature checked daily (day of use), records maintained.
The temperature is not being recorded to the tenth of a degree.
Please instruct analysts to record the strip incubator to the tenth of a degree.
Send copies of the temperature record for the next two months.

14d. Reader tapes or computer printouts maintained for two years.
It would be best to keep the printouts with the daily sheets as it is more difficult to look through separate stacks to match the tankers tested.

Comments/Recommendations: Optional Areas that may need to be addressed or LEO has some concern.

PERSONNEL AND PROCEDURES CERTIFIED

LEO IS TO LIST ALL THE PERSONNEL AND PROCEDURES THAT WERE EVALUATED AT THIS AUDIT. INCLUDE A LETTER (X, C, N, ETC.) THAT DENOTES THE STATUS OF ANALYSTS (REFERENCED AS BELOW) ON THE EVALUATION AND SPLIT SAMPLES.

CERTIFIED LAB

PERSONNEL AND PROCEDURES CERTIFIED

	SPC/PACCOLI/PCCPMC	D3	I1	C[3,9,10,12]	DMSCC	PHOS[28]		
Name Analyst 1	X/N	X/X	X	C	X	X	X	X
Name Analyst 2	X/P	X/X	X	X	X	X	X	X

[X denotes full certification in the indicated procedures pending acceptable performance in the annual proficiency testing program (split sample) for all procedures for which certification has been granted. P denotes provisional certification pending acceptable performance in the annual

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Date

proficiency testing program for all procedures for which certification has been granted. C denotes conditional certification pending acceptable performance in the annual proficiency testing program for all procedures for which certification has been granted. N denotes no certification status granted.].

APPENDIX N LAB

Certified Industry Analysts	2010 On-Site Evaluation TEST KIT	4/2010 Split Sample Survey TEST KIT
Name CIS 1	x (CIS)	x
Name CIS 2	x (CIS)	x
Name CIS 3	No Longer Employed	x

Industry Analysts	2010 On-Site Evaluation TEST KIT	6/2010 Split Sample Survey TEST KIT
Name IA 1	x	x
Name IA 2	x	x

CONCLUSION

Use the proper conclusion found on pages 24 & 25.

EXAMPLE REPORT #1

Report of a Biennial On-Site Evaluation of
{*Laboratory Name*}
{*Address of Physical Location*}
{*City, State & Zip Code*}

IMS LAB # {*SSXXX or SSXXXX*}

On

{*Date of Survey (Month Day(s), Year)*}

By

{*Name of LEO*}
Laboratory Evaluation Officer
State Department of {*Health or Agriculture*}
{*Physical / Mailing Address*}
{*City, State & Zip Code*}

Date of Last Evaluation: {*Month Day(s), Year*}
Prior Procedures (IMS Code): 5, 9C13, 9C14, 9D3, 12, 20, 22, 24, 28
Prior Laboratory Status: Fully Accredited

Evaluated Procedures: 5, 9C13, 9D3, 12, 16, 20 22, 24, 28
Present Laboratory Status: Fully Accredited, pending receipt of a satisfactory written response to the noted deviations on or before {*Month Day(s), Year - specified date usually 60 days from expected receipt of the narrative report*}.

Changes to IMS List: Drop procedure 9C14, add procedure 16.

A copy of the Grade "A" Milk Laboratory Evaluation Request and Agreement Form is signed and on file.

The following is a summary of the recent evaluation of your milk laboratory in accordance with the requirements of the Grade "A" Pasteurized Milk Ordinance. If FDA 2400 series forms accompany the narrative report, deviated items are marked with an "X"; undetermined items because of local conditions at the time of the evaluation are marked "U"; on the accompanying evaluation forms. laboratory procedures and/or equipment not used are marked "O"; optional procedural techniques and/or equipment not applicable to designated laboratory procedures are marked "NA"; repeat deviations from the previous on-site survey are marked with an asterisk "*"; and supplementary information or suggested good laboratory practices not specifically listed in the FDA 2400 series forms or considered stand-alone deviations but are intended to improve laboratory function are designated by "Note" and do not require a written response.

DEVIATIONS AND CORRECTIVE ACTIONS:

Item Method

{Cite procedure title and revision date for each FDA 2400 series form used to conduct the survey followed by any applicable deviations, notes or relevant remarks/comments}

{Item} *{First statement should be a concise descriptive representation of the observed issue with specific example(s) of occurrence(s) in one or two sentences}* {Second statement should specifically describe what, how and/or when the lab is to remedy the issue} {The third statement should specifically describe what is to be submitted by the lab along with the written response (copies of new or revised records, service manifest, new purchase shipping manifest, certificate of authenticity, etc.) to the LEO as verification that appropriate corrective action was taken, when applicable}.

Cultural Procedures – General Requirements (rev. 2/10)

2e During the review of the autoclave records it was noted that there were several data points written over. Analysts are to use proper protocol for correcting mistakes: cross out the error with a single line, initial and write the correct information next to it. Note that the date discovered/corrected should also be documented as a good laboratory practice. Lab is to send copies of the autoclave records from the time of the survey that demonstrate proper corrective action being taken.

3a Note: The graduations on the lower end of the NIST thermometer are so worn that it is difficult to read. If the graduations cannot be restored, it is suggested that a new thermometer be purchased. Optionally, the lab may use the new electronic/digital NIST traceable temperature measuring device (with access to certificate of accuracy and annual ice point check records) that is available for use in the rest of the laboratory.

3c3 Although the accuracy check was documented, no tag was found on the freezer thermometer. Tag the thermometer with the following information: identification or serial number (SN) / location, date of check, temperature checked and the correction factor. Send a copy of the new tag.

5b Over the past four months at least 50% of the days observed in the temperature monitoring records showed that the freezer was consistently greater than the acceptable temperature range with no corrective action documented. This is a serious violation and no reagents or controls may be kept in this freezer until it is proven that that the freezer holds the temperature within the acceptable temperature range (< -15.0 ºC). If this freezer cannot maintain the proper temperature, then a new freezer will need to be

purchased. Send copies of the repaired or new freezer temperature monitoring records for the next 4 months from the date of the survey.

13i There were no accuracy-checked thermometers for the spore incubation units used for the autoclave performance check. There must be a way to check the appropriate temperature range for the test. Lab must obtain/purchase thermometers dedicated for these units. Send a copy of the shipping manifest (if newly purchased), the accuracy check records and the temperature monitoring records for the following two months.

Petrifilm Aerobic and Coliform Counts (5 &20, rev. 1/09)

No deviations were noted.

Comment: The analysts showed marked improvement over the last biennial on-site survey.

Pasteurized Milk Containers (22, rev. 1/09)

10b2 One analyst held the bottle against the container while adding the rinse solution. Use aseptic technique while adding the rinse solution to the container, and do not touch the bottle while pouring the rinse solution to the container.

Appendix N – General Requirements (rev. 2/10)

1-8 See Cultural Procedures, items 1-32 (as applicable).

9 See Cultural Procedures, item 33 (as applicable).

10a Note: Suitability on new purchased lot of test kits should be conducted in a timely manner that allows enough time to replace the new lot of test kits upon failure and prior to running out of previous lot in use.

12 The lab records showed that a new bulk milk tanker sample was collected without a documented explanation to perform confirmation testing of a presumptive positive load. A resample may only be collected at the discretion of the State regulatory agency and with appropriate justification and documentation.

14 See Cultural Procedures, item 34 (as applicable).

15 See Cultural Procedures, items 35 (as applicable).

Delvotest P 5 Pack (9D3, rev. 2/10)

No deviations were noted.

Charm SL Beta-Lactam Test (IMS# 9C13 rev. 1/10)

4c1 Commingled raw milk was being collected from a raw milk silo for preparation of the Negative and subsequent Positive Controls without prior testing for the presence of drug residues. Silo milk must be shown to test negative using the test kit of use prior to preparing the controls for use or storage (previously tested negative). Send copy of records demonstrating that previously tested negative raw milk is used to prepare the Negative and Positive Controls.

Direct Microscopic Somatic Cell Count (12 rev. 2/10)

21e When preparing the milk smears, one analyst held the metal (positive displacement) syringe above the slide and dripped the milk sample test portion. Holding the syringe almost vertically and the syringe tip contacting the slide near the center of the delineated area for the milk smear gently depress the plunger to slowly expel the milk. Maintaining the plunger fully depressed, remove the tip from the milk and touch off to a dry spot.

Electronic Somatic Cell Count – Bentley 150 (16, rev. 10/07)

No deviations were noted.

Dairy Waters using Multiple Tube Fermentation (MTF) Technique by Most Probable Number (MPN), Heterotrophic Plate Count (HPC) and Idexx Colilert-24 by Presence-Absence (24, rev. 1/09)

No deviations noted.

Alkaline Phosphatase Test – Advanced Instruments Fluorophos (28 rev. 6/05)

15g2b The A/D value for substrate / buffer stability as part of the Daily Performance Check was missing on several days of official sample testing records reviewed during the survey period. While this may be from having to reconstitute a new bottle of substrate because the A/D value was greater than 1200, the corrective action must be documented with both the old and new values recorded.

PERSONNEL & PROCEDURES CERTIFIED:

Analyst	Procedures (IMS Codes)									**ON-SITE Last 2**	**SPLITS Last 2**
	5	9C13	9D3	12	16	20	22	24	28		
Analyst 1	F	F	F	F	F	F	F	F	F	m/yy, m/yy	m/yy, m/yy
Analyst 2	F	F	F	F	F	F	F	F	F	m/yy, m/yy	m/yy, m/yy
Analyst 3	F	F	F			F	F	F	F	m/yy, m/yy	m/yy, m/yy
Analyst 4	F	F	F			F	F	F	F	m/yy	m/yy
Analyst 5*	F	F	F	F	F	F	F	F	F	m/yy, m/yy	m/yy, m/yy

F = Fully Certified
P = Provisionally Certified
C = Conditionally Certified
N = Not Certified
* = Analyst excused – on medical leave.

To maintain certification, analysts must successfully participate in the Annual Proficiency Testing Program for all procedures for which certification has been granted.

CONCLUSION:

Although the procedures, records and/or equipment in use at the time of the evaluation were in substantial compliance with the requirements of the Grade "A" Pasteurized Milk Ordinance, the analyst/facility deviations noted must be corrected. This laboratory is accredited, pending correction of the deviations and receipt of a letter detailing the corrections made. Upon receipt of a satisfactory written response and other appropriate documentation detailing the corrective actions taken on or before {***Month Day(s), Year*** *- specified date usually 60 days from expected receipt of the narrative report*}, full accreditation status will be granted.

EXAMPLE REPORT #2

Report of a Supplemental {used for interim accreditation of *new analyst(s), new procedure(s), check surveys or walk-through*} On-Site Evaluation of

{Laboratory Name}
{Address of Physical Location}
{City, State & Zip Code}

IMS LAB # { *SSXXX or SSXXXX* }

On

{Date of Survey (Month Day(s), Year)}

By

{Name of LEO}
Laboratory Evaluation Officer
State Department of {*Health or Agriculture*}
{Physical / Mailing Address}
{City, State & Zip Code}

Date of Last Evaluation: *{Month Day(s), Year}*
Prior Procedures (IMS Code): 5, 9C13, 9C14, 9D3, 12, 20, 22, 24, 28
Prior Laboratory Status: Fully Accredited

Evaluated Procedure: 12 and 16
Participating Analysts: Analyst 3 and Analyst 4
Present Laboratory Status: Fully Accredited, pending receipt of a satisfactory written response to the noted deviations on or before {*Month Day(s), Year - specified date usually 60 days from expected receipt of the narrative report*}.

Changes to IMS List: None.

A copy of the Grade "A" Milk Laboratory Evaluation Request and Agreement Form is signed and on file.

The following is a summary of the recent evaluation of your milk laboratory in accordance with the requirements of the Grade "A" Pasteurized Milk Ordinance. If FDA 2400 series forms accompany the narrative report, deviated items are marked with an "X"; undetermined items because of local conditions at the time of the evaluation are marked "U"; on the accompanying evaluation forms. laboratory procedures and/or equipment not used are marked "O"; optional procedural techniques and/or equipment not applicable to designated laboratory procedures are marked "NA"; repeat deviations from the previous on-site survey are marked with an asterisk "*";

and supplementary information or suggested good laboratory practices not specifically listed in the FDA 2400 series forms or considered stand-alone deviations but are intended to improve laboratory function are designated by "Note" and do not require a written response.

DEVIATIONS AND CORRECTIVE ACTIONS:

Item **Method**

Cultural Procedures – General Requirements (rev. 2/10)

3 The thermometer used in the water bath dedicated for the Electronic Somatic Cell Count procedure was not labeled. Records for this thermometer's accuracy check were current. The thermometer label was replaced during the survey. No further corrective action is required.

20 See ESCC item 4a below.

Direct Microscopic Somatic Cell Count

25i Monthly comparison counts were not being evaluated properly. When 3 or more analysts are participating, the RpSm method of evaluation must be used (see PAC item 17a1). Submit copies of the monthly comparison counts from the date of this on-site survey showing the use of the RpSm method of evaluation.

No technique deviations were observed.

Electronic Somatic Cell Count – Bentley 150 (16, rev.)

4a The water in the ESCC water bath was not circulating. Lab must repair or replace the circulating water pump before the water bath can be used to warm the ESCC samples immediately prior to analysis. Submit itemized service receipt or shipping manifest along with written response.

No technique deviations were observed.

PERSONNEL & PROCEDURES CERTIFIED:

Analyst	Procedures (IMS Codes)									ON-SITE Last 2	SPLITS Last 2
	5	9C13	9D3	12	16	20	22	24	28		
Analyst 1	F	F	F	F	F	F	F	F	F	m/yy, m/yy	m/yy, m/yy
Analyst 2	F	F	F	F	F	F	F	F	F	m/yy, m/yy	m/yy, m/yy
Analyst 3	F	F	F	C	C*	F	F	F	F	m/yy, m/yy	m/yy, m/yy
Analyst 4	F	F	F	C	C*	F	F	F	F	m/yy	m/yy
Analyst 5	F	F	F	F	F	F	F	F	F	m/yy, m/yy	m/yy, m/yy

F = Fully Certified
P = Provisionally Certified
C = Conditionally Certified
N = Not Certified

* Conditional certification status was granted at the end of the on-site survey because the comparison study was submitted on {*Month Day, Year*} and found to be satisfactory as of {*Month Day, Year*}, and are on file.

To maintain certification, analysts must successfully participate in the Annual Proficiency Testing Program for all procedures for which certification has been granted.

CONCLUSION:

Although the procedures, records and/or equipment in use at the time of the evaluation were in substantial compliance with the requirements of the Grade "A" Pasteurized Milk Ordinance, the analyst/facility deviations noted must be corrected. This laboratory is accredited, pending correction of the deviations and receipt of a letter detailing the corrections made. Upon receipt of a satisfactory written response and other appropriate documentation detailing the corrective actions taken on or before {***Month Day(s), Year*** *- specified date usually 60 days from expected receipt of the narrative report*}, full accreditation status will be granted.

EXAMPLE REPORT #3

Report of a Supplemental On-Site Evaluation of
an Appendix N Bulk Milk Tanker Screening Facility at

{*Laboratory Name*}
{*Address of Physical Location*}
{*City, State & Zip Code*}

IMS LAB # {*SS6xx*}

On

{*Date of Survey (Month Day(s), Year)*}

By
{*Name of LEO*}
Laboratory Evaluation Officer
State Department of {*Health or Agriculture*}
{*Physical / Mailing Address*}
{*City, State & Zip Code*}

Date of Last Evaluation: {*Month Day(s), Year*}
Prior Procedures (IMS Code): 9C14
Prior Laboratory Status: Fully Accredited

Evaluated Procedures: 9C15
Participating Analysts: Analyst 1 and Analyst 2
Present Laboratory Status: Fully Accredited, pending receipt of a satisfactory written response to the noted deviations on or before {*Month Day(s), Year - specified date usually 60 days from expected receipt of the narrative report*}.

Changes to IMS List: Drop procedure 9C14 and add procedure 9C15.

A copy of the Grade "A" Milk Laboratory Evaluation Request and Agreement Form is signed and on file.

The following is a summary of the recent evaluation of your milk laboratory in accordance with the requirements of the Grade "A" Pasteurized Milk Ordinance. If FDA 2400 series forms accompany the narrative report, deviated items are marked with an "X"; undetermined items because of local conditions at the time of the evaluation are marked "U"; on the accompanying evaluation forms. laboratory procedures and/or equipment not used are marked "O"; optional procedural techniques and/or equipment not applicable to designated laboratory procedures are marked "NA"; repeat deviations from the previous on-site survey are marked with an asterisk "*"; and supplementary information or suggested good laboratory practices not specifically listed in the FDA 2400 series forms or considered stand-alone deviations but are intended to improve laboratory function are designated by "Note" and do not require a written response.

DEVIATIONS AND CORRECTIVE ACTIONS:

Item	Method
	Appendix N – General Requirements (rev. 2/10)
1c	During survey of analyst technique, the previously dedicated wall light was not used. The lighting measured 14-24 foot candles in the testing area, which was below the requirement of > 50 foot-candles at the working surface. The testing area had 83-105 foot candles when the wall light was utilized. Whenever testing is being conducted the wall light must be utilized.
3c3a	The tags for those temperature measuring devices in the media preparation area did not include correction factors. These tags are to include the correction factor determine at the temperature of use. Send copies of the revised tags.
	Charm 3 SL3 Beta-Lactam Test (9C15, rev. 11/12)
5b1	Two analysts shook samples 25 times, but always took greater than 7 sec. Analysts are to shake raw milk samples 25 times in 7 sec with 1 ft movement.

PERSONNEL & PROCEDURES CERTIFIED:

		− Procedures (IMS Codes) −		Last 2	Last 2
Analyst	Position	9C[14*]	9C[15]	Surveys	Splits
Analyst 1	CIS	N[1]	C	m/yy, m/yy	m/yy, m/yy
Analyst 2	CIS	N[1]	C	m/yy, m/yy	m/yy, m/yy
Analyst 3	IA	NA[2]		m/yy, m/yy	m/yy, m/yy
Analyst 4	IA	NA[2]		m/yy, m/yy	m/yy, m/yy

F = Fully Certified
FA = Fully Approved
P = Provisionally Certified
PA = Provisionally Approved
C = Conditionally Certified
CA = Conditionally Approved
N = Not Certified
NA = Not Approved

1 Laboratory accreditation, and as a consequence analyst certification has been removed due to voluntary withdraw during this on-site survey for the indicated procedure.
2 Approval status was removed due to analyst no longer employed.

To maintain approve status, analysts must successfully participate in annual milk split sample performance evaluation provided by the Industry Supervisor or a State Laboratory Evaluation Officer for all procedures for which approval has been granted.

CONCLUSION:

Although the procedures, records and/or equipment in use at the time of the evaluation were in substantial compliance with the requirements of the Grade "A" Pasteurized Milk Ordinance, the analyst/facility deviations noted must be corrected. This laboratory is approved, pending correction of the deviations and receipt of a letter detailing the corrections made. Upon receipt of a satisfactory written response and other appropriate documentation detailing the corrective actions taken on or before {***Month Day(s), Year*** *- specified date usually 60 days from expected receipt of the narrative report*}, fully accreditation status will be granted.

EXAMPLE REPORT #4

Report of a Biennial On-Site Evaluation of
an Appendix N Bulk Milk Tanker Screening Only Facility at

{*Laboratory Name*}
{*Address of Physical Location*}
{*City, State & Zip Code*}

IMS LAB # {*SS999-yyyy*}

On

{*Date of Survey (Month Day(s), Year)*}

By

{*Name of LEO*}
Laboratory Evaluation Officer
State Department of {*Health or Agriculture*}
{*Physical / Mailing Address*}
{*City, State & Zip Code*}

Date of Last Evaluation: {*Month Day(s), Year*}
Prior Procedures (IMS Code): 9I1
Prior Laboratory Status: Fully Approved

Evaluated Procedures: 9I1
Present Laboratory Status: Fully Approved, pending receipt of a satisfactory written response to the noted deviations on or before {*Month Day(s), Year - specified date usually 60 days from expected receipt of the narrative report*}.

A copy of the Grade "A" Milk Laboratory Evaluation Request and Agreement Form is signed and on file.

The following is a summary of the recent evaluation of your milk laboratory in accordance with the requirements of the Grade "A" Pasteurized Milk Ordinance. If FDA 2400 series forms accompany the narrative report, deviated items are marked with an "X"; undetermined items because of local conditions at the time of the evaluation are marked "U"; on the accompanying evaluation forms. laboratory procedures and/or equipment not used are marked "O"; optional procedural techniques and/or equipment not applicable to designated laboratory procedures are marked "NA"; repeat deviations from the previous on-site survey are marked with an asterisk "*"; and supplementary information or suggested good laboratory practices not specifically listed in the FDA 2400 series forms or considered stand-alone deviations but are intended to improve laboratory function are designated by "Note" and do not require a written response.

DEVIATIONS AND CORRECTIVE ACTIONS:

Item	Method
	Appendix N – General Requirements (rev. 2/10)
1c	Note: During the survey of analyst technique, the lighting in the immediate testing area measured 20-25 foot candles. Additional lighting should be added to the testing area, increasing the lighting to be >50 foot-candles. Whenever testing is being conducted the additional lighting should be utilized.
3	Digital thermometer placed in well of heat block fit loosely. Probe/sensor of digital/electronic temperature measuring device must have proper diameter to fit snugly into heat block or it must be placed in tube with water and placed in test well.
	Idexx New Snap Beta-Lactam Test (9I1, rev. 7/12)
6c	The sample and control tubes were not labeled during observation of the analysts' testing technique. All tubes and devices must be properly labeled for testing regardless of how many samples are being tested.

PERSONNEL & PROCEDURES APPROVED:

	− Procedures (IMS Codes) −	Last 2	Last 2
Analyst	9I[1]	Surveys	Splits
Analyst 1	FA	m/yy, m/yy	m/yy, m/yy
Analyst 2	FA	m/yy, m/yy	m/yy, m/yy
Analyst 3	FA	m/yy, m/yy	m/yy, m/yy
Analyst 4	FA	m/yy, m/yy	m/yy, m/yy

FA = Fully Approved
PA = Provisionally Approved
CA = Conditionally Approved
NA = Not Approved

To maintain approve status, analysts must successfully participate in annual milk split sample performance evaluation provided by the Industry Supervisor or a State Laboratory Evaluation Officer for all procedures for which approval has been granted.

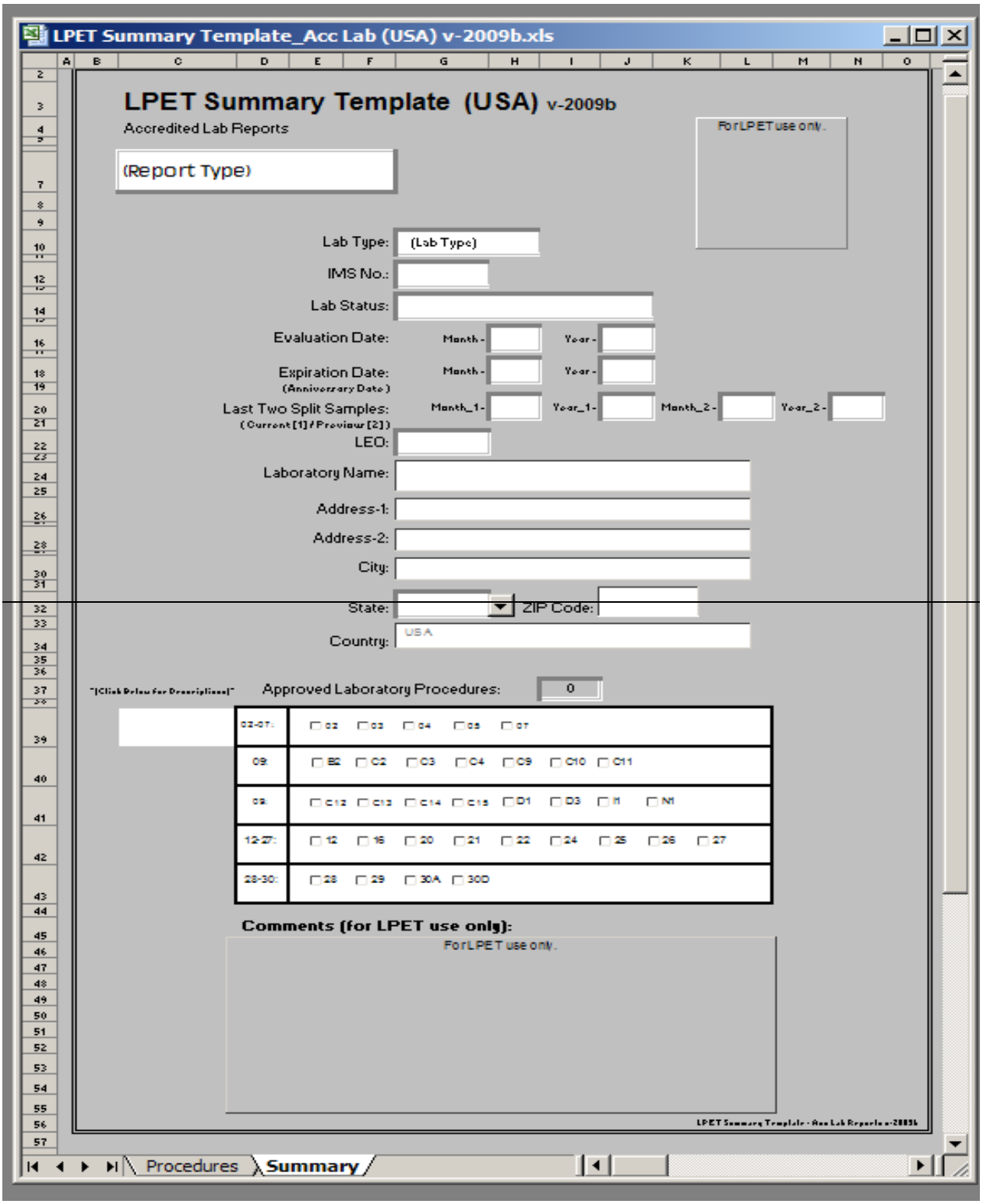
CONCLUSION:

Although the procedures, records and/or equipment in use at the time of the evaluation were in substantial compliance with the requirements of the Grade "A" Pasteurized Milk Ordinance, the

analyst/facility deviations noted must be corrected. This laboratory is approved, pending correction of the deviations and receipt of a letter detailing the corrections made. Upon receipt of a satisfactory written response and other appropriate documentation detailing the corrective actions taken on or before {***Month Day(s), Year*** *- specified date usually 60 days from expected receipt of the narrative report*}, fully approved status will be granted.

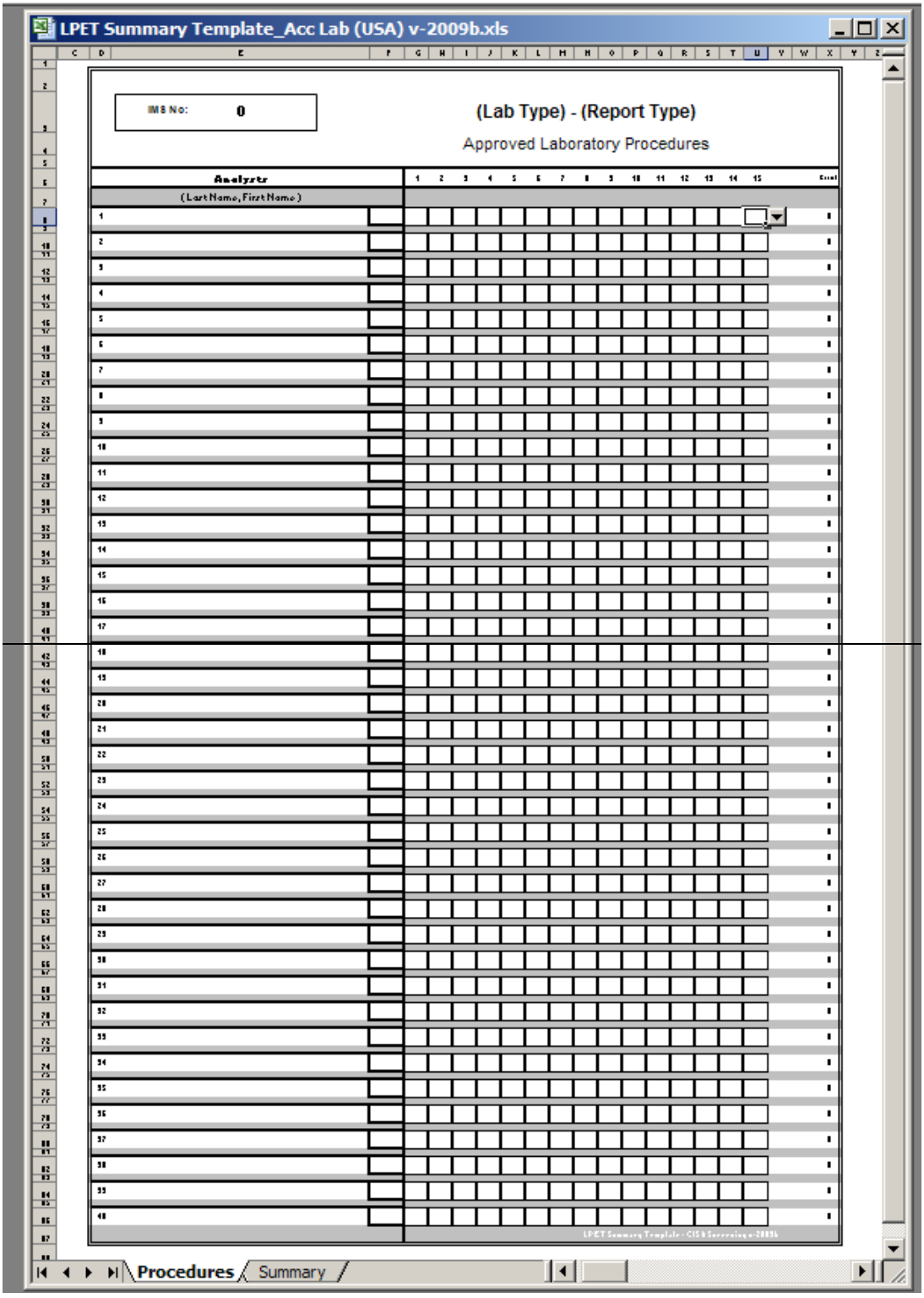
Page 37:

FDA SUMMARY TEMPLATES



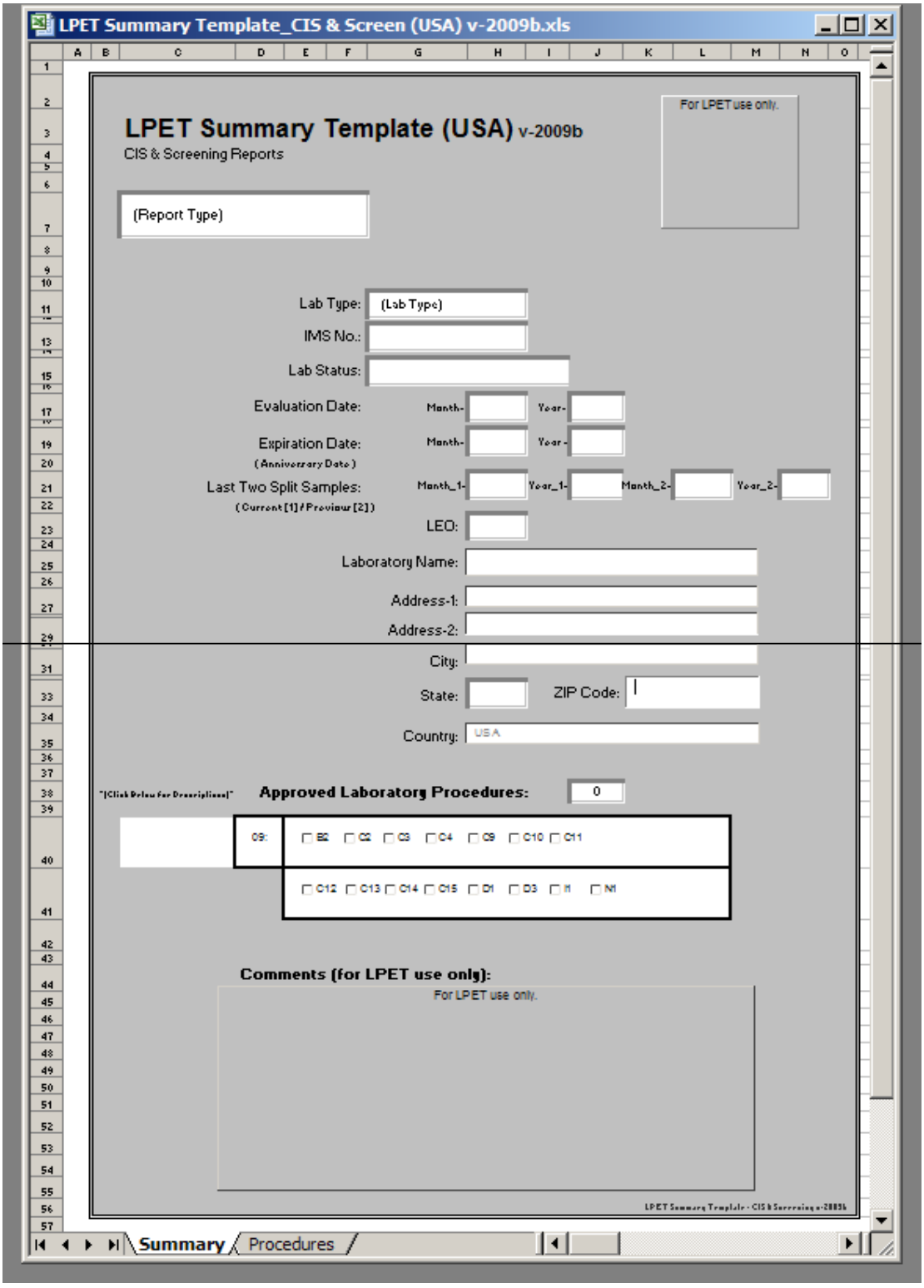
~~Figure 1: Summary sheet, LPET Summary Template_AccLab (USA) v-2009b.xls~~

Page 38:



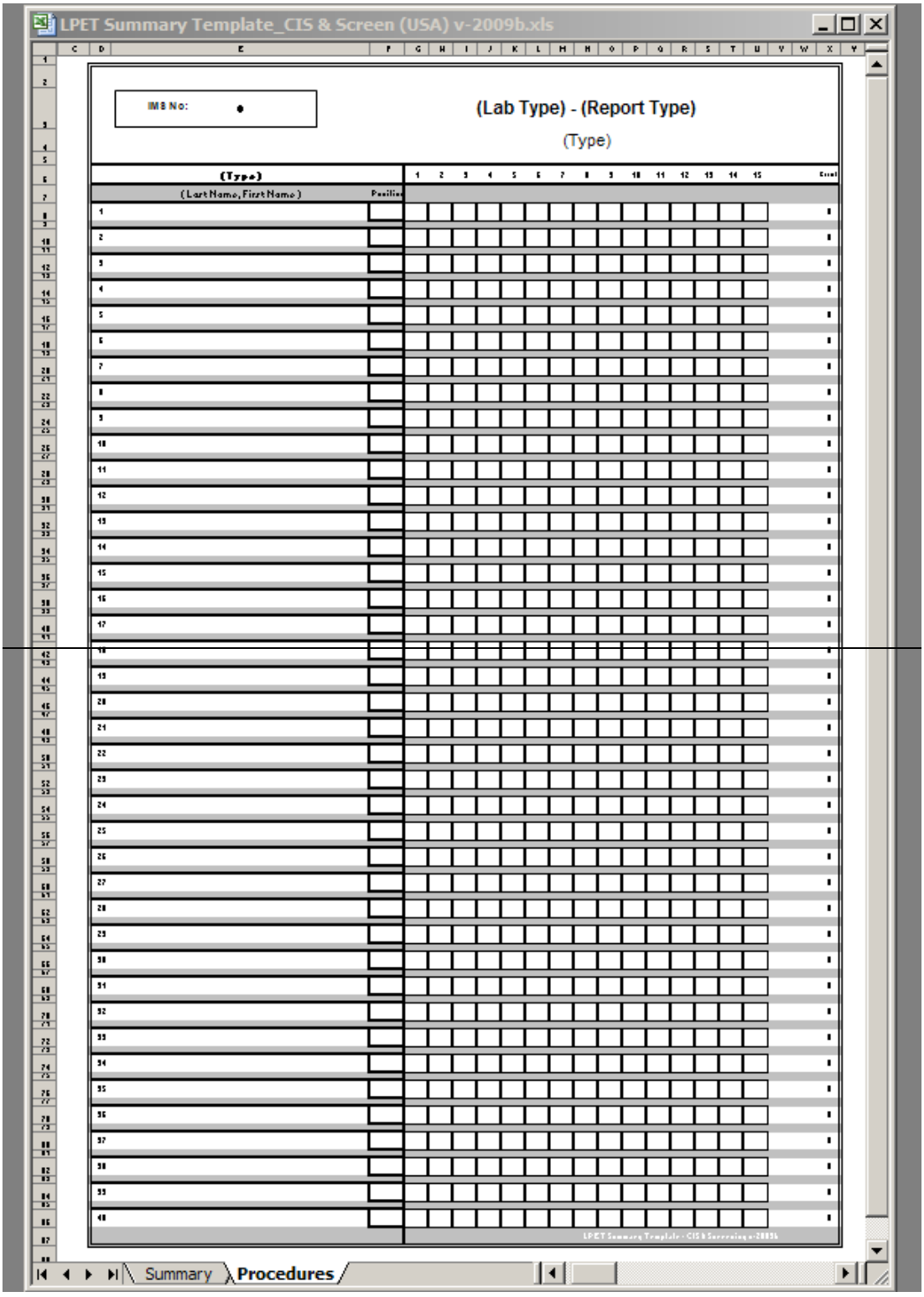
~~Figure 2: Procedures sheet, LPET Summary Template_AccLab (USA) v-2009b.xls~~

Page 39:



~~Figure 3: Summary sheet, LPET Summary Template_CIS & Screen (USA) v-2009b.xls~~

Page 40:



~~Figure 4: Procedures sheet, LPET Summary Template_CIS & Screen (USA) v-2009b.xls~~

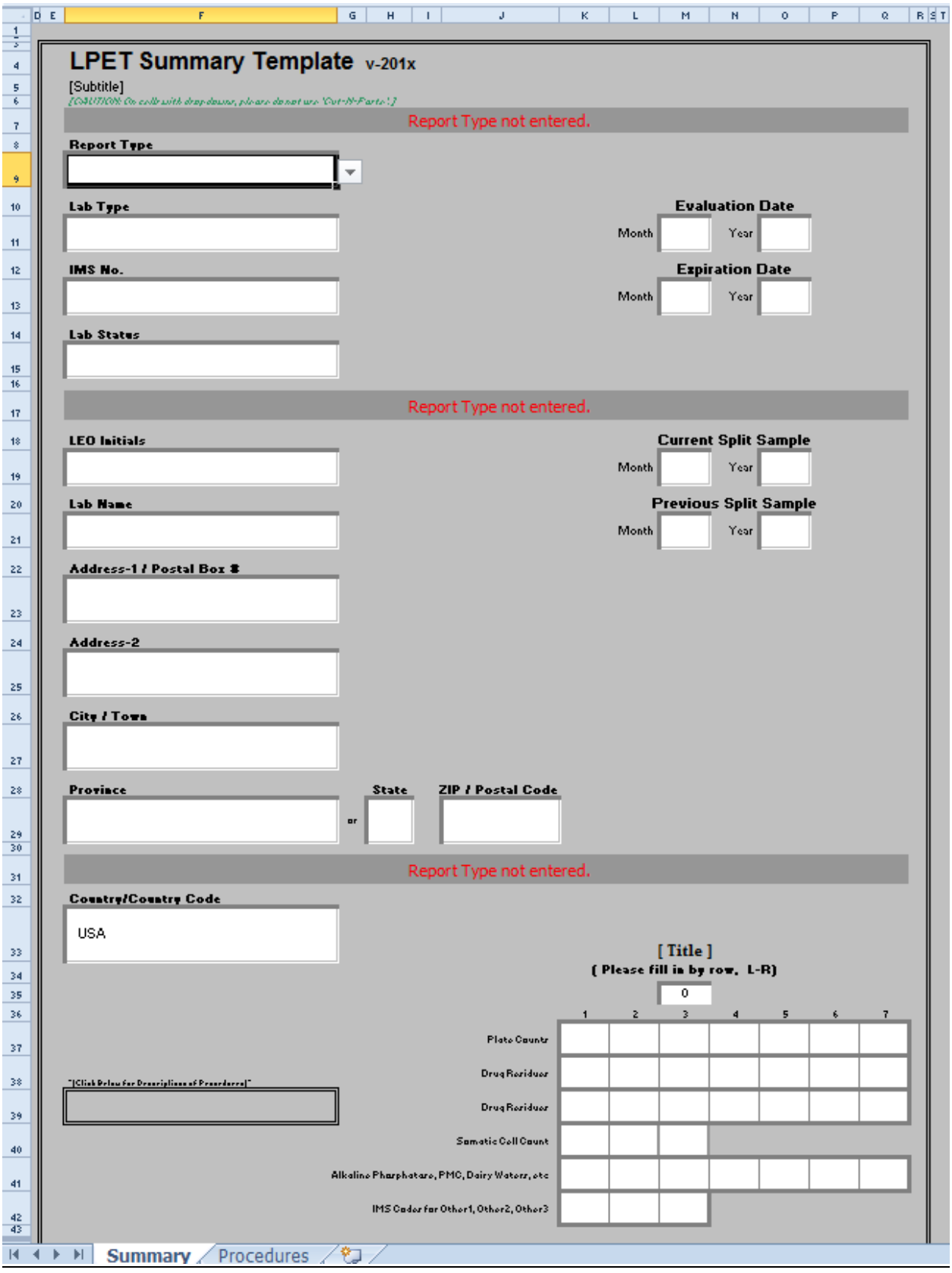

LPET Summary Template v-201x
[Subtitle]
[CAUTION: Do calls with drop-downs, please do not use 'Cut-N-Paste']
Report Type not entered.
Report Type
Lab Type
IMS No.
Lab Status
Evaluation Date
Month
Year
Expiration Date
Month
Year
Report Type not entered.
LEO Initials
Lab Name
Address-1 / Postal Box #
Address-2
City / Town
Province
or
State
ZIP / Postal Code
Current Split Sample
Month
Year
Previous Split Sample
Month
Year
Report Type not entered.
Country/Country Code
USA
[Title]
(Please fill in by row, L-R)
0
1 2 3 4 5 6 7
Plate Counts
Drug Residues
Drug Residues
Somatic Cell Count
Alkaline Phosphatase, PMC, Dairy Waters, etc
IMS Codes for Other1, Other2, Other3
"[Click Below for Descriptions of Procedures]"
Summary
Procedures

Figure 1: Summary sheet, LPET Summary Template_v-201x.xls

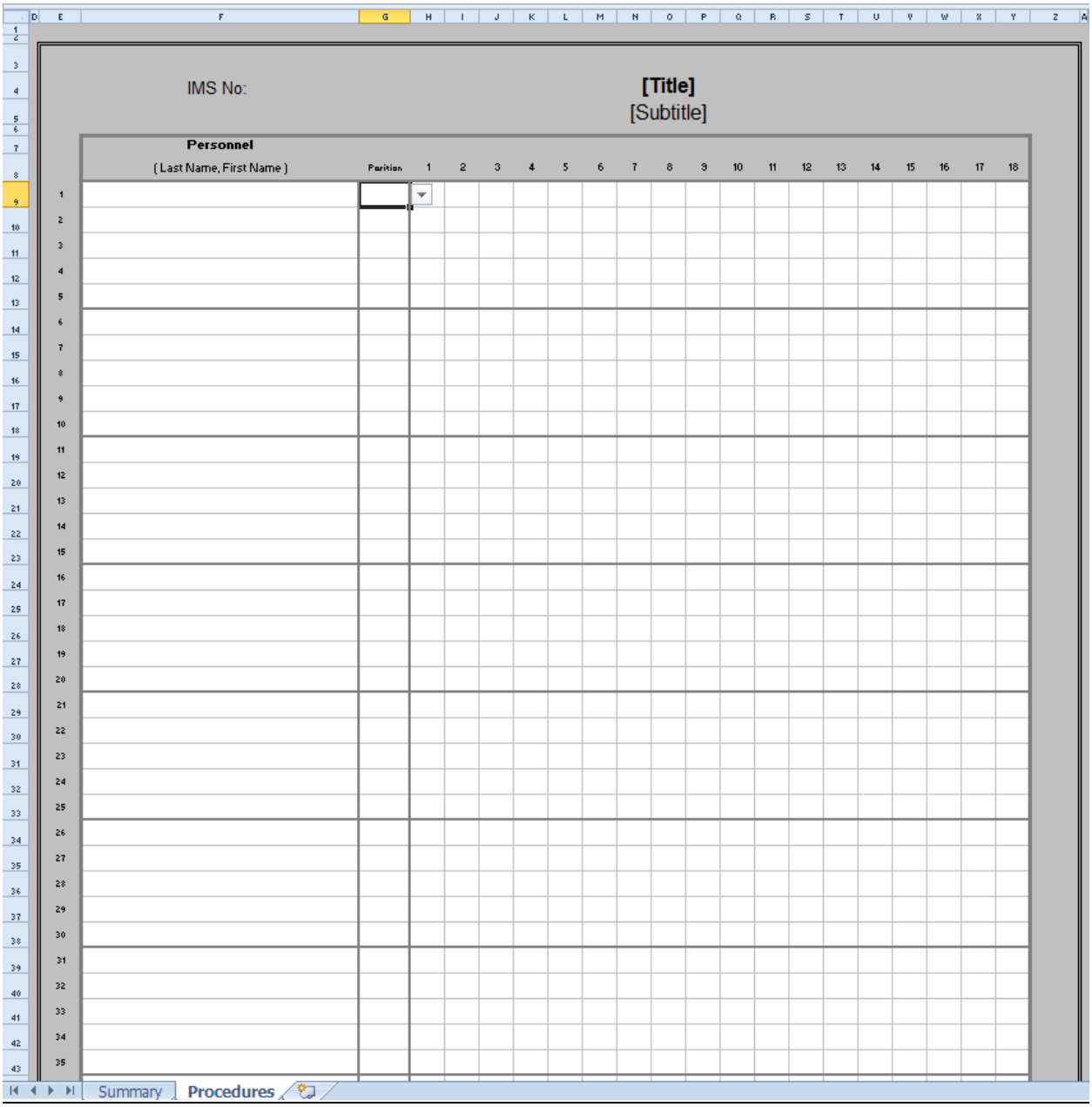


Figure 2: Procedures sheet, LPET Summary Template_v-201x.xls

Proposal: 216
Document: 2011 EML (Section 2; and Table 1)
Pages: 10-14, 27 and 28

Make the following changes to ***SECTION 2: PROFICIENCY TESTING PROGRAMS*** *on Pages 10-14, 27 and 28:*

Page 10:

SPLIT SAMPLE ANALYSIS

The Standard Plate Count (SPC), Petrifilm Aerobic Count (PAC), Plate Loop Count (PLC), BactoScan FC Count (BSC), Spiral Plate Count Loop Method (SPLC), Direct Microscopic Somatic Cell Count (DMSCC), Electronic Somatic Cell Count (ESCC)~~,~~ and Electronic Phosphatase Count ~~and Vitamin A and D_3~~ result of each certified analyst shall fall within the limits shown in Table 2, page 28. The Vitamin A and D_3 result of each certified analyst shall be evaluated by z-scores, which are based on ISO Standards, and are calculated for each individual set of split samples.

The steps for statistical analysis of split sample results are as follows: …

2. Calculate the logarithmic mean for the ~~Standard Plate Count~~ SPC, ~~Petrifilm Aerobic Count~~ PAC, ~~Plate Loop Count~~ PLC, ~~BactoScan FC Count (~~BSC~~)~~, ~~Spiral Plate Count Method (~~SPLC~~)~~, ~~Direct Microscopic Somatic Cell Count~~ DMSCC, ~~Electronic Somatic Cell Count~~ ESCC, and Electronic Phosphatase Count ~~and Vitamin A and D_3~~ results of each test sample; using a table of common logarithms, list the logarithms of all analyst counts for a given sample. Calculate the mean of the logarithms for the sample. …

Page 11:

6. Analysts certified for vitamin analysis shall meet the acceptance ~~limits (L_1 and L_2) and performance levels shown in Tables 2 and 3, page 28~~ criteria using z-scores. …

8. The annual proficiency testing (PT) program for vitamins A and D_3 shall be based on z-scores following ISO Standards. Data shall be converted to log base 10 values and a consensus mean determined. Based on the data for each PT, standard deviations shall be determined. Acceptable results shall be within plus or minus two (2) standard deviations.

ANALYST PERFORMANCE LEVEL

Analysts certified to perform the examinations required by the "Grade 'A' PMO" shall meet the following performance levels on an annual basis.

3. Analysts certified to perform the ~~Standard Plate Count~~ SPC, ~~Petrifilm Aerobic Count~~ PAC, ~~Plate Loop Count~~ PLC, ~~BactoScan FC Count~~ BSC, ~~Spiral Plate Count Method~~ SPLC, ~~Direct Microscopic Somatic Cell Count~~ DMSCC, ~~Electronic Somatic Cell Count~~ ESCC and Electronic Phosphatase Count ~~and Vitamin A and D_3~~ analysis~~,~~; and BIOs approved to operate

a BactoScan FC shall meet the acceptance limits and performance levels shown in Tables 2 and 3, page 28. …

Page 12:

6. Analysts certified to perform vitamin A and D_3 tests shall detect samples that contain vitamins A and D_3 and shall meet the acceptance limits and performance levels for the calculated z-scores, which are based on ISO Standards. Acceptable results shall be within plus or minus two (2) standard deviations.

Page 13:

SPLIT SAMPLES – CHEMISTRY

VITAMINS

The Grade "A" Vitamin ~~Proficiency Test~~ PT Program is operated by the FDA/LPET. In order to be accredited and be listed, laboratories ~~must~~ shall have analysts who have satisfactorily participated in at least two (2) consecutive split sample analyses and ~~must~~ shall have submitted satisfactory method validation and quality control/quality assurance (QC/QA) information. Participation in proficiency testing alone does not satisfy the criteria for analyst certification and laboratory accreditation.

The Grade ~~A~~ "A" Vitamin ~~Proficiency Testing~~ PT Program involves the analysis of sets of ~~four~~ six (6) to eight (8) samples sent to participating laboratories every ~~four (4)~~ six (6) months, i.e., ~~three~~ two (2) times a year with a minimum total of twelve (12) samples. Certification status is based in part on the ability of analysts to analyze samples and have their results fall within limits, ~~(L_1=0.300 and L_2=0.200, based on the statistical parameters set at the 1995 NCIMS Conference in St. Louis, MO)~~ which are evaluated using z-scores that are based on ISO Standards and calculated for each set of split samples. Conditional certification is granted to an analyst (not to a laboratory) when the analyst has satisfactorily analyzed two (2) sets of samples ~~(eight (8) samples~~ in two (2) consecutive shipments~~)~~. Analysts may have one (1) unsatisfactory result, i.e., miss (out of limits) one (1) sample, and still be considered as having satisfactory performance. After analyzing the next consecutive set of samples the analyst is considered fully certified if ~~no~~ not more than two (2) samples have been missed over the course of a one (1) year period ~~(twelve (12) consecutive samples analyzed)~~.

Once fully certified, analysts maintain certification by satisfactorily analyzing ~~all three (3)~~ both sets of split samples each year. During the course of the year full certification is maintained if ~~no~~ not more than two (2) samples ~~(of 12)~~ are missed. Failure without cause to analyze all ~~twelve (12)~~ samples during the course of the year ~~will~~ shall result in the down grading of an analyst's status. It is imperative that laboratory schedules be set up to allow for the analysis of these samples. If a fully certified analyst misses more than two (2) samples ~~(of 12)~~ then that analyst ~~will~~ shall be down graded to provisional certification. Full certification ~~will~~ shall be regained if that analyst misses ~~no~~ not more than one (1) sample of the next ~~eight (8)~~ set of samples that he/she analyzes. Provisionally or conditionally certified analysts that miss more than one (1)

sample in the next ~~eight~~ set of samples analyzed after receiving the respective status ~~will~~ shall have their certification/approval removed.

Once certification/approval is removed an analyst may only regain conditional certification by satisfactory performance on the next ~~eight~~ set of samples, i.e., miss ~~no~~ not more than one (1) sample. Full certification requires that the analyst meet the criteria described above.
For split sample purposes each analyst ~~must~~ shall independently analyze the samples. Routine analysis may be performed by multiple analysts working together or by partitioning duties. Certified analysts are responsible for conducting official analysis. Non-certified analysts may assist in analysis but may not solely perform official analyses or report official results.

Re-entry of laboratories that have voluntarily withdrawn or laboratories that have had their accreditation removed ~~is~~ are subject to meeting all of the requirements needed ~~from~~ for a new laboratory, including all quality control (QC) information. It is the responsibility of the laboratory to inform the FDA/LPET when a certified analyst is no longer employed at that laboratory. A laboratory that loses all of their certified analysts is no longer accredited to do official work and ~~must~~ shall seek new laboratory entry prior to resuming official analysis.

Page 14:

An acceptable annual proficiency testing program shall consist of the analyst examining pasteurized milk and milk products for Vitamins A and D_3, a minimum of ~~four (4)~~ six (6) samples ~~three (3)~~ two (2) times a year ~~for a total of twelve (12) samples annually~~ using the methods developed by the FDA, or methods that give statistically equivalent results to the FDA methods, for which the analyst has been approved, unless excused for due cause. The laboratory tests and recommended duplicates of samples are shown in Table 1, page 27.

Page 27:

TABLE 1: SPLIT SAMPLE COMPOSITION

PRODUCTS	NUMBER OF SAMPLES	DUPLICATES	ANALYSIS	NUMBER OF PRODUCT SAMPLES ANALYZED
HVD, or 2%, or Skim	3	1	Plate Count /Coliforms	3
			Phosphatase	1
			Vitamins	~~3~~ 1-8
Cream, heavy	2	1	Plate Count /Coliforms	2
			Phosphatase	2
			Vitamins	~~2~~ 1-8
Cream, light	2[a]	0 or 1	Plate Count /Coliforms	1
			Phosphatase	2[b]

			Vitamins	~~1~~ 1-8
Chocolate	2	1	Plate Count /Coliforms	2
			Phosphatase	1
			Vitamins	~~2~~ 1-8
Raw	6	3	Plate Count	6
Raw	8	4	Inhibitors	8
			Somatic Cells	8
			Added Water[c]	8
Dairy Water	8	4	Coliforms	8
			Heterotrophic Plate Count	8
Milk Totals	23[a]	10 or 11	Plate Count	14
			Coliforms	8
			Phosphatase	6
			Vitamins	~~8~~ 12-16
			Inhibitors	8
			Somatic Cells	8
			Added Water[c]	8
Dairy Water Total	8	4	Coliforms	8
			Heterotrophic Plate Count	8

a - One (1) of these samples serves as the temperature control (TC).
b - These two (2) samples are tested for both residual and reactivated phosphatase.
c - This analysis is optional.

Page 28:

TABLE 2: STATISTICAL LIMITS

TEST	REJECTION LIMIT 1 (L_1)*	REJECTION LIMIT 2 (L_2)*
Plate Counts	0.268	0.179
Direct Somatic Cell Count	0.300	0.200
Electronic Somatic Cell Count	0.212	0.143
Vitamins~~**~~	~~0.300~~ N/A	~~0.200~~ N/A
Electronic Phosphatase Count	0.300	0.200
Dairy ~~water~~ Water MPN	0.949	0.632
Heterotrophic Plate Count	0.300	0.200

* To be used with logarithmic mean.
** Limits for vitamin test results shall be based on z-scores. Acceptable results shall be within plus or minus two (2) standard deviations.

Proposal: 218
Document: 2011 EML (Section 6)
Page: 25

*Make the following changes to **SECTION 6: LABORATORY EVALUATION REPORTS** on Page 25:*

FDA SUMMARY TEMPLATES

The narrative report sent to FDA/LPET must be accompanied by the appropriate, completed FDA summary template for the laboratory, specifically representing the information required for verifying and updating the IMS List of accredited laboratories ~~and CISs~~ along with other useful information to be used by FDA/LPET. Only the current revision of the FDA summary templates, authored by FDA/LPET, may be used. There are two FDA summary templates: one for full service laboratories and one for Appendix N Screening Only facilities (CIS and IS). The information captured on the FDA summary template must match the information provided in the narrative report (i.e., IMS number, facility identification, accreditation and certification status, dates, procedures, conclusion, etc.). The information captured may also lend itself to analyst/laboratory tracking and filing by the State LEO.

Proposal: 223
Document: FDA 2400 Forms

Change the ranges for the standards for calibrating/ validating instruments used to provide somatic cell counts in milk to the following: 100-200, 250-350, 400-550, and 650-800. These changes would apply to standards used on all approved electronic cell counters,
If the 2013 Conference adopts a change in the regulatory somatic cell level to a lower value, the hourly check sample would be the one that falls most closely in line with the newer regulatory level. (Example: If the Conference reduces the regulatory level for Grade A raw milk to 600,000 per ml, the hourly check sample will be the 650-800 level. If the regulatory level is changed to 400,000 per ml, the hourly check sample will be the 400-550 level.) If the 2013 Conference does not adopt a change in the regulatory level for somatic cells in raw milk, the current levels for standards for electronic somatic cell counts would remain as they are currently listed.

Proposal: 224
Document: FDA 2400 Forms
Page: 1

*Make the following changes to the **FDA 2400 Form**:*

Remove IDEXX New SNAP Beta-Lactam 2400, page 1, Apparatus & Reagents, Section 3. Equipment, item f. and re- letter remaining Section 3. Items.

~~f. Kits received refrigerated~~
~~g.~~ f.
~~h.~~ g.
~~i.~~ h.

Proposal: 225
Document: FDA 2400 Forms
Page: 1

*Make the following changes to the **FDA 2400 Form**:*

Modify the IDEXX New SNAP Beta-Lactam 2400, title section for the milk sample.

(raw commingled cow, ~~and~~ raw commingled camel and raw commingled goat milk)

Proposal: 226
Document: FDA 2400 Forms
Pages: 1, 4, 5 and 8

*Make the following changes to the **FDA 2400 Form**:*

Page 1:

Title: Somascope MKII/SomaScope Smart/CombiScope

Page 1 of 9:

Section 3, Automated Electronic Somatic Cell Counters

d. CombiScope

Page 4 of 9:

Section 7, Other Working Solutions, a. Detergent Container

2. SomaScope Smart/CombiScope

Page 5 of 9:

Section 7, Other Working Solutions, b. Water Container(s), 5. Dispense
c) CombiScope

1. Pour the solution above into the "Triton Water" containers provided with the instrument

Section 8, Somatic Cell Counter, b. Instrument Initiation

3. CombiScope
a. The CombiScope instrument is designed to be turned on at all times
b. Turn on the personal computer (PC)
c. Key in the defined password for the respective user
d. Double-click the CombiScope icon to start up the user interface
e. Perform a zero and clean sequence

Page 8 of 9:

Section 13, Shut down procedure

c. CombiScope
1. The CombiScope instrument is designed to be turned on at all times
2. Perform a clean cycle twice
3. Clean the auto sampler
4. Switch off PC
5. Put instrument pipette in beaker of Triton Water solution (item 7b)

Proposal: 227
Document: FDA 2400 Forms
Pages: First page of each

*Make the following changes to the **FDA 2400 Forms**:*

First page of each:

The NCIMS Laboratory Committee in conjunction with FDA/LPET will add the IMS test codes to each of the 2400 Series Forms.

Proposal: 228
Document: FDA 2400 Forms

***NOTE:** Proposal 228 in its entirety, including the PMO changes is included on Page 181 of this document.*

*Make the following changes to the **FDA 2400 Form**:*

Make changes to the Form FDA 2400n – Appendix N General Requirements to reflect that samples of previously frozen sheep milk may be tested using methods validated for sheep milk, provided the sheep milk is sampled in accordance with an approved sampling and handling

protocol. Also, make changes to Form FDA 2400n-1 Charm SL / SL6 / SL3 to reflect that samples of previously frozen sheep milk can be officially tested using the Charm SLBL method after properly thawing using the same instructions as given for control samples provided the sheep milk is sampled in accordance with an approved sampling and handling protocol.

Proposal: 229
Document: FDA 2400 Forms
Page 7:

*Make the following changes to the **FDA 2400 Form**:*

2400a-4

Page 7 of 13

12. Samples Other than Milk _____

a. Weigh 11g aseptically into a 99mL dilution blank heated to 40-45°C _____

13. Dry Milk Product Samples _____

a. Weigh 11 g aseptically into a 99 mL dilution blank heated to 40-45 °C _____

1. Use standard dilution blank _____
2. Or, 2.0 % sodium citrate blank (pH<8.0) for relatively insoluble sample (e.g. whey) _____

b. Wet sample completely with gentle inversions _____
c. Let soak a minimum of 2 min; shake 25 times in 7 sec with a 1 ft movement; use within 3 min of agitation _____

INCUBATION

~~13~~ 14. Incubating Petrifilm Plates (see CP item 15) _____

a. Stack plates in horizontal position, clear side up _____

1. PAC/PCC – no more than 20 high _____
2. HSCC – no more than 10 high _____

b. Incubate within 10 min _____

1. PAC - 48±3 hours at 32±1°C _____
2. PCC/HSCC - 24±2 hours at 32±1°C _____

Renumber all Subsequent Items

Proposal: 231
Document: FDA 2400 Forms

*Make the following changes to the **FDA 2400 Form**:*

2400m Dairy Waters

1. Laboratory Requirements

e. Transit time does not exceed ~~30~~ 48 hours
f. Samples examined within ~~30~~ 48 hours of collection or within 2 hours of receipt (item 1d)

FDA DID NOT CONCUR WITH THIS PROPOSAL AS CITED IN THEIR LETTER TO THE NCIMS CHAIR DATED SEPTEMBER 3, 2013

FDA maintains that there was not appropriate science provided by the author of this Proposal and reviewed by the Scientific Advisory Committee to justify this change.

During the October 9-10, 2013 NCIMS Executive Board meeting, FDA and the Executive Board did not reach mutual concurrence with Proposal 231; therefore, Proposal 231 in accordance with Section IX-Application of Conference Agreements, A-Implementation of Changes, 4. of the *Procedures* will be referred to the next Conference for discussion.

Proposal: 220
Document: No Document Referenced

The NCIMS Chair is to appoint a study committee or assign to a standing committee to examine the issue when drug residue screening is conducted with an unapproved test for contractual or export obligations and at a testing level different than the safe/tolerance level, when a Food and Drug Administration (FDA) approved test does exist.

The appointed study committee or assigned standing committee will provide a report on the topic at the 35th National Conference on Interstate Milk Shipments in 2015. The report will examine current obligations under the Grade "A" Pasteurized Milk Ordinance and may propose additional requirements via a formal proposal.

Proposal: 222
Document: No Document Referenced

Assign a committee to review the EPA Final Revised Total Coliform Rule signed by the EPA Administrator on December 20, 2012 for publication in the Federal Register and report to the 2015 NCIMS Conference on any suggested changes to the PMO.

Proposal: 301

NOTE: *Proposal 301 in its entirety, including the PROCEDURES changes is included on Page 296 of this document.*

FDA requests the NCIMS Chair to assign the following charges to the identified NCIMS standing committee(s) and to report back to the 2015 NCIMS Conference:

- SSCC and Methods Committees Jointly: To develop listing and withdrawal of listing criteria for SSCC manufacturers. Consultants that currently have SSCC listings on the IMS List shall participate on these Committees.

- SSCC Committee: To develop qualifications, authorization, certification/recertification procedures, etc. for consultants that currently certify or wish to certify SSCC manufacturers located outside the geographical boundaries of NCIMS Member States. Consultants that currently have SSCC listings on the IMS List shall participate on this Committee.

Proposal: 305

NOTE: *Proposal 305 in its entirety, including the PMO, PROCEDURES, CONSITUTION AND BYLAWS, MMSR and EML changes is included on Page 5 of this document.*

The ICPPC requests the NCIMS Chair to assign the following charges to the SSCC Committee and to report back to the 2015 NCIMS Conference:

Develop qualifications, authorization, certification/recertification procedures, etc. for consultants that currently certify or wish to certify SSCC manufacturers located outside the geographical boundaries of NCIMS Member States. Consultants that currently have SSCC listings on the IMS List shall participate on this Committee.

All Proposals that make changes to the NCIMS documents will be incorporated into the next edition of the affected document as they are updated. Copies of this memorandum are enclosed for distribution to Regional Milk Specialists, State Milk Regulatory Agencies, State Laboratory Evaluation Officers, and State Milk Rating Officers. This memorandum should be widely distributed to representatives of the milk industry and other interested parties, and will be available on the FDA Web Site at www.fda.gov at a later date.

If you would like an electronic version of this document prior to it being available on the FDA Web Site, please e-mail your request to Robert.Hennes@fda.hhs.gov.

Robert F. Hennes, RS, MPH
CAPT, US Public Health Service
Dairy and Egg Branch