NCIMS
National Conference on Interstate Milk Shipments

Procedures Governing the Cooperative State–Public Health Service/ Food and Drug Administration Program of the National Conference on Interstate Milk Shipments

Includes the Constitution and Bylaws

2023 Revision

PREFACE

The safety of fluid milk and milk products shipped interstate as well as intrastate has been of major importance to both the dairy industry and regulatory agencies for many years. In 1946, the Conference of State and Territorial Health Officers requested the U.S. Public Health Service (PHS) to develop a plan for the certification of interstate milk shippers. Such a plan was developed and submitted to the States; however, at the time, few States were able to undertake the additional responsibilities involved. In 1949, the Association of State and Territorial Health Officers again requested PHS to assist the States with ensuring a safe milk supply. Similar demands were made by State Health Departments and State Agricultural Departments, Local Health Officials and representatives of the milk industry. In December 1949, representatives of several Midwestern States met in Indianapolis, Indiana, for the purpose of discussing the problems and determining whether some plan could be developed to address a more effective and efficient system of regulating the interstate shipment of milk and milk products. As a result, representatives of eleven (11) Midwestern States met in Chicago, Illinois, in February 1950, to investigate the problem and to arrange for a National Conference.

This committee requested the Surgeon General of the United States to invite all States to have their representatives attend a National Conference in St. Louis, Missouri, June 1, 1950. Representatives of the dairy industry, State Health Departments and State Agricultural Departments, comprising 22 States and the District of Columbia, attended and participated in the Conference. As a result of the Conference and joint planning, certain basic conclusions and procedures were established to be used in developing and administering a voluntary Interstate Milk Shipper Certification Program that would provide Regulatory Agencies with reliable data on the safety of milk and milk products shipped in interstate commerce.

The procedures accepted by the first Conference in 1950 have been used to advantage by many States in developing sound, and more uniform, milk sanitation programs. They have also led to the development of a greater degree of reciprocity between States on acceptance of inspection and laboratory results. These procedures have also been used by many States as a basis of programs for the supervision and certification of intrastate milk sources.

The National Conference on Interstate Milk Shipments (NCIMS) has served as a model cooperative program between PHS/Food and Drug Administration (PHS/FDA), the States and the dairy industry. It is a shining example of esprit de corps, and reflects the cooperative spirit of all those committed to ensuring a safe and wholesome supply of milk and milk products. A history of the NCIMS is available through the Executive Secretary of the NCIMS and www.ncims.org.

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ALSO INCLUDES:

ABBREVIATIONS AND ACRONYMS

ACLE (Aseptic Critical Listing Element)
AOAC (Association of Official Analytical Chemists)
AQFPSS (Aseptic-Qualified Filler and Product Sterilizer System)

BTU (Bulk Tank Unit)

CCP (Critical Control Point)
CFR (*Code of Federal Regulations*)
CIS (Certified Industry Supervisor)
CL (Critical Limit)
CLE (Critical Listing Element)

DDEMP (Division of Dairy, Egg and Meat Products)
dSSO (delegated Sampling Surveillance Regulatory Agency Official)
DRC (Document Review Committee)

EML (*Evaluation of Milk Laboratories*)
ER (Enforcement Rating)

FDA (Food and Drug Administration)
FFD&CA (*Federal Food, Drug, and Cosmetic Act*)
FHA (Fermented High-Acid)
FIMA (Federal Import Milk Act)
FR (*Federal Register*)

HACCP (Hazard Analysis Critical Control Point)
HHST (Higher-Heat-Shorter-Time)
HIC (HACCP Implementation Committee)
HTST (High-Temperature-Short-Time)

ICP (International Certification Program)
IMS (Interstate Milk Shipper)
IDFA (International Dairy Foods Association)
IMS-a (Memorandum of Conference Actions)

LEO (Laboratory Evaluation Officer)
LOI (Letter of Intent)
LOU (Letter of Understanding)
LPET (Laboratory Proficiency and Evaluation Team)

M-a (Memorandum of Interpretation)
M-b (Memorandum of Milk Ordinance Equipment Compliance)
MC (Milk Company)
M-I (Memorandum of Information)
MMPB (Milk and Milk Products Branch)
MMSR (*Methods of Making Sanitation Ratings of Milk Shippers and the Certifications/Listings of Single-Service Containers and/or Closures for Milk and/or Milk Products Manufacturers*)

MOA (Memorandum of Agreement)
MOU (Memorandum of Understanding)
MS (Milk Specialist)

NCIMS (National Conference on Interstate Milk Shipments)
NMPF (National Milk Producers Federation)

OFS (Office of Food Safety)
OMA (*Official Methods of Analysis*)
ORA (Office of Regulatory Affairs)
OSCP (Office of State Cooperative Programs)

pH (Potential Hydrogen-acid/alkaline balance of a solution)
PHS (Public Health Service)
PHS/FDA (Public Health Service/Food and Drug Administration)
PMO (*Pasteurized Milk Ordinance*)
Procedures (*Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments*)

RPPS (Retort Processed after Packaging System)

SAP (Strategic Action Plan)
SCC (Somatic Cell Count)
SCR (Sanitation Compliance Rating)
SRO (Sanitation Rating Officer)
SSC (Single-Service Consultant**)**
SSO (Sampling Surveillance Officer)

TPC (Third Party Certifier)

U.S.C. (United States Code)
USDA (United States Department of Agriculture)

PROCEDURES GOVERNING THE COOPERATIVE STATE-PUBLIC HEALTH SERVICE/FOOD AND DRUG ADMINISTRATION PROGRAM OF THE NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

SECTION I. PURPOSE

The *Procedures* document was established to develop a more uniform milk sanitation program. It establishes the criteria governing the Cooperative Program of the National Conference on Interstate Milk Shipments (NCIMS). As a result of these *Procedures*, there is a greater degree of reciprocity between States on acceptance of inspection and laboratory results.

Contained in this document are the *Procedures* for establishing milk sanitation standards, rating procedures, sampling procedures, laboratory procedures, laboratory evaluation and sample collection procedures. It also contains the *Constitution of the NCIMS*, the *Bylaws of the NCIMS*, the *Memorandum of Understanding* (*MOU*) *Between the U. S. Food and Drug Administration and the NCIMS*,.

This *Procedures* is the governing document of the NCIMS and contains the information necessary to maintain a national program that is both uniform and acceptable to the States, U. S. Public Health Service/Food and Drug Administration (PHS/FDA) and the dairy industry. It helps all concerned parties to assure a safe supply of Grade "A" milk and milk products to consumers.

SECTION II. SCOPE

A. PRODUCTS COVERED

Agreements adopted by the NCIMS shall apply to Grade "A" raw milk and/or milk products for pasteurization, heat-treated products, pasteurized, 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, fermented high-acid, shelf-stable milk and/or milk products, condensed and dry milk products, whey and whey products, and single-service containers and/or closures for milk and/or milk products produced under the NCIMS Grade "A" Milk Safety Program.

B. SUPERVISION REQUIREMENTS

Supervision of the Grade "A" milk supply, condensed and dry milk products, whey and whey products to be rated for listing on the *IMS List-Sanitation Compliance and Enforcement Ratings of the Interstate Milk Shippers (IMS List)* shall be based on the criteria and procedures for Grade "A" standards set forth in Section VI., and procedures for Grade "A" standards set forth in Section VI., E., or regulations pertaining to supervision substantially equivalent thereto.

NOTE: If a dry powdered blend is to be used as an ingredient in the production of a Grade "A" milk and/or milk product from an IMS listed milk plant, the dry powder blend shall be labeled Grade "A" and the milk plant(s) where the Grade "A" dairy powder is (are) manufactured and the facility where the dry powder is blended and packaged shall each have an IMS listing.

SECTION III. DEFINITIONS

Terms used in these *Procedures*, not specifically defined herein, are those within Title 21, *Code of Federal Regulations* (CFR) and/or the *Federal Food, Drug, and Cosmetic Act* (FFD&CA) as amended.

A. **ADVERSE ACTION:** A re-rating or withdrawal of the IMS listing of an individual IMS listed milk shipper or the withdrawal of the certification of an individual IMS listed single-service containers and/or closures manufacturer.

B. **AREA RATING:** An area rating, if used, shall apply to Grade "A" raw milk for pasteurization, aseptic processing and/or packaging, retort processed after packaging and fermented high-acid, shelf-stable processing and packaging. 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 and has attained an acceptable Sanitation Compliance Rating (SCR) and Enforcement Rating (ER) necessary for inclusion on the *IMS List*. An individual Grade "A" dairy farm shall only be included in one (1) IMS listing.

C. **ASEPTIC PROCESSING AND PACKAGING SYSTEM (APPS)**: For the purposes of these *Procedures*, the Aseptic Processing and Packaging System (APPS) in a Grade "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 APPS shall be regulated in accordance with the applicable requirements of 21 CFR Parts 108, 113 and 117. The 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 aseptic processed and packaged Grade "A" low-acid milk and/or milk product.

D. **ASEPTIC-QUALIFIED FILLER AND PRODUCT STERILIZER SYSTEM (AQFPSS):** A filler and product sterilizer and associated equipment which are used for aseptic processing and packaging as defined in 21 CFR 113.3(a). This system will be described within filings for aseptic low-acid products that have been filed with and reviewed by the Food Processing Evaluation Team in FDA/CFSAN's Office of Food Safety. The aseptic-qualified filler (which includes the package sterilizer) is operated as described within the Form FDA 2541g filing submission. The aseptic-qualified product sterilizer is operated in a manner that is sufficient to destroy the vegetative cells of microorganisms of public health significance and those of non-health significance capable of reproducing in the food under conditions of ambient storage. The scope of the AQFPSS includes the filler and product sterilizer described within the Form FDA 2541g filing submission and any other equipment or processes which will be defined in written documentation provided by the Process Authority that are critical to maintain the safety of the product.

E. **BULK TANK UNIT (BTU):** A Grade "A" dairy farm or group of Grade "A" dairy farms from which Grade "A" raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, retort processed after packaging and/or fermented high-acid, shelf-stable processing and packaging is collected under the routine supervision of one (1) Regulatory Agency and which is rated as a single entity and has attained an acceptable SCR and ER necessary for inclusion on the *IMS List*. An individual Grade "A" dairy farm shall only be included in one (1) IMS listing.

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

G. **CERTIFIED MILK SANITATION RATING OFFICER (SRO):** A Regulatory or Rating Agency employee who has been certified by the PHS/FDA; has a valid certificate; and does not have direct responsibility for the routine regulatory inspection and enforcement or regulatory auditing of the milk shipper to be rated or IMS listed. Directors, administrators, supervisors, etc. may be certified as Milk Sanitation Rating Officers (SROs). An SRO may be certified to make IMS listings of Grade "A" NCIMS HACCP milk plants, aseptic milk plants, milk plants, BTUs, receiving stations or transfer stations, and single-service manufacturers.

H. **CERTIFIED SAMPLING SURVEILLANCE OFFICER (SSO):** A Regulatory Agency, Rating Agency or Milk Laboratory Control Agency employee who has been certified by the PHS/FDA and has a valid certificate. Directors, administrators, supervisors, etc., SROs, LEOs, etc. may be certified as SSOs.

I. **CERTIFIED SINGLE-SERVICE CONSULTANT (SSC)**: An individual who has been certified by the PHS/FDA; has a valid certificate to conduct the certification listing of foreign single-service containers and/or closures for milk and/or milk products manufacturers on the *IMS List* and does not have direct responsibility for the routine regulatory inspection and enforcement or regulatory auditing of the foreign single-service containers and/or closures manufacturer to be certified for IMS listing.

J. **CHECK RATING:** The designated PHS/FDA *Procedures* method to ensure that the published rating of a milk shipper on the *IMS List* is valid and maintained during the interval between ratings.

K. **DAIRY FARM:** A Grade "A" dairy farm is any place or premises where one (1) or more lactating animals (cows, goats, sheep, water buffalo, camels or other hooved mammal) are kept for milking purposes, and from which a part or all of the raw milk or milk product(s) is provided, sold or offered for sale to a milk plant, receiving station or transfer station.

L. **ENFORCEMENT RATING (ER):** This is a measure of the degree to which enforcement provisions of the *Grade "A" Pasteurized Milk Ordinance (Grade "A" PMO)* are being applied by the Regulatory Agency.

M. **IMS LISTED SHIPPER:** An interstate milk shipper (BTU, receiving station, transfer station, milk plant or a receiving station, transfer station, or milk plant with an attached supply of Grade "A" raw milk), which has been rated by a SRO and has attained an acceptable SCR and ER necessary for inclusion 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 and the Certifications/Listings of Single-Service Containers and/or Closures for Milk and/or Milk Products Manufacturers (MMSR)*. For milk plants that produce aseptically processed and packaged Grade "A" low-acid milk and/or milk products, retort processed after packaged Grade "A" low-acid milk and/or milk products and/or fermented high-acid, shelf-stable processed and packaged Grade "A" milk and/or milk products, prior to the milk plant participating in the NCIMS Aseptic Processing and Packaging Program, and/or NCIMS Retort Processed after Packaging Program and/or NCIMS Fermented High-Acid, Shelf-Stable Processing and Packaging Program, respectively, the 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, and/or NCIMS Retort Processed after Packaging Program and/or NCIMS Fermented High-Acid, Shelf-Stable Processing and Packaging Program. An individual Grade "A" dairy farm shall only be included in one (1) IMS listing.

N. **INDIVIDUAL RATING:** An individual rating is the rating of a single producer group, Grade "A" dairy farm, milk plant, receiving station, transfer station, or milk plant, receiving station or transfer station with an attached supply of Grade "A" raw milk under the supervision of a single Regulatory Agency and has attained an acceptable SCR and ER necessary for inclusion on the *IMS List*. Milk plants producing Grade "A" condensed and/or dried milk and/or milk products and/or Grade "A" condensed and/or dry whey and/or whey products may be rated separately from the same milk plant producing other Grade "A" milk and/or milk products, provided each IMS listing holds a separate permit. 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, and/or fermented high-acid, shelf-stable processed and packaged Grade "A" milk and/or milk products shall be rated separately from plants that produce pasteurized Grade "A" milk and/or milk products. Provided that an NCIMS HACCP IMS listing for 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 and/or fermented high-acid, shelf-stable processed and packaged Grade "A" milk and/or milk products shall have only an NCIMS HACCP IMS listing. An individual Grade "A" dairy farm shall only be included in one (1) IMS listing.

O. **INTERNATIONAL CERTIFICATION PROGRAM (ICP):** The 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.

P. **LETTER OF INTENT (LOI):** A formal written signed agreement between a TPC, authorized under the NCIMS voluntary ICP, and a MC that intends to be rated and IMS listed under the NCIMS voluntary ICP. A copy of each written signed agreement shall be immediately submitted to the ICP Committee following it being signed by the TPC and MC.

Q. **LETTER OF UNDERSTANDING (LOU):** A formal written signed agreement between a TPC and the NCIMS Executive Board that acknowledges the NCIMS' authorization of the TPC to operate under the NCIMS ICP. It also cites the TPC's responsibilities under the NCIMS

voluntary ICP; their agreement to execute them accordingly; and their understanding of the consequences for failing to do so. The LOU shall include, but is not limited to, the issues and concerns addressed in all NCIMS documents involved in the NCIMS voluntary ICP.

R. **MEMORANDUM OF AGREEMENT (MOA):** A formal written signed memorandum that 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 NCIMS documents involved in the NCIMS voluntary ICP. 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.

S. **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 Office of State Cooperative Programs, Division of Milk Safety staff and Regulatory/Rating Agencies.

T. **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 Office of State Cooperative Programs, Division of Milk Safety staff and Regulatory/Rating Agencies.

U. **MEMORANDUM OF INTERPRETATION (M-a):** A memorandum issued by PHS/FDA, following these *Procedures* , providing clarification of the intent or meaning of wording related to the *Grade "A" PMO, MMSR*, *Procedures* and the *EML* to PHS/FDA Office of State Cooperative Programs, Division of Milk Safety staff and Regulatory/Rating Agencies.

V. **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 Office of State Cooperative Programs, Division of Milk Safety staff and Regulatory/Rating Agencies.

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

X. **MILK PLANT:** A milk plant is any place, premises, or establishment where Grade "A" milk and/or milk products are collected, handled, processed, stored, pasteurized, aseptically processed and packaged, retort processed after packaged, fermented high-acid, shelf-stable processed and packaged, condensed, dried, blended, packaged, or prepared for distribution.

Y. **RATING AGENCY:** A Rating Agency shall mean a State Agency, which conducts ratings on interstate milk shippers (BTUs, milk plants, receiving stations and transfer stations) that have achieved an acceptable SCR and ER 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 *MMSR*. Ratings are conducted by FDA certified SROs. They also certify and list single-service containers and closures for milk and/or milk products

manufacturers for inclusion on the *IMS List*. The certification listings are based on compliance with the requirements of Appendix J. Standards for the Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products of the *Grade "A" PMO* and were conducted in accordance with the procedures set forth in the *MMSR*. The definition of a Rating Agency also includes a TPC that conducts ratings of 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.

Z. **RECEIVING STATION:** A Grade "A" receiving station is any place, premises, or establishment where Grade "A" raw milk is received, collected, handled, stored, or cooled and prepared for further transporting.

AA. **RECIPROCITY:** For the purpose of the NCIMS agreements, reciprocity shall mean no action or requirements on the part of any Regulatory Agency will cause or require any action in excess of the requirements of the current edition of the *Grade "A" PMO* and related NCIMS documents of the NCIMS agreements.

BB. **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 an IMS listed milk shipper. The term, "Regulatory Agency", whenever it appears in these *Procedures* shall also mean the appropriate TPC having jurisdiction and control over the applicable matters cited within these *Procedures*.

CC. **REGULATORY/RATING AGENCY NCIMS GRADE "A" MILK SAFETY PROGRAM EVALUATION:** An evaluation of a Regulatory/Rating Agency's NCIMS Grade "A" Milk Safety Program by PHS/FDA. This shall include check ratings of IMS listed milk shippers, an assessment of the Regulatory/Rating Agency's administrative procedures and records, adoption of the *Grade "A" PMO* (or equivalent laws and regulations), and compliance with the NCIMS *Procedures*.

DD. **RETORT PROCESSED AFTER PACKAGING SYSTEM (RPPS):** For the purposes of these *Procedures*, the RPPS in a milk plant is comprised of the processes and equipment used to retort process after packaging Grade "A" low-acid milk and/or milk products. The RPPS shall be regulated in accordance with the applicable requirements of 21 CFR Parts 108, 113 and 117. The 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 retort processed after packaging Grade "A" low-acid milk and/or milk product.

EE. **SINGLE-SERVICE CONTAINERS AND/OR CLOSURES MANUFACTURER:** A single-service containers and/or closures manufacturer shall mean any person or company in the business of manufacturing a single-service container and/or closure for the packaging or sampling of Grade "A" milk and/or milk products in accordance with Appendix J. Standards for the Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products of the *Grade "A" PMO.*

FF. **SINGLE-SERVICE CONTAINERS AND/OR CLOSURES MANUFACTURER AUDIT:** The designated PHS/FDA *Procedures* method to ensure that the published

certification/listing of a single-service containers and/or closures for milk and/or milk products manufacturer on the *IMS List* is valid and maintained during the interval between certification IMS listings.

GG. **SINGLE-SERVICE CONTAINERS AND/OR CLOSURES MANUFACTURER CERTIFICATION IMS LISTING:** This is the certification listing conducted by a SRO for U.S. manufacturers of single-service containers and/or closures for milk and/or milk products; or a TPC's SRO; or a SSC for foreign manufacturers of single-service containers and/or closures for milk and/or milk products, which measures the degree to which the provisions of Appendix J. Standards for the Fabrication of Single-Service Containers and Closures for Milk and/or Milk Products of the *Grade "A" PMO* are being complied with by the single-service containers and/or closures manufacturer for inclusion on the IMS List. The certification listing is based on compliance with the requirements of Appendix J. of the *Grade "A" PMO* and is conducted in accordance with the procedures set forth in the *MMSR*.

HH. **THIRD PARTY CERTIFIER (TPC):** A TPC is a non-governmental individual(s) or organization authorized under the NCIMS voluntary 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 Grade "A" 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 ICP. TPC provides the means for the rating and IMS listing of Grade "A" 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 *IMS List*. To be authorized under the NCIMS voluntary ICP, a valid LOU shall be signed between the NCIMS Executive Board and the TPC.

II. **TRANSFER STATION:** A Grade "A" transfer station is any place, premises, or establishment where Grade "A" raw milk and/or milk products are transferred directly from one (1) milk tank truck to another.

SECTION IV. OVERSIGHT AND RESPONSIBILITIES

A. PHS/FDA RESPONSIBILITIES

1. Standardization of Personnel

   PHS/FDA Milk and Milk Products Branch (MMPB) shall standardize at least every three (3) years the rating procedures of:

   a. PHS/FDA Office of State Cooperative Programs, Division of Milk Safety personnel who:

      1.) Meet the qualification requirements of the PHS/FDA NCIMS Grade "A" Milk Safety Program;

2.) Comply with the directives of the PHS/FDA NCIMS Grade "A" Milk Safety Program as administered by the PHS/FDA MMPB; and

3.) Shall not fail, without cause, to attend the PHS/FDA Milk Seminar when offered, the PHS/FDA Milk Specialists Conference, and attended at least one (1) training course on "Special Problems in Milk Protection" or other training courses judged by PHS/FDA MMPB to be equivalent.

b. SROs who comply with Section V., D.

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

d. PHS/FDA shall standardize, in accordance with Section V, I., the certification procedures of SSCs.

2. Training

a. PHS/FDA shall extend to Regulatory and Rating Agencies and educational institutions assistance in the training of personnel, including SROs, LEOs, SSOs and dairy industry personnel.

b. In order to coordinate ratings and evaluation procedures and interpretations, PHS/FDA shall sponsor Milk Seminars annually or biennially for milk rating and milk laboratory personnel. The content and agenda of the Milk Seminar shall be mutually concurred with by PHS/FDA MMPB and appropriate PHS/FDA Milk Specialists (MS). Each Milk Seminar shall be open to representatives of Regulatory/Rating Agencies, including SROs, LEOs and SSOs; and certified SSCs. Dairy industry personnel shall be permitted to attend appropriate sessions of such Milk Seminars.

c. PHS/FDA shall provide consultation and training in order to correct any deficiency in Regulatory/Rating Agency's NCIMS Grade "A" Milk Safety Programs. Reasonable action shall be taken to resolve any dispute between PHS/FDA and the Regulatory/Rating Agency over interpretations and implementation of any NCIMS Grade "A" Milk Safety Program components.

3. Regulatory/Rating Agency Program Evaluations

a. A PHS/FDA MS or PHS/FDA MMPB personnel shall conduct a triennial written NCIMS Grade "A" Milk Safety Program evaluation administered by each Member State and TPC, respectively. This triennial written NCIMS Grade "A" Milk Safety Program evaluation shall be submitted to the Regulatory Agency, the Rating Agency, if applicable, and PHS/FDA MMPB. The evaluation shall concentrate on the following areas:

1.) The organizational structure or a review of the organizational changes, which may have occurred since the last triennial evaluation.

2.) Identification of regulatory responsibilities:

A.) Inspection procedures and follow-up,
B.) Sampling procedures and follow-up, and
C.) Enforcement procedures.

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

4.) Identification of IMS responsibilities:

A.) SROs,
B.) LEOs,
C.) Sampling surveillance and SSOs,
D.) Adherence to the *Grade "A" PMO* and related NCIMS documents,
E.) Reciprocity,
F.) A summary and review of ratings and check ratings conducted within the triennial NCIMS Grade "A" Milk Safety Program evaluation period, and
G.) Summary and Conclusions.

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

A.) Adequate proof of disposition of contaminated loads.

A report signed by the Regulatory Agency or responsible industry person would be acceptable. The report shall include the following:

1.) Name of the milk plant,
2.) Date,
3.) Tanker identification,
4.) Test method used,
5.) Time,
6.) Results including clearing samples,
7.) Disposition of milk,
8.) Dairy producer identification,
9.) Confirmatory method and location,
10.) Tester or supervisor identification, and
11.) Signature of responsible person.

B.) Adequate proof of dairy producer follow-up and penalty shall be determined by:

1.) A procedure to check for repeated violations within a twelve (12) month period,
2.) Confirmation of action if two (2) or three (3) violations occur within a twelve (12) month period, and
3.) Assessment of penalties should be determined by a review of documents produced in the normal course of business.

6.) Regulatory compliance with Appendix B. Milk Sampling, Hauling and Transportation and other *Grade "A" PMO* milk sampling, hauling, and transportation requirements shall be determined by the PHS/FDA MS and/or PHS/FDA MMPB personnel for TPCs and shall be reported as part of the written triennial NCIMS Grade "A" Milk Safety Program evaluation. This portion of the written triennial NCIMS Grade "A" Milk Safety Program evaluation shall include a review of:

A.) Milk Sampling:

1.) SSO certifications,
2.) Delegation of sampling surveillance authority,
3.) Sampler training program,
4.) Sampler evaluations (adequacy and frequency),
5.) Observed sampling practices,
6.) Sampling permit issuance and suspensions, and
7.) Associated records.

B.) Milk Hauling and Transportation:

1.) The issuing of milk tank truck permits,
2.) Milk tank truck inspection (adequacy and frequency),
3.) Actions taken against those milk tank trucks or milk transportation companies not in compliance,
4.) Forwarding results of milk tank truck inspections, performed on milk tank trucks permitted by another Regulatory Agency, to that Regulatory Agency in a timely manner,
5.) Follow-up actions taken when a violative milk tank truck inspection report is received from another Regulatory Agency regarding a milk tank truck permitted by this Regulatory Agency,
6.) Inspection, enforcement and permitting program for unattached milk tank truck cleaning facilities, and
7.) Adequacy of associated records.

7) The Minimum State Program Evaluation Requirements and Criteria cited in Section X of these *Procedures* shall be used to determine if a Regulatory/Rating Agency Program is "in compliance" or "not in compliance" with the requirements of the *Grade "A" PMO* and *Procedures*.

1.) The Regulatory/Rating Agency Program shall be determined to be "in compliance" if:

A.) There are not any public health weaknesses identified that could realistically lead to a potential health hazard; and
B.) There has not been a departure from PHS/FDA and the NCIMS program requirements as indicated by:

1.) None of the Minimum State Program Evaluation Requirements and Criteria cited in Section X of these *Procedures* that automatically trigger a Strategic

Action Plan (SAP) to be jointly developed by PHS/FDA and the State or TPC, respectively, if the percent Compliance falls below the identified level are identified; and
2.) The identification of other program requirements not meeting the minimum criteria do not indicate the development and implementation of a SAP.

2.) The Regulatory/Rating Agency Program shall be determined to be "not in compliance" if:

A.) There is a public health weakness(es) identified that could realistically lead to a potential health hazard; and
B.) There is a departure from PHS/FDA and the NCIMS program requirements as indicated by:

1.) One (1) or more of the Minimum State Program Evaluation Requirements and Criteria cited in Section X of these *Procedures* that automatically trigger a SAP to be jointly developed by PHS/FDA and the State or TPC, respectively, if the percent Compliance falls below the identified level is/are identified; and
a.) The identification of other program requirements not meeting the minimum criteria indicate the development and implementation of a SAP.

b. Any State or TPC not in "substantial compliance" as determined by PHS/FDA shall be referred to the NCIMS Executive Board for determination of listing on a separate page on the *IMS List*. The State or TPC, upon notification of PHS/FDA and the NCIMS Executive Board, shall have an opportunity to address the NCIMS Executive Board to explain why they believe they should not be so listed. If such listing is required, annual written Regulatory/Rating NCIMS Grade "A" Milk Safety Program 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 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 shall not be an active participant in future NCIMS Conferences until substantial compliance is achieved.

c. If the next written triennial program evaluation meets the criteria cited in b. above, the Regulatory/Rating Agency Program shall be determined "in substantial non-compliance" with the requirements of the *Grade "A" PMO* and *Procedures*.

d. If two (2) consecutive written triennial Regulatory/Rating Agency Program evaluations are conducted and completed/issued within the established required time frames for the reports and both are classified as being "in compliance" with the requirements of the *Grade "A" PMO* and *Procedures*, the PHS FDA MS and/or PHS/FDA MMPB personnel for TPCs shall inform the State or TPC, respectively, of their option to have their Regulatory/Rating Agency Program evaluation conducted every five (5) years instead of every three (3) years. If the State or TPC elects to have this five (5) year option that shall be documented in writing to their appropriate PHS/FDA MS or PHS/FDA MMPB for TPCs.

4. Laboratory Evaluations

a. PHS/FDA LPET shall evaluate and approve the laboratory facilities and procedures of Regulatory Agencies or Milk Laboratory Control Agencies and TPCs to assure compliance with NCIMS 2400 Forms and, where appropriate, the current edition of *Official Methods of Analysis of AOAC International (OMA)*.

b. PHS/FDA LPET shall periodically evaluate milk laboratories of participating States and TPCs to assure compliance with NCIMS 2400 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 SCRs and ERs

a. PHS/FDA shall provide an electronic publication of the *IMS List* on their web site. The electronic *IMS List* is available at https://www.fda.gov/food/federalstate-food-programs/interstate-milk-shippers-list. The SCRs of IMS listed milk shippers, the ERs of Regulatory Agencies and the IMS listed milk shippers' expiration rating dates contained on the electronic publication are certified by the 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 MS or PHS/FDA MMPB for TPCs for publication.

Receiving stations, transfer stations, BTUs, and milk plants shall achieve an SCR and ER of 90 percent (90%) or higher, except as cited in Section VIII., C.,5. for HACCP IMS listings, in order to be eligible for an initial listing on the *IMS List* and shall maintain a SCR of 90 percent (90%) or higher, except as cited in Section VIII., C., 5. for a HACCP listings to maintain their listing on the *IMS List*. Individual SCRs for receiving stations, transfer stations and milk plants will not be identified on the *IMS List*.

PHS/FDA shall update the *IMS List* not less than monthly.

b. PHS/FDA shall list ratings on the *IMS List* only from Rating Agencies, and/or milk shippers, which are in substantial compliance with these *Procedures*.

c. The *IMS List* shall identify those milk shippers located in States where complete reciprocity as defined in Sections VI., A. and B., is not recognized by the State, Regional and/or Local Regulatory Agency.

d. PHS/FDA shall identify on the *IMS List* milk laboratories approved by PHS/FDA LPET, Regulatory Agencies, 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 multi-use and single-service milk containers and closures.

e. PHS/FDA shall identify on the *IMS List*, certified IMS listed single-service containers and/or closures manufacturers and their certification's expiration dates contained on the electronic publication as certified by the Rating Agency or SSC, as applicable, to be those

established by certifications conducted in accordance with the *MMSR* by certified SROs or SSCs, as applicable, when FORM FDA 2359d-REPORT OF CERTIFICATION (*Fabrication of Single-Service Containers and/or Closures for Milk and Milk Products*) is signed and submitted to the appropriate PHS/FDA MS or PHS/FDA MMPB for TPCs and SSCs for publication.

Single-service containers and/or closures manufacturers shall achieve a SCR of 80 percent (80%) or higher in order to be eligible for a listing on the *IMS List*. SCRs for single-service containers and/or closures manufacturers will not be identified on the *IMS List*.

PHS/FDA shall list certifications only from Rating Agencies, SSCs, and/or single-service containers and/or closures manufacturers, which are in substantial compliance with these *Procedures*.

6. Electronic Publication of PHS/FDA MSs and PHS/FDA Certified SROs, LEOs, SSOs, and SSCs

a. PHS/FDA shall provide a list of PHS/FDA MSs and SROs whose rating methods and interpretations of the *Grade "A" PMO* have been evaluated and standardized or certified by PHS/FDA on the *IMS List*.

b. PHS/FDA shall provide a list of LEOs whose competence in interpreting and evaluating milk laboratory methods in accordance with the *EML* have been evaluated and certified by PHS/FDA LPET on the *IMS List*.

c. PHS/FDA shall provide a list of SSOs whose competence in interpreting and evaluating the sample collection and hauling procedures and practices of sample collectors have been evaluated and certified by PHS/FDA on the *IMS List*.

d. PHS/FDA shall provide a list of SSCs whose certification methods and interpretations of Appendix J. Standards for the Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products of the *Grade "A" PMO* have been evaluated and certified by PHS/FDA on the *IMS List*.

7. Interpretations and Editorial Updates

a. Interpretations of the *Grade "A" PMO, MMSR, Procedures* and *EML* as referenced in Section VI. of these *Procedures* shall be issued to the Regulatory and Rating Agencies in accordance with the following procedure:

Procedure for Issuing Interpretations of the *Grade "A" PMO, MMSR, Procedures* and *EML* (M-a's)

1. PHS/FDA is requested or determines the necessity to issue an M-a.
2. PHS/FDA develops the draft M-a, with a proposed implementation date, after seeking input from appropriate sources.
3. PHS/FDA disseminates the draft M-a to all Regulatory and Rating Agencies and the NCIMS 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 Regulatory and Rating Agencies and the NCIMS 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.

4. All comments shall be submitted to the Executive Secretary, NCIMS Executive Board.
5. The Executive Secretary shall forward comments to PHS/FDA MMPB and the NCIMS Executive Board within fifteen (15) days of the end of the comment period.
6. The NCIMS Executive Board may, within seventy-five (75) days of the dissemination of the draft M-a, with the majority of the Executive Board consenting, request PHS/FDA to consider modifying the draft M-a as provided by the Board.
7. Within one hundred and five (105) days of the dissemination of the draft M-a, PHS/FDA shall provide to the NCIMS Executive Secretary sufficient copies of each draft M-a for submission to the NCIMS voting delegates for their approval or disapproval. After receipt from PHS/FDA of the draft M-a, the NCIMS Executive Secretary shall forward within fifteen (15) days a copy of the draft M-a to the current NCIMS voting delegates, along with a ballot and instructions for returning their vote. The Executive Secretary shall include a copy of the comments and the minutes covering the discussion between PHS/FDA and the NCIMS Executive Board. All ballots shall contain a date fifteen (15) days from the date the ballot was mailed or sent (if by other means) by which time, the ballot shall be received by the NCIMS Executive Secretary to be counted.
8. The NCIMS Executive Secretary may use any available method for delivering copies of each draft M-a and the voting ballots including, but not limited to:
    a.) The mail;
    b.) Private carriers;
    c.) Facsimile;
    d.) Email; or
    e.) Other electronic means.

    The Executive Secretary has fifteen (15) days from the end of the voting period to forward the results (votes per State) to PHS/FDA.
9. 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.
10. PHS/FDA shall, at the next duly convened NCIMS Conference, submit a Proposal, incorporating the requirements of any M-a, issued between NCIMS Conferences, into the appropriate NCIMS document(s).

NOTE: In the event of a public health emergency, PHS/FDA shall exercise its authority to protect the public health under the provisions of the *FFD&CA* and the Public Health Service Act. Federal regulations that impact the regulation of the Grade "A" dairy industry are not subject to this "Procedure for Issuing Interpretations".

b. After each NCIMS Conference and/or request by the NCIMS Executive Board, PHS/FDA shall incorporate editorial updates into the *Constitution of the National Conference on Interstate Milk Shipments, Bylaws of the National Conference on Interstate Milk Shipments, Grade "A" PMO*, the *MMSR*, the *Procedures* and the *EML* in accordance with the guidelines developed jointly by PHS/FDA and the NCIMS Executive Board.

Procedure for Issuing M-I's Related to Answers to Questions Received from the Field (Milk Seminars, FDA Training Courses, Workshops, etc.)

1. PHS/FDA develops the draft M-I, with proposed answers to questions that were received from the field (milk seminars, FDA training courses, workshops, etc.).
2. PHS/FDA will provide the draft M-I to the NCIMS Document Review Committee (DRC) for review.
3. The NCIMS DRC will provide comments to PHS/FDA within forty-five (45) days of receiving the draft M-I.
4. Within forty-five (45) days PHS/FDA will provide responses to all comments received from the NCIMS DRC.
5. The NCIMS DRC and PHS/FDA will have thirty (30) days to mutually resolve outstanding issues/concerns.
6. If an issue/concern is not resolved and/or the NCIMS DRC identifies a specific question and answer that the committee has determined goes beyond providing guidance/information on what FDA's current thinking is on a specific subject/scenario/situation and has been determined to be more interpretive in nature, then the specific question and answer will be removed from the draft M-I.
7. PHS/FDA will finalize the mutually agreed upon M-I and distribute the memorandum to the NCIMS Executive Board, FDA MSs, Regulatory/Rating Agencies, LEOs and SROs.

8. <u>PHS/FDA Check Ratings of the Sanitation Compliance Status of IMS Listed Milk Shippers</u>

a. PHS/FDA shall conduct, each year, check ratings of the Sanitation Compliance status of IMS listed milk shippers. To conduct check ratings of aseptic or retort milk plants, the PHS/FDA MS and/or PHS/FDA MMPB personnel for TPCs shall have completed a training course that is acceptable to the NCIMS and PHS/FDA MMPB addressing the procedures for conducting check ratings under the NCIMS Aseptic Processing and Packaging Program, the NCIMS Retort Processed after Packaging Program or the Fermented High-Acid, Shelf-Stable Processing and Packaging Program, respectively. Within a State or a TPC's jurisdiction, check ratings shall be conducted of a representative number of IMS listed milk shippers. The selection of IMS listed milk shippers to be check rated in a given State or a TPC's jurisdiction shall be made randomly.

b. In order to make effective use of PHS/FDA Office of State Cooperative Programs, Division of Milk Safety personnel, the random selection of IMS listed milk shippers to be check rated shall be selected in advance and assignments scheduled in each State and/or TPC's jurisdiction. Selection of Grade "A" dairy farms shall be made from records provided at the time of the check rating.

c. The number of IMS listed milk shippers selected to be check rated shall be based on consideration of the number of IMS listed milk shippers in the State or TPC's jurisdiction as well as the demonstrated validity of the State's or TPC's Regulatory/Rating Agency NCIMS Grade "A" Milk Safety Program. Validity shall be measured by estimating the number of adverse actions (reratings and withdrawals of IMS listings) in the State's or a TPC's jurisdiction based on the results of previous check ratings. This approach shall shift attention from States or TPCs with demonstrated validity to problem States or TPCs while still preserving an adequate level of monitoring.

d. A check rating cannot be conducted with a greater frequency than the official rating or audit for an IMS listing.

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

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

g. ERs shall be conducted as part of check ratings.

9. PHS/FDA Audits of the SCR Status of SRO IMS Listed Single-Service Containers and/or Closures Manufacturers

a. PHS/FDA shall conduct, each year, audits of the SCR status of SRO certified/IMS listed single-service containers and/or closures manufacturers. Within a State or a TPC's jurisdiction, audits shall be conducted of a representative number of IMS listed single-service containers and/or closures manufacturers. The selection of IMS listed single-service containers and/or closures manufacturers to be audited in a given State or a TPC's jurisdiction shall be made randomly.

b. In order to make effective use of PHS/FDA Office of State Cooperative Programs, Division of Milk Safety or MMPB personnel, the random selection of IMS listed single-service containers and/or closures manufacturers to be audited shall be selected in advance and assignments scheduled in each State and/or TPC's jurisdiction.

c. The number of IMS listed single-service containers and/or closures manufacturers selected to be audited shall be based on consideration of the number of single-service containers and/or closures manufacturers in the State or TPC's jurisdiction as well as the demonstrated validity of the State's or TPC's Grade "A" Milk Safety Program. Validity shall be measured by estimating the number of adverse actions (withdrawals of IMS listing) in the State or TPC's jurisdiction based on the results of audits. This approach shall shift attention from States or TPCs with demonstrated validity to problem States or TPCs while still preserving an adequate level of monitoring.

d. An audit cannot be conducted with a greater frequency than the official certification for an IMS listing.

e. For action to be taken if the PHS/FDA audit indicates the IMS listing is not justified, refer to Section IV., B., 7.c. For the purpose of these *Procedures* and all related forms, the terms "listed certification/audit", "official certification/audit" and "published certification/audit" relating to single-service containers and/or closures manufacturers shall mean the most recent certification/audit, which is accompanied by written permission from

the single-service containers and/or closures manufacturer to publish, and submitted by the Rating Agency to the appropriate PHS/FDA MS or PHS/FDA MMPB for TPCs

f. Except as provided in Section IV., B., 7.c., PHS/FDA shall release the detailed results of its audits of certified IMS listed single-service containers and/or closures manufacturers only to the Rating Agency which certified the single-service containers and/or closures manufacturer for an IMS listing and the single-service containers and/or closures manufacturer's Regulatory Agency.

B. STATE, TPC, AND SSC RESPONSIBILITIES

1. Ratings of Milk Shippers and Certification Audits of Single-Service Containers and/or Closures Manufacturers for an IMS Listing

a. The Rating Agency of the shipping State or TPC shall certify the results of ratings of each IMS listed milk shipper to the appropriate PHS/FDA MS or PHS/FDA MMPB for TPCs, which in turn shall transmit the ratings to the PHS/FDA Center for Food Safety and Applied Nutrition (CFSAN) for inclusion on the *IMS List*. (Refer to Section IV., A., 5) The rating results, together with other pertinent information, shall be forwarded on FORM FDA 2359i, FORM NCIMS 2359-MILK PLANT INSPECTION REPORT (Includes Dry Milk/Condensing Plants, Receiving Stations, Transfer Stations, and Milk Tank Truck Cleaning Facilities), FORM NCIMS 2359L-STATUS OF MILK PLANTS (INCLUDING DRYING AND CONDENSING MILK PRODUCTS PLANTS, RECEIVING STATIONS AND TRANSFER STATIONS), and FORM NCIMS 2359j-MILK SANITATION RATING REPORT.

b. The Rating Agency shall immediately provide a completed copy of FORM FDA 2359i and all applicable rating/listing Forms used to complete the rating/listing to the Regulatory Agency upon completion of any rating.

c. When the SCR status of a listed milk shipper's supply changes as a result of a new rating made within the twenty-four (24) month eligibility period, the most recent rating, including ER, shall apply and shall be submitted to PHS/FDA.

d. When an IMS listed BTU, milk plant, receiving station, transfer station with an attached or unattached supply of Grade "A" raw milk changes status because of permit revocation or change in the SCR to less than ninety percent (90%), the shipping State or TPC shall immediately (within five (5) days) withdraw the milk shipper from the *IMS List* and notify in writing all known receiving States and/or TPCs and the appropriate PHS/FDA MS or PHS/FDA MMPB for TPCs.

NOTE: Grade "A" dairy farm(s) included in an IMS listing of a milk plant, receiving station or transfer station with an attached supply of Grade "A" raw milk, shall be included in the re-rating when conducted. Both the Grade "A" dairy farm(s) and the milk plant, receiving station, or transfer station, shall achieve a SCR of ninety percent (90%) or higher in order to be eligible for inclusion on the *IMS List*.

e. When an IMS listed BTU, milk plant, receiving station, or transfer station receives an ER of less than ninety percent (90%), the State or TPC shall re-rate the supply within six

(6) months of that rating plus the remaining days of the month, and only after the Rating Agency receives written notification from an authorized representative of the Regulatory Agency indicating that the IMS listed milk shipper is in substantial compliance. Should this re-rating result in either a SCR and/or ER of less than ninety percent (90%), the State or TPC shall immediately (within five (5) days) withdraw the milk shipper from the *IMS List* and notify in writing all known receiving States and/or TPCs and the appropriate PHS/FDA MS or PHS/FDA MMPB for TPCs. If a re-rating of the original rating is not requested and conducted within six (6) months of the earliest rating date plus the remaining days of the month of the rating with the ER not equal to ninety percent (90%) or greater, the milk shipper shall be immediately withdrawn from the *IMS List* and the State or TPC shall immediately notify all known receiving States and/or TPCs and the appropriate PHS/FDA MS or PHS/FDA MMPB for TPCs.

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

g. The Rating Agency shall furnish their Regulatory Agency with copies of coded memoranda, including interpretations of the *Grade "A" PMO, MMSR, Procedures* and *EML* and rating procedures received from PHS/FDA.

h. The Rating Agency shall keep current the ratings of all IMS listed milk shippers within its State or a TPC's jurisdiction.

i. The State Rating Agency shall certify U.S. manufacturers of single-service containers and/or closures for milk and/or milk products based on compliance with Appendix J. of the *Grade "A" PMO* and in accordance with the *MMSR* for inclusion on the *IMS List*.

j. A TPC's SRO or a SSC shall certify foreign manufacturers of single-service containers and/or closures for milk and/or milk products based on compliance with Appendix J. of the *Grade "A" PMO* and in accordance with the *MMSR* for inclusion on the *IMS List*.

k. When an IMS listing of a manufacturer of single-service containers and/or closures for milk and/or milk products is no longer valid because of a change in the SCR to less than eighty percent (80%); or permit revocation, the shipping State, TPC or SSC, as applicable, shall immediately (within five (5) days) request PHS/FDA to withdraw the single-service containers and/or closures manufacturer from the *IMS List* and notify all known receiving States and/or TPCs.

Receiving States or TPCs shall notify shipping States, TPCs and/or SSCs, as applicable, of any irregularities in the single-service containers and closures for milk and/or milk products supply received. (Refer to Section IV., B., 7.)

The Rating Agency shall keep current the IMS listings of all single-service containers and/or closures manufacturers within its State or a TPC's jurisdiction.

The SSC shall keep current the IMS listings of all single-service containers and/or closures manufacturers that they have IMS listed.

The Rating Agency or SSC, as applicable, shall submit all required certification/listing paperwork and forms to the appropriate PHS/FDA MS or PHS/FDA MMPB for TPCs and SSCs upon the completion of all certifications/listings conducted by the Rating Agency or SSC, respectively.

2. Enforcement Ratings

ERs shall be conducted as part of Milk SCRs.

3. Laboratory Evaluation

a. If written split sample results of an IMS listed laboratory/Certified Industry Supervisor (CIS) used by an IMS listed milk shipper are not received by PHS/FDA LPET within sixteen (16) months of the last previous split sample date, PHS/FDA LPET shall immediately notify the IMS listed laboratory/CIS in writing of their withdrawal of accreditation from the *IMS List*. A copy of the PHS/FDA LPET notice for the withdrawal of accreditation shall be sent to the Milk Laboratory Control/Regulatory and/or Rating Agency, the applicable PHS/FDA MS and the PHS/FDA MMPB

b. If written results of an official laboratory evaluation are not received by PHS/FDA LPET within twenty-six (26) months of the previous laboratory evaluation date, PHS/FDA LPET shall immediately notify the IMS listed laboratory in writing, of their withdrawal of accreditation from the *IMS List*. A copy of the PHS/FDA LPET notice for the withdrawal of accreditation shall be sent to the Milk Laboratory Control/Regulatory Agency and/or Rating Agency, the applicable PHS/FDA MS and PHS/FDA MMPB.

4. Response to Regulatory/Rating Agency NCIMS Grade "A" Milk Safety Program Evaluations

The State or TPC shall cooperate with PHS/FDA in order to correct any deficiencies identified in the State's or TPC's NCIMS Grade "A" Milk Safety 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 MMPB. 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 and SSCs.

6. Reports to Third Party Database

Regulatory or Rating Agencies shall submit drug residue summary data to a third party database.

7. Challenges and Remedies

a. Complaints from Receiving States or TPCs

1.) Complaints as to the sanitary quality of Grade "A" milk and/or milk products and/or single-service containers and/or closures for milk and/or milk products being received and challenges related to the validity of ratings and/or single-service containers and/or closures IMS listings shall be made in writing by the receiving State and/or TPC to the Rating Agency of the shipping State, TPC, or SSC, as applicable, with a copy to the appropriate PHS/FDA MS or PHS/FDA MMPB for TPCs.

2.) The written complaint or challenge shall provide specific and factual information, such as violation of bacterial counts and cooling temperature, adulteration, improper heat treatment, or non-conformance with other requirements, changes in sanitation status of supply, etc. The written complaint shall specifically verify that all sampling and testing procedures, used in the determination of changes in sanitation status of the supply, have been conducted in accordance with the laboratory procedures specified in Section VI., G. and I.

3.) The Rating Agency of the shipping State, TPC, or SSC, as applicable, 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 MS or PHS/FDA MMPB for TPCs and SSCs.

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

A.) Notify the receiving State(s) and/or TPC(s) and appropriate PHS/FDA MS or PHS/FDA MMPB for TPCs and SSCs that the complaint has been resolved; or
B.) Withdraw the IMS listing of the milk shipper or single-service containers and/or closures manufacturer and notify the receiving State(s) and/or TPC(s) and the appropriate PHS/FDA MS or PHS/FDA MMPB for TPCs and SSCs of such action; or
C.) Conduct a new rating for milk shippers or new certification listing for single-service containers and/or closures manufacturers within sixty (60) days, and after obtaining a written permission to publish from the milk shipper or single-service containers and/or closures manufacturer, forward the new rating or certification listing, respectively to the appropriate PHS/FDA MS or PHS/FDA MMPB for TPCs and SSCs for listing 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, TPC, or SSC, as applicable.

5.) If the Rating Agency of the shipping State, TPC, or SSC, as applicable, 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.) Immediately notify the appropriate PHS/FDA MS or PHS/FDA MMPB for TPCs and SSCs, and the State and/or TPC making the complaint. Such notification shall be considered by PHS/FDA as tantamount to the withdrawal of the current

IMS listing of the milk shipper or single-service containers and/or closures manufacturer involved.

B.) Immediately notify the milk shipper or the single-service containers and/or closures manufacturer involved, and any other interested parties, that in accordance with NCIMS agreements, the current IMS listing, respectively, is being withdrawn until such time as the complaint may be investigated or a new rating or certification listing is conducted.

b. Complaints from Shipping States and/or TPCs

1.) Complaints from shipping States 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 MS or PHS/FDA MMPB for TPCs.

2.) The Rating Agency of the receiving State(s) and/or TPC(s) 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 MS or PHS/FDA MMPB for TPCs.

b. Action to be Taken if the PHS/FDA Check Rating or Single-Service Containers and/or Closures Manufacturer's Audit Indicates the IMS Listing, is No Longer Justified:

1.) Grade "A" Dairy Farms (Grade "A" Raw Milk)

A.) Action to be Taken

The following table shall be used to determine action to be taken if the SCR from a check rating of an IMS listed milk shipper's Grade "A" dairy farm(s) indicates the IMS listing is no longer justified:

GRADE "A" DAIRY FARM(S) (GRADE "A" RAW MILK)

SCR FROM THE CHECK RATING	ACTION REQUIRED
100 to 85	No Action
84 to 80	Re-rate Within Sixty (60) Days SCR Shall Be Ninety Percent (90%) Or Higher to Maintain IMS Listing
79 or less	Withdraw IMS Listing

B.) Re-Rating

When check rating data indicates that the SCR of an IMS listed milk shipper's Grade "A" dairy farm(s) requires a re-rating, PHS/FDA shall officially notify the Rating Agency that a re-rating of the Grade "A" dairy farm(s) shall be required within sixty (60) days.

NOTE: If a Grade "A" dairy farm(s) is included in an IMS listing of a milk plant, receiving station or transfer station with an attached supply of Grade "A" raw milk, then the milk plant, receiving station or transfer station, respectively, shall be included in the re-rating conducted within sixty (60) days. Both the Grade "A" dairy farm(s) and the individual milk plant, receiving station or transfer station, respectively, shall achieve a SCR of ninety percent (90%) or higher in order to be eligible for a listing on the *IMS List*.

C.) Withdrawal of IMS Listing

When check rating data indicates that the SCR of an IMS listed milk shipper's Grade "A" dairy farm(s) requires a withdrawal of their IMS listing, the Rating Agency, upon written recommendation of PHS/FDA, shall immediately withdraw the IMS listing of the milk shipper and notify such milk shipper, the appropriate PHS/FDA MS or PHS/FDA MMPB for TPCs, 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 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 to the IMS listed milk shipper by the Rating Agency. Such letter shall be dated within five (5) working days following the date of the official notification by PHS/FDA.

NOTE: If a Grade "A" dairy farm(s) in included in an IMS listing of a milk plant, receiving station or transfer station with an attached supply of Grade "A" raw milk then the milk plant, receiving station or transfer station, respectively, shall be included in the new rating conducted in accordance to the time period cited above. Both the Grade "A" dairy farm(s) and the individual milk plant, receiving station or transfer station, respectively, shall achieve a SCR of ninety percent (90%) or higher in order to be eligible for a listing on the IMS List.

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 SCR from a check rating of a milk plant, receiving station and/or transfer station indicates the IMS listing is no longer justified:

MILK PLANTS, RECEIVING STATIONS AND/OR TRANSFER STATIONS

REINSPECTION SCR FROM THE CHECK RATING	ACTION REQUIRED
100 to 81	No Action
80	Reinspect Within Thirty (30) Day SCR Shall Be Equal to or better than the Published Rating.
79 or Less	Withdraw IMS Listing

B.) Reinspection

When check rating data indicates that the SCR of an IMS listed milk plant, receiving station or transfer station requires a reinspection, PHS/FDA shall officially notify the Rating Agency that a reinspection of the milk plant, receiving station or transfer station shall be required within thirty (30) days. If the reinspection indicates a level of sanitation compliance below that of the published rating, the 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 appropriate PHS/FDA MS or PHS/FDA MMPB for TPCs shall be so advised by the Rating Agency and no further action shall be necessary.

NOTE: If the milk plant, receiving station or transfer station is included in an IMS listing with an attached supply of Grade "A" raw milk, then the Grade "A" dairy farm(s) shall be included in the reinspection conducted within thirty (30) days. Both the Grade "A" dairy farm(s) and the individual milk plant, receiving station or transfer station, respectively, shall achieve a SCR equal to or better than the published rating in order to be eligible for a listing on the *IMS List*.

C.) Withdrawal of IMS Listing

When check rating data indicates that the SCR of an IMS listed milk plant, receiving station and/or transfer station requires a withdrawal of their IMS listing, the Rating Agency, upon written recommendation of PHS/FDA, shall immediately withdraw the IMS listing of the milk shipper and notify such milk shipper, the appropriate PHS/FDA MS or PHS/FDA MMPB for TPCs, 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 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 to the IMS listed milk plant, receiving station or transfer station by the Rating Agency. Such letter shall be dated within five (5) working days following the date of the official notification by PHS/FDA. A withdrawal of an IMS listing is also required if an aseptic, retort, or fermented high-acid, shelf-stable milk plant has any Critical Listing Element (CLE) identified as not being in compliance on FORM NCIMS 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND/OR RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products) or on FORM NCIMS 2359q NCIMS ASEPTIC PROGRAM COMMITTEE – CRITICAL LISTING ELEMENTS for Grade "A" fermented high-acid, shelf-stable milk and/or milk products – pH of 4.6 or below obtained by fermentation using live and active cultures following the procedures cited above.

NOTE: If the milk plant, receiving station or transfer station is included in an IMS listing with an attached supply of Grade "A" raw milk, then the Grade "A" dairy farm(s) shall be included in the new rating conducted in accordance with the time

period cited above. Both the Grade "A" dairy farm(s) and the individual milk plant, receiving station or transfer station, respectively shall achieve a SCR of ninety percent (90%) or higher in order to be eligible for a listing on the *IMS List*.

3.) Single-Service Containers and/or Closures for Milk and/or Milk Products

A.) Action to be Taken

The following table shall be used to determine action to be taken if the SCR from a PHS/FDA audit of an IMS listed single-service containers and/or closures for milk and/or milk products manufacturer indicates the IMS certification listing is no longer justified:

SINGLE-SERVICE CONTAINERS AND/OR CLOSURES MANUFACTURERS

SCR FROM THE AUDIT	ACTION REQUIRED
100 to 80	No Action
79 or Less	Withdraw IMS Certification Listing

B.) Withdrawal of IMS Listing

When PHS/FDA audit data indicates that the SCR of an IMS listed single-service containers and/or closures manufacturer requires a withdrawal of their IMS certification listing, the Rating Agency upon written recommendation of PHS/FDA, shall immediately withdraw the IMS listing of the single-service containers and/or closures manufacturer and notify such single-service containers and/or closures manufacturer, the appropriate PHS/FDA MS or PHS/FDA MMPB for TPCs, and all known receiving States and TPCs thereof, in accordance with Section IV., B., 1.l. In case of withdrawal, a new certification listing 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 listing within a lesser time period would result in an acceptable certification 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 from PHS/FDA.

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

5.) If a Rating Agency indicates that it is not in a position to make a re-rating for Grade "A" dairy farms; a new rating for Grade "A" dairy farms, milk plants, receiving stations or transfer stations; or a new certification listing for single-service containers and/or closures for milk and/or milk product manufacturers within the sixty (60) day period or a re-rating for milk plants, receiving stations or transfer stations within the thirty (30) day period, PHS/FDA shall identify those States or TPCs on 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 check rate the sanitation compliance status of IMS listed milk shippers or audit IMS listed single-service containers and/or closures for milk and/or milk product manufacturers, PHS/FDA shall identify those States or TPCs on the *IMS List* as not being in compliance with the provisions of this paragraph.

7.) If a Rating Agency or SSC fails to request the removal of a milk plant, receiving station or transfer station; or a single Grade "A" dairy farm BTU; or single-service containers and/or closures for milk and/or milk product manufacturer from the *IMS List* as provided for in Section IV., B., 1.f. and B., 1.l., respectively, PHS/FDA shall, after five (5) days, provide this information to all known receiving States and/or TPCs.

SECTION V. QUALIFICATIONS AND CERTIFICATIONS

A. SUPERVISION REQUIREMENTS

1. Supervision of the Grade "A" milk supply, milk and milk products, condensed and dry milk products and whey and whey products to be rated for an IMS listing shall be based on the criteria and procedures for Grade "A" standards set forth in Section VI. and Section VI., E., or regulations pertaining to supervision substantially equivalent thereto.

2. The milk shipper to be rated shall be under the full-time supervision of a State or TPC Regulatory Agency.

3. Sampling procedures and laboratory examinations are a fundamental and basic component of supervision. The surveillance of sample collection procedures shall be conducted as prescribed in the *Grade "A" PMO*. Samples of Grade "A" raw milk from each Grade "A" dairy farm and Grade "A" milk and/or milk products from each milk plant shall be examined for the required tests at the frequency prescribed in the *Grade "A" PMO*.

NOTE: All Grade "A" raw, 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. Grade "A" milk and/or milk products that do not have validated and accepted test methods are not required to be tested. (Refer to M-a-98, latest version, for the specific Grade "A" milk and/or milk products that have FDA validated and NCIMS accepted test methods.)

B. **PROCEDURES FOR REQUESTING A MILK SHIPPER SANITATION RATING OR SINGLE-SERVICE CONTAINERS AND/OR CLOSURES FOR MILK AND/OR MILK PRODUCTS MANUFACTURER CERTIFICATION/LISTING**

A milk shipper desiring a rating of their Grade "A" milk and/or milk products for the purpose of IMS listing shall submit a request to the Rating Agency in their own State or to their TPC, respectively.

A U.S. manufacturer of single-service containers and/or closures for milk and/or milk products desiring a certification/listing of their single-service containers and/or closures for the purpose of IMS listing shall submit a request to the State Rating Agency in their own State.

A foreign manufacturer of single-service containers and/or closures for milk and/or milk products desiring a certification/listing of their single-service containers and/or closures for the purpose of IMS listing shall submit a request to a TPC or SSC that is listed on the *IMS List*.

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

Ratings to be made on each milk shipper or certifications/listings on each single-service containers and/or closures for milk and/or milk products manufacturer, respectively who desires an IMS listing or certification listing shall include:

1. SCRs on Grade "A" dairy farms, transfer stations, receiving stations, milk plants, dry powder blending plants, condensed and dry milk and/or milk products plants, whey and/or whey products plants and single-service containers and/or closures for milk and/or milk products manufacturers.

2. ERs of the Regulatory Agency for Grade "A" dairy farms, transfer stations, receiving stations, milk plants, dry powder blending plants, condensed and dry milk and/or milk products plants and whey and/or whey products plants.

D. **MILK SANITATION RATING PERSONNEL**

SCRs and ERs shall be conducted by certified SROs and the certification/listing of U.S. manufacturers of containers and closures for milk and/or milk products shall be conducted by certified State SROs who meet the following requirements:

1. Have submitted to PHS/FDA a written request for certification including the following: applicant name and contact information, education, training, work experience, list of training courses attended and categories for which certification are being requested.

2. Have been certified by PHS/FDA as an SRO and hold a valid certificate in one (1) or any combination of the following categories:

a. Grade "A" dairy farms;

b. Milk plants, including HACCP, and/or aseptic processing and packaging, and/or retort processed after packaging, and/or fermented high-acid, shelf-stable processing and packaging, and/or single-service containers and closures manufacturers, if appropriate; and

c. Transfer/receiving stations, including HACCP if appropriate.

The PHS/FDA 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, upon the request of that State's or TPC's Regulatory/Rating Agency as long as the SRO's certification is valid.

3. An SRO applicant for initial 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, applicable to the category(ies) for which the applicant is being certified:

a. Twenty-five (25) producer dairies. Milking time evaluations should be included.

b. Five (5) milk plants. Milk plants of varying sizes using, vat, HTST and HHST pasteurization; aseptic processing and packaging; retort processed after packaging; and/or fermented high-acid, shelf-stable processing and 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) milk plants.

c. One (1) dry milk plant, if applicable. The dry milk plant may be used as one (1) of the required five (5) milk plants.

d. If HACCP certified for milk plants, receiving or transfer stations, in addition to meeting the requirements listed above for milk plants for a SRO, one (1) mock-listing audit conducted separate from an official NCIMS HACCP listing audit is required. (Refer to Section VIII., E.7. for additional NCIMS HACCP certification procedures.)

e. One (1) single-service containers and/or closures manufacturing plant, if applicable.

f. Five (5) receiving and/or transfer stations if certification is only for these types of facilities.

4. The requirements listed in 3. above will be dependent on the applicant's range of responsibilities and the category(ies) for which they are being certified.

5. Applicants shall also have attended a course on "Milk Pasteurization Controls and Tests" and demonstrate proficiency in applying pasteurization equipment tests in at least one (1) milk plant, including demonstrating knowledge of milk and/or milk product flow through individual pasteurization systems.

6. To conduct ratings of aseptic processing and packaging milk plants, retort processed after packaging milk plants and/or fermented high-acid, shelf-stable processing and 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, the NCIMS Retort Processed after

Packaging Program or the Fermented High-Acid, Shelf-Stable Processing and Packaging Program, respectively.

7. Applicants shall demonstrate the ability to conduct and compute SCRs and ERs by completing all of the necessary forms.

8. A certified SRO shall be 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 SRO 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, applicable to the category(ies) for which the SRO is being re-certified:

a. Ten (10) producer dairies. Milking time evaluations should be included.

b. Three (3) milk plants. Milk plants of varying sizes using, vat, HTST and HHST pasteurization; aseptic processing and packaging; retort processed after packaging; and/or fermented high-acid, shelf-stable processing and packaging, if applicable, should be included in these evaluations.

c. One (1) dry milk plant, if applicable. The dry milk plant may be used as one (1) of the required three (3) milk plants.

d. If NCIMS HACCP certified for milk plants, receiving or transfer stations, in addition to meeting the requirements listed above for milk plants for a SRO, one (1) re-certification audit is required. The 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 personnel and SRO. (Refer to Section VIII., E.7. for additional HACCP certification procedures.)

e. One (1) single-service containers and/or closures manufacturing plant, if applicable.

f. Three (3) receiving and/or transfer stations if certification is only for these types of facilities.

9. The requirements listed in 8. above will be dependent on a SRO's range of responsibilities and the category(ies) for which they are being re-certified.

10. To be re-certified, a certified SRO shall have during the three (3) year period attended at least one (1) PHS/FDA Milk Seminar, attended at least one (1) training course, which includes the auditing of milk plant NCIMS HACCP Systems and NCIMS HACCP IMS 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 MMPB to be equivalent and appropriate.

11. Should PHS/FDA determine that a certified SRO has failed to demonstrate proficiency in the applicable re-certification procedures cited in 8. above; PHS/FDA shall require the certified SRO to perform the applicable initial certification procedures cited in 3. above.

12. An SRO shall not have direct responsibility for the routine regulatory inspection and

enforcement or regulatory auditing of the milk shipper to be rated or IMS listed. Directors, administrators, etc. may be certified as SROs.

E. DRUG RESIDUE COMPLIANCE

A milk shipper desiring a rating of their Grade "A" milk and/or milk products shall comply with Appendix N. of the *Grade "A" PMO.*

F. FOOD SAFETY PLAN COMPLIANCE

An IMS listed milk plant shall comply with the applicable Food Safety Plan requirements cited in Appendix T. of the *Grade "A" PMO* as determined at least once every thirty-six (36) months during a PHS/FDA Check Rating or, upon written agreement between FDA and the State Rating/Dairy Regulatory Agency, and in consultation with FDA-CFSAN's MMPB, during a State Rating Agency Individual Rating or a State Regulatory Inspection. Appendix T. compliance may only be evaluated by those FDA MSs, SROs or State Regulatory Officials that have successfully completed *Grade "A" PMO* Preventive Controls training for Regulatory/Rating Agencies (FD378) or Preventive Controls for Human Food Regulators Course (FD254).

If, after consultation with and concurrence by FDA-CFSAN's MMPB , a milk plant is not in substantial compliance with Appendix T. of the *Grade "A" PMO,* then the milk plant shall develop and implement a written plan of correction, determined to be acceptable by the State and FDA.

G. SAMPLING SURVEILLANCE PERSONNEL

Evaluation of sampling practices shall be made by certified sampling surveillance personnel who meet the following requirements:

1. Hold a valid certificate as an SRO, LEO, or in the case of a State or TPC Regulatory Supervisor hold a valid certificate as a dSSO.

2. Have submitted to PHS/FDA a written request for certification including the following: applicant name and contact information, education, training, work experience, a list of training courses attended and the category for which certification is being requested.

3. Have been certified by PHS/FDA as an SSO and hold a valid certificate in one (1) of the following categories:

a. Bulk milk hauler/samplers and plant samplers (dairy plant samplers and industry plant samplers);

b. Bulk milk hauler/samplers; or

c. Plant samplers (dairy plant samplers and industry plant samplers).

The PHS/FDA shall issue a certificate, valid for three (3) years, to each individual who meets the criteria listed in 4. and 6. below, as applicable.

4. Initial Certification: An SSO applicant for initial 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/or plant samplers, applicable to the category for which the applicant is being certified, at dairy facilities:

a. Five (5) bulk milk hauler/samplers during a routine milk pick-up at a producer dairy, if applicable.

b. One (1) dairy plant sampler that collects raw and finished Grade "A" milk and milk product samples and single-service containers/closures at one (1) milk plant, if applicable.

c. One (1) industry plant sampler that collects a Grade "A" raw milk sample from a milk tank truck at one (1) milk plant, if applicable.

5. The requirements listed in 4. above will be dependent upon the applicant's range of responsibilities and the category in which the applicant is being certified.

6. Re-certification: A certified SSO shall continue to hold a valid certificate as an SRO, LEO, or in the case of a State or TPC Regulatory Supervisor, hold a valid certificate as an SSO. The SSO shall be re-certified once each three (3) years which includes the remaining days of the month in which the certification expires, 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 SSO 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/or plant samplers, applicable to the category for which the SSO is being re-certified, at dairy facilities:

a. Three (3) bulk milk hauler/samplers during a routine milk pick-up at a producer dairy, if applicable.

b. One (1) dairy plant sampler that collects Grade "A" raw and finished milk and milk product samples and single-service containers/closures at one (1) milk plant, if applicable.

c. One (1) industry plant sampler that collects a Grade "A" raw milk sample from a milk tank truck at one (1) milk plant, if applicable.

7. The requirements listed in 6. above will be dependent upon the SSO's range of responsibilities and the category for which the SSO is being re-certified.

8. Should PHS/FDA determine that the certified SSO has failed to demonstrate proficiency in the re-certified procedures cited in 6. above; PHS/FDA shall require the certified SSO to perform the applicable initial certification procedures cited in 4. above.

9. An SSO may delegate the inspection/evaluation of bulk milk hauler/samplers, who collect samples of Grade "A" raw milk for pasteurization, aseptic processing and packaging, retort

processed after packaging or fermented high-acid, shelf-stable processing and packaging from individual dairy farms, and/or the inspection of dairy plant samplers and industry plant samplers to other qualified State or TPC 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.

When the delegation of sampling surveillance responsibilities is necessary, the SSO certified by PHS/FDA, shall initially certify responsible individuals in one (1) of the following categories following the same procedures that govern initial SSO certification:

a. Bulk milk hauler/samplers and plant samplers (dairy plant samplers and industry plant samplers);

b. Bulk milk hauler/samplers; or

c. Plant samplers (dairy plant samplers and industry plant samplers).

dSSOs shall be re-certified every three (3) years in accordance with the procedures listed in c. below. Reports of all joint evaluations shall be submitted to PHS/FDA.

a. Initial Certification: The applicant for the delegation of sampling surveillance responsibilities shall be evaluated 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/or plant samplers, applicable to the category for which the applicant is being certified, at dairy facilities:

1.) Five (5) bulk milk hauler/samplers during a routine milk pick-up at a producer dairy, if applicable.

2.) One (1) dairy plant sampler that collects Grade "A" raw and finished milk and milk product samples and single-service containers/closures at one (1) milk plant, if applicable.

3.) One (1) industry plant sampler that collects a Grade "A" raw milk sample from a milk tank truck at one (1) milk plant, if applicable.

b. The requirements listed under Initial Certification above will be dependent on the applicant's range of responsibilities and the category for which the applicant is being certified.

c. Re-certification: A certified dSSO shall be re-certified once each three (3) years which includes the remaining days of the month in which the certification expires, 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 dSSO 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/or plant samplers, applicable to the category for which the dSSO is being re-certified, at dairy facilities:

1.) Two (2) bulk milk hauler/samplers during a routine milk pick-up at a producer dairy, if applicable.

2.) One (1) dairy plant sampler that collects Grade "A" raw and finished milk and milk product samples and single-service containers/closures at one (1) milk plant, if applicable.

3.) One (1) industry plant sampler that collects a Grade "A" raw milk sample from a milk tank truck at one (1) milk plant, if applicable.

d. The requirements listed under Re-certification above will be dependent on the dSSO's range of responsibilities and the category for which the dSSO is being re-certified.

e. Should the SSO determine that the dSSO has failed to demonstrate proficiency in the re-certification procedures cited under Re-certification above; the SSO shall require the dSSO to perform the applicable initial certification procedures cited under Initial Certification above.

H. MILK LABORATORY EVALUATION PERSONNEL

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

1. Have been certified and approved by PHS/FDA LPET as an LEO per the requirements and criteria listed in the most recent edition of the *EML*. (Refer to Section 4 of the *EML*.)

2. Holds a valid certificate or provisional endorsement of qualification.

3. Shall not fail, without cause, to attend once within their three (3) year period of certification, the PHS/FDA Milk Seminar, and, in addition, attend at least one (1) LEO Workshop or other training courses judged by PHS/FDA LPET to be equivalent.

I. SSC PERSONNEL

1. The SCR and certification of foreign manufacturers of single-service containers and/or closures for milk and/or milk products shall be conducted by certified SSCs who meet one (1) of the following requirements:

a. Hold a current valid certification as a SRO, which includes the evaluation of single-service containers and/or closures manufacturers; or

b. Currently is listed under "Single-Service Consultants for Foreign Single-Service Manufacturer's Certification" on the *IMS List* and has been found to be acceptable by PHS/FDA; or

c. Have submitted to PHS/FDA MMPB a written request for certification including the following: applicant name and contact information, education, training, work experience, list of training courses attended, work with other SSCs; and has been certified by PHS/FDA as a SSC and hold a valid certificate for the certification/listing of foreign manufacturers of containers and/or closures for milk and/or milk products. The PHS/FDA shall issue a certificate, valid for three (3) years, to each individual who meets the criteria listed below, as applicable:

1.) An SSC applicant for initial certification shall be evaluated by PHS/FDA personnel in an independent side-by-side comparison of five (5) single-service containers and/or closures for milk and/or milk products manufacturing plants using the items listed on FORM NCIMS 2359c-MANUFACTURING PLANT INSPECTION REPORT (*Single-Service Containers and/or Closures for Milk and/or Milk Products)*. Single-service containers and/or closures for milk and/or milk products manufacturing plants shall be of varying sizes, manufacturing processing, such as injection molding, extrusion, blow-molding, paperboard, etc., and single-service containers/closures. The applicant and PHS/FDA personnel shall be in agreement at least eighty percent (80%) of the time on each listed item.

2.) Applicants shall demonstrate the ability to conduct and compute SCRs and certification listings by completing FORM NCIMS 2359c-, FORM NCIMS 2359e-STATUS OF MANUFACTURING PLANTS (*Single-Service Containers and/or Closures for Milk and/or Milk Products)* and FORM FDA 2359d.

3.) A certified SSC shall be re-certified once each three (3) years by PHS/FDA personnel in an independent side-by-side comparison of at least two (2) single-service containers and/or closures manufacturing facilities using the items listed on FORM NCIMS 2359c. The applicant and PHS/FDA personnel shall be in agreement at least eighty percent (80%) of the time on each listed item.

4.) To be re-certified, a certified SSC during the three (3) year period shall also have certified/listed at least one (1) single-service containers and/or closures for milk and/or milk products manufacturer annually and attended at least one (1) PHS/FDA Milk Seminar. If a SSC has not fulfilled the certification/listing of at least one (1) single-service containers and/or closures for milk and/or milk products manufacturer annual obligation, PHS/FDA MMPB shall request a meeting with the SSC to discuss why they should continue to be certified. The meeting shall take place at a time, location and manner (in person or via teleconference) agreed upon by PHS/FDA MMPB and the SSC. If an agreement cannot be reached, the meeting shall take place at a reasonable time, location and manner as determined by PHS/FDA MMPB.

If PHS/FDA MMPB's decision is to not re-certify the SSC that decision shall be provided through written notification to the SSC to officially notify the SSC that they will not be re-certified. PHS/FDA MMPB shall issue an M-I officially announcing the suspension of the SSC to participate in the NCIMS Grade "A" Milk Safety Program and immediately withdraw the SSC and any of the SSC's IMS listed single-service containers and/or closures for milk and/or milk products manufacturers from the *IMS List*.

5.) Should PHS/FDA determine that a certified SSC has failed to demonstrate proficiency in the above re-certification procedures; PHS/FDA may require the certified SSC to perform the initial certification procedures.

6.) A SSC shall not have direct responsibility for the routine regulatory inspection and enforcement or regulatory auditing of the foreign single-service containers and/or closures manufacturer to be certified for IMS listing.

2. Code of Ethics

A SSC is obligated to abide by the following Code of Ethics:

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 certification/listing 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 SSC shall maintain strict confidentiality of proprietary information learned through their certification/listing oversight activities;

g. Shall avoid conflicts of interest or the appearance of a conflict of interest. The SSC 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 SSC, their spouses and dependents 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 certification/listing activities whose interests may be substantially affected by the performance or non-performance of their duties.

3. The SSC's certification may be revoked by PHS/FDA upon findings that the SSC:

a. Fails to carry out the provisions of Appendix J. of the *Grade "A" PMO* and the *MMSR;*

b. Is in violation of any of the Code of Ethics tenets; or

c. Fails to meet the requirements specified for maintaining certification.

The hearing procedure for revoking the certification of a SSC shall follow Section V., J.

J. THE HEARING PROCEDURE FOR REVOKING THE CERTIFICATION OF AN SRO, SSO, LEO, OR SSC

1. Certification Hearing Panel Members

Representatives from the following organizations will comprise the Certification Hearing Panel:

a. The Director of the Office of State Cooperative Programs or designee.

b. The Director of the Office of Partnerships or designee.

c. The Director of the Division of Dairy, Egg and Meat Products or designee.

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

If the PHS/FDA Standard (MS, or PHS/FDA MMPB personnel, or member of LPET, respectively) makes an initial determination to revoke certification, PHS/FDA shall notify the SRO, SSO, LEO, or SSC in writing of its intent to revoke their certification. The notification shall specify:

a. The facts and the reasons that are the basis for the revocation;

b. Deadline for submitting a request for a hearing;

c. Where to send a request for a hearing; and

d. The date revocation will be effective if a hearing is not requested.

3. Request for a Hearing

The SRO, SSO, LEO, or SSC, after being notified of PHS/FDA's intent to revoke their certification, may request a hearing. This request shall be received by the Director of the Division of Dairy, Egg and Meat Products within fifteen (15) days of the date the SRO, SSO, LEO, or SSC receives written notification of the intent to revoke their certification. The hearing request shall identify one (1) or more substantial issues of fact for which a hearing is requested.

Within fifteen (15) days after the receipt of a timely request for a hearing, the Certification Hearing Panel shall determine whether the material submitted by the SRO, SSO, LEO, or

SSC raises any genuine and substantial issues of fact relevant to whether certification should be revoked.

If the Certification Hearing Panel determines that the material submitted by the SRO, SSO, LEO, or SSC does not raise any genuine and substantial issue of fact, the request for the hearing shall be denied. The Certification Hearing Panel shall notify the SRO, SSO, LEO, or SSC of the decision in writing, and the revocation of the certification shall be effective immediately. If the Certification Hearing Panel determines that the material submitted by the SRO, SSO, LEO, or SSC raises one (1) or more genuine and substantial issues of fact, the Certification Hearing Panel shall notify the SRO, SSO, LEO, or SSC and the PHS/FDA Standard in writing that a hearing will be held.

4. Hearings

The hearing shall take place at a time, location and manner (in person or via teleconference) agreed upon by the SRO, SSO, LEO, or SSC, the PHS/FDA Standard, and the Certification Hearing Panel. If an agreement cannot be reached, the hearing shall take place at a reasonable time, location, and manner as determined by the Certification Hearing Panel.

At a hearing, the PHS/FDA Standard will first give a statement of the proposed revocation, including the reasons supporting it, and may present relevant oral or written information. The SRO, SSO, LEO, or SSC may then present any oral or written information relevant as to why certification should not be revoked. The hearing is informal in nature, and the rules of evidence do not apply. If either party requests that the proceeding be transcribed, the requesting party shall be responsible to cover all cost associated with the request. The Certification Hearing Panel will have the opportunity to question the PHS/FDA Standard, the SRO, SSO, LEO, or SSC, and any witnesses.

5. Decision

Any time after a hearing is requested, the Certification Hearing Panel may issue a summary decision on any issue in the hearing if the Certification Hearing Panel determines from material submitted in connection with the hearing or from matters officially noticed, that there is no genuine and substantial issue of fact respecting that issue.

The Certification Hearing Panel shall make a written decision whether to revoke the certification of the SRO, SSO, LEO, or SSC. All relevant written material presented at the hearing shall be attached to the decision. The Certification Hearing Panel may uphold or reverse the initial determination to revoke certification or may resolve the issues presented at the hearing in another manner, such as by developing an action plan with requirements for the SRO, SSO, LEO, or SSC to retain certification.

Decisions of the Certification Hearing Panel shall require a simple majority vote of its members. Decisions of the Certification Hearing Panel are PHS/FDA's final decision on the matter.

K. **AREA RATINGS**

1. Area ratings shall be made at a frequency of at least once every twenty-four (24) months plus the remaining days of the month.

NOTE: If Grade "A" raw milk from an area rating is rating with a milk plant, receiving station or transfer station as an attached supply of Grade "A" raw milk, then both the Grade "A" dairy farm(s) and the individual milk plant, receiving station or transfer station, respectively, shall achieve an SCR of ninety percent (90%) or higher in order to be eligible for a listing on the *IMS List.*

2. If an area rating receives an SCR of less than ninety percent (90%), the Rating Agency shall issue written notification to the area's milk shippers that their IMS listing will be withdrawn. Such written notification shall be dated within five (5) working days following the earliest rating date. A new rating of the area shall be conducted after written notification from an authorized representative of the Regulatory Agency to the Rating Agency that the area is in substantial compliance. The new rating of the area shall be initiated in not more than fifteen (15) days, from the date of receipt of the written notification from the Regulatory Agency, unless the Rating Agency has a reason to believe a new rating within a lesser time would result in an acceptable rating.

3. If an area rating receives an ER of less than ninety percent (90%), the area milk shipper may be IMS listed. A re-rating of the area shall be conducted by the Rating Agency within six (6) months of the earliest rating date of this rating plus the remaining days of the month after the Rating Agency receives written notification from an authorized representative of the Regulatory Agency indicating that the area is in substantial compliance. A re-rating of the area, which includes both an SCR and ER, shall be initiated in not more than fifteen (15) days from the date of receipt of the written notification from an authorized representative of the Regulatory Agency.

L. **INDIVIDUAL RATINGS**

1. Individual ratings shall be made at least once every twenty-four (24) months plus the remaining days of the month in which the individual rating is due.

NOTE: If Grade "A" raw milk is rated with a milk plant, receiving station or transfer station as an attached supply of Grade "A" raw milk, then both the Grade "A" dairy farm(s) and the individual milk plant, receiving station or transfer station, respectively, shall achieve an SCR of ninety percent (90%) or higher in order to be eligible for a listing on the *IMS List*.

2. If an individual IMS listed milk shipper receives an SCR of less than ninety percent (90%), the Rating Agency shall issue written notification to the IMS listed milk shipper that their IMS listing will be withdrawn. Such written notification shall be dated within five (5) working days following the earliest rating date. A new rating shall be conducted after written notification from an authorized representative of the milk shipper to the Rating Agency that the IMS listed milk shipper is in substantial compliance. The new rating shall be initiated in not more than fifteen (15) days, from the date of receipt of the written notification from an authorized representative of the milk shipper, unless the Rating Agency has a reason to believe a new rating within a lesser time would result in an acceptable rating.

3. If an aseptic or retort milk plant has any Aseptic Critical Listing Element (ACLE) identified by a SRO, PHS/FDA MS, or PHS/FDA MMPB personnel as not being in compliance on FORM NCIMS 2359p, the IMS listing shall be immediately denied or withdrawn.

4. If an IMS listed fermented high-acid, shelf-stable milk plant has any Critical Listing Element (CLE) identified by a SRO, PHS/FDA MS, or PHS/FDA MMPB personnel as not being in compliance on FORM NCIMS 2359q-NCIMS ASEPTIC PROGRAM COMMITTEE - CRITICAL LISTING ELEMENTS for Grade "A" fermented high-acid, shelf-stable milk and/or milk products - pH of 4.6 or below obtained by fermentation using live and active cultures, the IMS listing shall be immediately denied or withdrawn.

5. If an individual IMS listed milk shipper receives an ER of less than ninety percent (90%), the milk shipper may be IMS listed. A re-rating of the milk shipper shall be conducted by the Rating Agency within six (6) months of the earliest rating date plus the remaining days of the month of this rating, after the Rating Agency receives written notification from an authorized representative of the Regulatory Agency indicating that the IMS listed milk shipper is in substantial compliance. A re-rating of the IMS listed milk shipper, which includes both an SCR and ER, shall be initiated in not more than fifteen (15) days from the date of receipt of the written notification from an authorized representative of the Regulatory Agency.

M. RE-RATINGS

Whenever a rating results in the withdrawal of the IMS listing of a milk shipper, the Rating Agency shall provide written notification to the IMS listed milk shipper of their withdrawal from the *IMS List*. Such written notification shall be dated within five (5) working days following the earliest rating date. If an authorized representative of the milk shipper requests in writing a new rating stating that the milk shipper is in substantial compliance, the effective date for the new rating shall be determined from the date of the written notification from the milk shipper. A new rating shall be initiated in not more than fifteen (15) days from the date of the receipt of the written notification from an authorized representative of the milk shipper, unless the Rating Agency has a reason to believe a new rating within a lesser time would result in an acceptable rating.

N. DENIAL OF RATINGS

Requests for ratings of milk shippers, which are not under supervision as described in Section V., A., shall be denied.

O. SINGLE-SERVICE CONTAINERS AND/OR CLOSURES MANUFACTURER CERTIFICATION LISTINGS

1. Individual certification listings conducted by Rating Agencies of manufacturers of single-service containers and/or closures for milk and/or milk products shall be made at a frequency specified in Section I of the *MMSR*.

2. Individual certification listings conducted by SSCs of foreign manufacturers of single-service containers and/or closures for milk and/or milk products shall be made at a frequency

of not less than every twelve (12) months plus the remaining days of the month in which the rating is due.

3. If a single-service containers and/or closures for milk and/or milk products manufacturer receives an SCR of less than eighty percent (80%), the Rating Agency or SSC, as applicable, shall issue written notification to the IMS listed single-service containers and/or closures for milk and/or milk products manufacturer that their IMS listing will be withdrawn. Such written notification shall be dated within five (5) working days following the earliest certification/listing date.

P. SINGLE-SERVICE CONTAINERS AND/OR CLOSURES MANUFACTURER NEW CERTIFICATION LISTINGS

Whenever a certification listing results in the withdrawal of the IMS listing of a single-service containers and/or closures for milk and/or milk products manufacturer, the Rating Agency shall provide written notification to the single-service containers and/or closures for milk and/or milk products manufacturer of their withdrawal from the *IMS List*. Such written notification shall be dated within five (5) working days following the earliest certification listing date. If an authorized representative of the single-service containers and/or closures for milk and/or milk products manufacturer requests in writing a new certification listing stating that the single-service containers and/or closures facility is in substantial compliance, the effective date for the new certification listing shall be determined from the date of the written notification from an authorized representative of the single-service containers and/or closures for milk and/or milk products manufacturer. A new certification listing shall be initiated in not more than fifteen (15) days from the date of receipt of the written notification from an authorized representative of the single-service containers and/or closures of milk and/or milk products manufacturer, unless the Rating Agency has a reason to believe a new certification listing within a lesser time would result in an acceptable IMS certification listing.

SECTION VI. STANDARDS

A. POINTS BEYOND THE LIMITS OF ROUTINE INSPECTION

Grade "A" milk and/or milk products from points beyond the limits of routine inspection shall be acceptable under the principles of reciprocity, 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 SCR and ER by a certified SRO.

B. RECIPROCITY FOR THE PURPOSE OF NCIMS AGREEMENTS

Reciprocity for the purpose of NCIMS agreements shall mean that no action or requirements on the part of any Regulatory Agency will cause or require any action in excess of the requirements of the current edition of the *Grade "A" PMO* and related NCIMS documents of the NCIMS agreements.

C. *PROCEDURES* PURPOSE IN THE DISTRICT OF COLUMBIA AND EACH PARTICIPATING U.S. TERRITORY

For the purpose of these *Procedures* and the NCIMS in total, the District of Columbia and each participating U.S. Territory shall be considered as a State with all the rights, duties, responsibilities, and privileges of a State.

D. ***PROCEDURES*** PURPOSE IN EACH PARTICIPATING NON-U.S. COUNTRY OR POLITICAL SUBDIVISION

For the purpose of these *Procedures* and the NCIMS in total, each participating non-U.S. country or political subdivision thereof shall be considered as a State with all the rights, duties, responsibilities, and privileges of a State, providing the governing regulatory body of such non-U.S. country or political subdivision thereof shall meet the requirements of Part A. of this Section by establishing a MOU with PHS/FDA, which provides an acceptable basis for the NCIMS to verify equivalence in the State or Local area concerned.

The determination that a foreign country's public health regulatory program and the government oversight of that program have an equivalent effect on the safety of the regulated Grade "A" milk or milk product is the responsibility of PHS/FDA. To provide for clarity and transparency, PHS/FDA shall regularly inform and confer with the NCIMS to answer questions and address NCIMS member concerns prior to finalizing a determination of equivalence. This engagement shall include general reporting on PHS/FDA's work, an opportunity for receiving and answering questions and addressing concerns of NCIMS members and issuing a notice to the NCIMS Executive Board prior to the intent to issue an approval of equivalence determination.

PHS/FDA shall publish for public review and comment such proposed equivalence determinations through the *Federal Register*.

The foreign government shall provide adequate assurance that the level of public health protection provided by the NCIMS Grade "A" Milk Safety Program is met by their program. When PHS/FDA determines that a foreign country's milk regulatory program and government oversight of that program are equivalent, *Grade "A" PMO* defined Grade "A" milk and milk products from that country are accepted in the NCIMS Grade "A" Milk Safety Program.

E. MILK SANITATION STANDARDS

The current edition of the *Grade "A" PMO* shall be used as the basic sanitation standards in making SCRs of interstate milk shippers.

The current edition of Appendix J. of the *Grade "A" PMO* shall be used as the basic sanitation standards in making SCRs of single-service containers and/or closures for milk and/or milk products manufacturers.

F. RATING PROCEDURES

The procedures outlined in the current edition of the *MMSR* and *Procedures* shall be used in determining compliance with sanitation provisions and enforcement procedures contained in the applicable Standards specified in A. through E. above.

G. **SAMPLING PROCEDURES**

Sampling procedures used to collect Grade "A" milk and milk products of interstate milk shippers, as well as milk and/or milk product containers and closures, shall conform substantially to the procedures in the current edition of *Standard Methods for the Examination of Dairy Products*, published by the American Public Health Association. Dairy plant samplers, bulk milk hauler/samplers and industry plant samplers shall be evaluated in accordance with the applicable provisions of the *Grade "A" PMO*.

H. **LABORATORY EVALUATION PROCEDURES**

The procedure outlined in the current edition of the *EML* shall be used in determining compliance with the laboratory provisions and enforcement procedures contained in the applicable Standards specified in E. above.

I. **LABORATORY PROCEDURES**

Laboratory procedures used to examine Grade "A" milk and milk products of IMS listed milk shippers shall conform to the procedures in the current revisions of the NCIMS 2400 Forms and the *OMA,* using only methods approved by the NCIMS. Vitamin testing shall be performed in a laboratory, which has been accredited by PHS/FDA and which is acceptable to the Regulatory Agency using test methods acceptable to PHS/FDA and other official methodologies that give statistically equivalent results to the PHS/FDA methods.

SECTION VII. PROCEDURES GOVERNING A STATE'S OR TPC'S PARTICIPATION IN THE COOPERATIVE PROGRAM FOR THE IMS LISTING OF MILK SHIPPERS

REGULATORY/RATING AGENCY GRADE 'A' PROGRAM EVALUATIONS

A. PHS/FDA shall evaluate the inspection, supervisory, and rating work of Regulatory and Rating Agencies triennially to determine whether milk regulations are being interpreted and enforced in accordance with the provisions of the *Grade "A" PMO* and *Procedures*. (Refer to Section IV.,A.,3.)

B. Any State or TPC in "substantial non-compliance" as determined by PHS/FDA shall be referred to the NCIMS Executive Board for determination of listing on a separate page on the *IMS List*. The State or TPC upon notification of PHS/FDA and the NCIMS Executive Board shall have an opportunity to address the NCIMS Executive Board to explain why they believe they 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 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 shall not be an active participant in future NCIMS Conferences until substantial compliance is achieved.

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

A. PURPOSE AND SCOPE

1. Purpose

Contained in this Section are the procedures for establishing milk sanitation standards and NCIMS HACCP IMS listing procedures.

2. Products Covered Under NCIMS HACCP IMS Listings

Agreements adopted by the NCIMS shall apply to Grade "A" raw milk and/or milk products for pasteurization, heat-treated products, pasteurized, ultra-pasteurized, aseptically processed and packaged Grade "A" low-acid milk and/or milk products, and/or retort processed after packaging Grade "A" low-acid milk and/or milk products, fermented high-acid, shelf-stable milk and/or milk products, condensed and dry milk products, and whey and/or whey products produced under the NCIMS Grade "A" Milk Safety Program. IMS listings conducted under the NCIMS voluntary HACCP IMS listing system described in this Section may be made for milk plants, receiving stations and transfer stations.

3. Supervision Requirements

Supervision of the Grade "A" milk supply, condensed and dry milk products, whey and whey products to be NCIMS HACCP IMS listed shall be based on the criteria and procedures for Grade "A" standards set forth in Section VI., and in Section VI., E., or regulations pertaining to supervision substantially equivalent thereto.

B. HACCP DEFINITIONS:

In addition to the definitions in Section III., the following shall apply to milk plants, receiving stations and transfer stations with NCIMS HACCP Systems regulated under Appendix K. HACCP Program of the *Grade "A" PMO*.

1. **AUDIT:** An evaluation conducted by the Regulatory Agency of the entire Grade "A" 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 APPS for aseptic processing and packaging Grade "A" milk plants, the RPPS for retort processed after packaging Grade "A" milk plants or the AQFPSS for fermented high-acid, shelf-stable processing and packaging milk plants, respectively.

2. **CERTIFIED MILK SANITATION RATING OFFICER (SRO):** The definition in Section III. shall apply as written except that, for purposes of this Section, an SRO may be certified to make NCIMS HACCP IMS listings. An SRO who has been certified to make

NCIMS HACCP IMS listings does not have direct responsibility for the routine regulatory audits of the Grade "A" milk shipper to be IMS listed.

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

4. **PHS/FDA AUDIT:** An evaluation conducted by PHS/FDA of the entire Grade "A" 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 APPS for aseptic processing and packaging Grade "A" milk plants, RPPS for retort processed after packaging Grade "A" milk plants and/or AQFPSS for Grade "A" fermented high-acid, shelf-stable milk plants, respectively.

5. **HACCP LISTED MILK SHIPPER:** A milk plant, receiving station, or transfer station that has been IMS listed by an SRO. The IMS listing is based on compliance with the NCIMS voluntary HACCP Program.

6. **NCIMS LISTING AUDIT:** An evaluation conducted by an SRO of the entire Grade "A" 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 APPS for aseptic processing and packaging Grade "A" milk plants, the RPPS for retort processed after packaging Grade "A" milk plants or the AQFPSS for Grade "A" fermented high-acid, shelf-stable processing and packaging milk plants, respectively.

7. **NCIMS HACCP IMS LISTING**: An inclusion of the *IMS List* based on an SROs evaluation of a Grade "A" milk plant's, receiving station's or transfers station's NCIMS HACCP Program and other applicable NCIMS requirements.

8. **REGULATORY/RATING AGENCY GRADE "A" MILK SAFETY PROGRAM EVALUATION:** Definition BB in Section III shall apply as written, except that for purposes of this Section the words "check ratings of IMS listed milk shippers" shall include "PHS/FDA audits of IMS listed milk shippers".

C. **PHS/FDA HACCP RESPONSIBILITIES**

1. Standardization of Personnel

PHS/FDA shall standardize at least every three (3) years the NCIMS HACCP IMS listing procedures of:

a. PHS/FDA Office of State Cooperative Programs, Division of Milk Safety personnel who:

1.) Meet the qualification requirements of the PHS/FDA NCIMS Grade "A" Milk Safety Program;

2.) Comply with the directives of the PHS/FDA NCIMS Grade "A" Milk Safety Program as administered by the PHS/FDA MMPB; and

3.) Shall not fail, without cause, to attend the Milk Seminar when offered, the PHS/FDA Milk Specialists Conference, and attended at least one (1) training course on "Special Problems in Milk Protection" or other training courses judged by the PHS/FDA MMPB to be equivalent.

4.) PHS/FDA personnel responsible for PHS/FDA NCIMS HACCP audits and Regulatory/Rating Agency NCIMS Grade "A" Milk Safety Program Evaluations in States and TPCs participating in the NCIMS voluntary HACCP Program shall, at a minimum, be required to meet the same level of training and certification required for SROs who make NCIMS HACCP IMS listing audits.

b. SROs who comply with E. 4. of this Section.

2. NCIMS HACCP Training

Section IV., A. 2. shall apply as written. In addition the following NCIMS HACCP training requirements shall apply:

a. NCIMS HACCP training for industry, Regulatory, SROs, and PHS/FDA personnel will be based on the current HACCP Principles and Application Guidelines of the U.S. National Advisory Committee on Microbiological Criteria for Foods, the current PHS/FDA HACCP recommendations, and the requirements of Appendix K. of the *Grade "A" PMO*.

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

c. It is recommended that industry, Regulatory, SROs and PHS/FDA personnel be trained together.

d. Specialized Training for NCIMS HACCP Auditing and IMS Listing Procedures

1.) PHS/FDA shall assist in providing training to Regulatory officials and SROs in the evaluation, licensing and regulatory concerns of facilities, which choose to bring their processing facility into the NCIMS voluntary HACCP Program.

2.) Training shall include procedures for conducting the NCIMS HACCP IMS listing audit; and providing feedback and guidance to the milk plant. Others charged by law with the enforcement of NCIMS voluntary HACCP Program regulations, along with representatives of the regulated industry, should attend such training.

3.) These individuals should be familiar with the elements of public health protection and the requirements of the *Grade "A" PMO* from previous training. In addition, they should already be familiar with the principles of HACCP and the requirements for developing, implementing, and maintaining a HACCP Plan.

4.) PHS/FDA personnel responsible for HACCP audits shall, at a minimum, be required to meet the same level of training and standardization required for SROs.

3. Regulatory/Rating Agency NCIMS Grade "A" Milk Safety Program Evaluations

In the event a State or TPC has a participating NCIMS HACCP milk plant, receiving station, or transfer station, PHS/FDA shall conduct an evaluation of their NCIMS voluntary HACCP Program, as a part of the Regulatory/Rating Agency NCIMS Grade "A" Milk Safety Program Evaluation.

4. Laboratory Evaluations

Section IV., A. 4. shall apply as written.

5. Electronic Publication of SCRs and ERs

Section IV., A. 5. shall apply as written, except that for purposes of this Section:

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/federalstate-food-programs/interstate-milk-shippers-list. The NCIMS HACCP IMS listings and IMS listed milk shipper's expiration listing dates contained in the electronic publication are certified by the Rating Agency to be those established by NCIMS HACCP IMS listing audits conducted in accordance with the *MMSR* by HACCP certified SROs when FORM FDA 2359i is signed and submitted to the appropriate PHS/FDA MS or PHS/FDA MMPB for TPCs for electronic publication.

Milk plants, receiving stations, and transfer stations shall achieve an acceptable NCIMS HACCP IMS listing in order to be eligible for a listing on the *IMS List*.

b. PHS/FDA shall identify NCIMS HACCP IMS listings only from Rating Agencies and/or shippers, which are in compliance with Appendix K. of the *Grade "A" PMO* and these *Procedures*.

6. Electronic Publication of PHS/FDA MSs, and PHS/FDA Certified SROs, LEOs, SSOs and SSCs

Section IV., A. 6. shall apply as written, except that for purposes of this Section:

PHS/FDA shall provide a list of PHS/FDA MSs and SROs whose NCIMS HACCP IMS listing methods and interpretations of the PHS/FDA recommended *Grade "A" PMO* have been evaluated and standardized or certified, respectively, by PHS/FDA on the *IMS List*.

7. Interpretations and Editorial Updates

Section IV., A. 7. shall apply as written.

8. PHS/FDA Audits of NCIMS HACCP IMS Listings

a. PHS/FDA shall conduct, each year, PHS/FDA audits of NCIMS HACCP IMS listed milk shippers. To conduct audits of NCIMS HACCP aseptic processing and packaging milk plants, retort processed after packaging milk plants and/or fermented high-acid, shelf-stable processed and packaged milk plants, the PHS/FDA MS and/or PHS/FDA MMPB personnel for TPCs shall have completed a training course that is acceptable to the NCIMS and PHS/FDA addressing the procedures for conducting audits and the implementation of the NCIMS Aseptic Processing and Packaging Program, the NCIMS Retort Processed after Packaging Program and/or the NCIMS Fermented High-Acid, Shelf-Stable Processing and Packaging Program, respectively. Within a State or a TPC conducting the NCIMS voluntary HACCP Program, PHS/FDA audits shall be conducted of a representative number of NCIMS HACCP IMS listed milk shippers. The selection of milk shippers to be audited in a given State's or a TPC's jurisdiction shall be made randomly.

b. In order to make effective use of PHS/FDA Office of State Cooperative Programs, Division of Milk Safety personnel, the random selection of milk shippers to be audited shall be selected in advance and assignments scheduled in each State's and/or TPC's jurisdiction.

c. The number of NCIMS HACCP IMS listed milk shippers selected to be PHS/FDA audited shall be based on consideration of the number of NCIMS HACCP IMS listed milk shippers in the State's or TPC's jurisdiction as well as the demonstrated validity of the State's or TPC's NCIMS Grade "A" Milk Safety Program. Validity shall be measured by estimating the number of adverse actions (re-audits or withdrawals of NCIMS HACCP IMS listings) in the State's or a TPC's jurisdiction based on the results of previous PHS/FDA NCIMS HACCP audits. This approach 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.) a PHS/FDA NCIMS HACCP audit shall not be conducted with a greater frequency than the official NCIMS HACCP IMS listing.

e. For action to be taken when a PHS/FDA NCIMS HACCP audit indicated that an NCIMS HACCP IMS listing is no longer justified, refer to Section VIII., D. 7. c. For the purpose of these *Procedures* and all related forms, the terms "IMS listed/ IMS listing", "official IMS listing" and "published IMS listing" shall mean the most recent IMS listing, which is accompanied by a written permission to publish from the milk shipper, and submitted to the appropriate PHS/FDA MS or PHS/FDA MMPB for TPCs by the 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 PHS/FDA NCIMS HACCP audits of NCIMS HACCP IMS listed milk shippers only to the Rating Agency, which originally certified the milk shipper for IMS listing, and the milk shipper's Regulatory Agency.

g. If a Grade "A" dairy farm(s) is listed with a NCIMS HACCP IMS listed milk plant, receiving station or transfer station, the Grade "A" dairy farms(s) shall be check rated in conjunction with the PHS/FDA NCIMS HACCP audit.

NOTE: If milk plants, receiving stations or transfer stations are audited with an attached supply of Grade "A" raw milk, then the Grade "A" dairy farm(s) shall achieve an SCR of ninety percent (90%) or higher and the individual milk plant, receiving station or transfer station, respectively shall receive an acceptable audit in order to be eligible for a listing on the *IMS List*.

h. PHS/FDA shall conduct on-site milk plant, receiving station and transfer station audits of the NCIMS HACCP compliance status of IMS listed milk shippers. These PHS/FDA NCIMS HACCP audits shall be conducted using the procedures for NCIMS HACCP IMS listing audits as described in the *MMSR*. These NCIMS HACCP audits shall be used in the overall Regulatory/Rating Agency NCIMS Grade "A" Milk Safety Program Evaluation. Provided, that for NCIMS HACCP IMS listed milk plants producing aseptically processed and packaged Grade "A" low-acid milk and/or milk products, retort processed after packaging Grade "A" low-acid milk and/or milk products and/or Grade "A" fermented high-acid, shelf-stable milk and/or milk products, PHS/FDA NCIMS HACCP audits shall be conducted using the procedures. These procedures are identified in the NCIMS Aseptic Processing and Packaging Program, the NCIMS Retort Processed after Packaging Program or the NCIMS Fermented High-Acid, Shelf-Stable Processing and Packaging Program related to the inspection/auditing and regulation of the APPS, RPPS, or AQFPSS as described in the *Grade "A" PMO* and *MMSR*, along with the completion of FORM NCIMS 2359p and/or FORM NCIMS 2359q.

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

Based on this investigation, if there are substantial Grade "A" milk and/or milk product safety program weaknesses, PHS/FDA shall send a written 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 after this investigation of NCIMS HACCP IMS listings, PHS/FDA determines that the State or TPC is not able to fulfill its obligations under the NCIMS voluntary HACCP Program and Grade "A" 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 written notification 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 Grade "A" milk and/or milk product safety remains in doubt PHS/FDA shall not accept any new NCIMS HACCP IMS listings from the State or TPC and PHS/FDA may audit the existing NCIMS HACCP IMS listings as necessary to protect the public health.

D. STATE AND TPC NCIMS HACCP RESPONSIBILITIES

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

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

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

b. When the SCR status of an IMS listed milk shipper's supply changes as a result of a new IMS listing made within the twenty-four *(*24) month eligibility period, the most recent listing and FORM NCIMS 2359m and FORM NCIMS 2359n shall apply. Provided that for NCIMS HACCP IMS listed milk plants producing aseptically processed and packaged Grade "A" low-acid milk and/or milk products, retort processed after packaging Grade "A" low-acid milk and/or milk products and/or Grade "A" fermented high-acid, shelf-stable milk and/or milk products, FORM NCIMS 2359p and/or FORM NCIMS 2359q shall also be completed.

c. When an IMS listed BTU or milk plant, receiving station or transfer station with an attached supply of Grade "A" raw milk has a change in the SCR or ER 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 MS or PHS/FDA MMPB for TPCs. The Regulatory Agency shall notify the Rating Agency when a re-rating is necessary.

NOTE: If a Grade "A" dairy farm(s) is included in an NCIMS HACCP IMS listing of a milk plant, receiving station or transfer station, respectively, shall be included in the NCIMS HACCP re-audit conducted within thirty (30) days. The Grade "A" dairy farm(s) shall achieve an SCR of ninety percent (90%) or higher and the individual milk plant, receiving station or transfer station, respectively shall receive an acceptable NCIMS HACCP re-audit in order to be eligible for an NCIMS HACCP listing on the *IMS List*.

d. The State or TPC shall immediately request the appropriate MS or PHS/FDA MMPB, respectively, to withdraw the milk shipper from the IMS list and notify all know receiving States and/or TPCs for any of the following:

- A change in the SCR or ER score to less than ninety percent (90%) on the entire attached Grade "A" raw milk supply (multiple OR single farm BTU) for the milk plant, transfer station or receiving station, as when cited in IV., B.1.,e.
- A change in the NCIMS HACCP IMS listing status of the milk plant, receiving station, or transfer station.
- A change in the SCR or ER score to less than ninety percent (90%) on a milk plant, transfer station and/or receiving station, as when cited in IV.,B.1.,e.
- The permit for the milk plant, receiving station or transfer station is revoked.
- The permit for the entire attached Grade "A" raw milk supply for the milk plant, transfer station or receiving station is revoked.

e. The Rating Agency shall furnish their Regulatory Agency with copies of coded memoranda, including interpretations of the *Grade "A" PMO, MMSR, Procedures* and *EML* and NCIMS HACCP IMS listing procedures received from PHS/FDA.

f. The Rating Agency shall keep current the HACCP listings of all IMS listed milk shippers within its State or TPC's jurisdiction.

2. NCIMS HACCP Enforcement Responsibilities

A NCIMS HACCP System Regulatory Agency review shall be conducted and FORM NCIMS 2359n shall be completed as a part of all NCIMS HACCP IMS listings.

Based on this report, if PHS/FDA finds there may be reason to doubt the safety of the State's or TPC's Grade "A" milk and/or milk products that are being handled and/or processed in an NCIMS HACCP IMS listed milk plant, receiving station or transfer station, PHS/FDA shall immediately investigate the State's or TPC's NCIMS Grade "A" Milk Safety Program and may evaluate/audit the milk plants, receiving stations or transfer stations affected. This applies even if FORM NCIMS 2359m finds that the NCIMS HACCP IMS listing of the milk plant, receiving station or transfer station is satisfactory.

If there are substantial Grade "A" milk and/or milk product safety program weaknesses, PHS/FDA shall send a written 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 Grade "A" 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 written notification 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 Grade "A" milk and/or milk product safety remains in doubt, PHS/FDA shall not accept any new NCIMS HACCP IMS listings from the State or TPC and PHS/FDA may audit the existing NCIMS HACCP IMS listings as necessary to protect the public health.

3. Laboratory Evaluation

Section IV., B. 3. shall apply as written.

4. Response to Regulatory/Rating Agency NCIMS Grade "A" Program Evaluations

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

6. Reports to Database

Section IV., B. 6. shall apply as written.

7. Challenges and Remedies

a. Complaints from Receiving States and/or TPCs

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

1.) Complaints as to the sanitary quality of Grade "A" milk and/or milk products being received and challenges of the validity of NCIMS HACCP IMS listings shall be made in writing by the receiving State and/or TPC to the Rating Agency of the shipping State or TPC, with a copy to the appropriate PHS/FDA MS or PHS/FDA MMPB for TPCs.

2.) 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 MS or PHS/FDA MMPB for TPCs.

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

A.) Make a new NCIMS HACCP IMS listing audit within sixty (60) days and, after obtaining a written permission to publish from the milk shipper, forward the new NCIMS HACCP IMS listing to the appropriate PHS/FDA MS or PHS/FDA MMPB for TPCs for publication 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.

4.) If the Rating Agency of the shipping State or TPC for any reason cannot make a prompt investigation called for in 7.a.2.) above, or the new NCIMS HACCP IMS listing called for in 7.a.1.) above, it shall:

A.) Immediately notify the milk shipper involved, and any other interested parties, that in accordance with NCIMS agreements, the current NCIMS HACCP IMS listing is being withdrawn until such time as the complaint may be investigated or a new NCIMS HACCP IMS listing audit is conducted.

b. Complaints from Shipping States and/or TPCs

1.) Complaints from shipping States 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 MS or PHS/FDA MMPB for TPCs.

2.) The Rating Agency of the receiving State(s) and/or TPC(s) 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 MS or PHS/FDA MMPB for TPCs.

c. Action to be Taken if the PHS/FDA NCIMS HACCP Audit Indicates the IMS Listing is No Longer Justified:

1.) Grade "A" Dairy Farms (Grade "A" Raw Milk)

Section IV., B. 7. c.1.) shall apply as written.

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 the NCIMS HACCP IMS listing. When Grade "A" milk and/or milk product safety is in doubt, based on Regulatory Agency practices or concerns, PHS/FDA shall immediately investigate and may NCIMS HACCP audit other milk plants, receiving stations and transfer stations affected.

Based on this investigation, if there are substantial Grade "A" milk and/or milk product safety program weaknesses, PHS/FDA shall send a written 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, after this investigation of NCIMS HACCP IMS listing, PHS/FDA determines that the State or TPC is not able to fulfill its obligations under the NCIMS voluntary HACCP Program and Grade "A" milk and/or milk product safety remains in doubt,

PHS/FDA shall provide written notification to the State or TPCs specifying the reasons this determination was made.

This written notification 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 Grade "A" milk and/or milk product safety remains in doubt, PHS/FDA shall not accept any new NCIMS HACCP IMS listings from the State or TPC and PHS/FDA may audit the existing NCIMS HACCP IMS 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 from the *IMS List*, the deficiencies and/or non-conformities shall be corrected, and the corrections confirmed by a NCIMS HACCP re-audit conducted a HACCP certified SRO. The period of time allowed to correct the HACCP System deficiencies and/or non-conformities shall be specified in writing by the PHS/FDA MS and/or PHS/FDA MMPB personnel for TPCs to the State or TPC. A NCIMS HACCP re-audit is not required if the deficiencies and/or non-conformities are immediately corrected, or are minor and can be corrected within the specific time period, which will neither present a risk to public health nor result in Grade "A" milk and/or milk product adulteration.

NOTE: If a Grade "A" dairy farm(s) is included in a NCIMS HACCP IMS listing of a milk plant, receiving station or transfer station with an attached supply of Grade "A" raw milk then the milk plant, receiving station or transfer station, respectively, shall be included in the NCIMS HACCP re-audit conducted in accordance to the time period cited above. The Grade "A" dairy farm(s) shall achieve an SCR of ninety percent (90%) or higher and the individual milk plant, receiving station or transfer station, respectively shall receive an acceptable NCIMS HACCP re-audit in order to be eligible for an NCIMS HACCP listing on the *IMS List*.

If the NCIMS HACCP re-audit indicates that the NCIMS HACCP System deficiencies and/or non-conformities have not been corrected, the milk plant's, receiving station's or transfer station's NCIMS HACCP IMS listing shall be withdrawn by the State or TPC.

If the NCIMS HACCP re-audit indicates that the NCIMS HACCP System deficiencies and/or non-conformities have been corrected, the Rating Agency shall submit the acceptable NCIMS HACCP re-audit report with the required forms to the appropriate PHS/FDA MS or PHS/FDA MMPB for TPCs for NCIMS HACCP IMS listing.

C.) Withdrawal of NCIMS HACCP IMS Listing

1.) An NCIMS HACCP IMS listing shall be requested to be withdrawn when one (1) or more CLE have been noted on FORM NCIMS 2359m indicating that the milk plant, receiving station or transfer station has failed to recognize or correct a deficiency(ies) and/or non-conformity(ies) indicating:

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

NOTE: A Grade "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 Grade "A" milk and/or milk product hazard will occur in the particular type of Grade "A" milk and/or milk product being processed.
ii.) Series of observations that leads to a finding of a potential NCIMS HACCP System failure that is likely to result in a compromise to Grade "A" milk and/or milk product safety;
iii.) Drug residue testing and trace back requirements are not met; or
iv.) Milk is received from a supply other than an IMS listed source or from an IMS listed source with an SCR below ninety percent (90%).

2.) Significant deficiencies involving one (1) or more CLEs constitute grounds for withdrawal of an NCIMS HACCP IMS listing. Observations of CLE related concerns and anomalies that do not meet these criteria, should be discussed with the milk plant, receiving station or transfer station being NCIMS HACCP audited and/or the Regulatory Agency but not debited on the audit report as a CLE or used to justify the removal of a NCIMS HACCP IMS listing. In this case, professional judgment should be exercised to allow the milk plant, receiving station or transfer station to retain its NCIMS HACCP IMS listing and benefit from the observation by making the necessary corrections to their NCIMS HACCP System.

NOTE: CLEs are noted on FORM NCIMS 2359m with a double Star (**) and cover the following areas of the NCIMS voluntary HACCP Program:

1. **HAZARD ANALYSIS:** Flow Diagram and Hazard Analysis conducted and written for each kind or group of Grade "A" milk and/or milk products processed.
2. **HACCP PLAN:** HACCP Plan prepared for each kind or group of Grade "A" milk and/or milk products processed.
3. **HACCP PLAN CRITICAL LIMITS (CLs):** CLs are adequate to control the hazard identified.
4. **HACCP PLAN CORRECTIVE ACTION:** Corrective action taken for Grade "A" milk and/or milk products produced during a deviation from CLs defined in the HACCP Plan.

5. **HACCP PLAN VERIFICATION AND VALIDATION:** Calibration of Critical Control Point (CCP) process monitoring instruments performed as required and at the frequency defined in the HACCP Plan.
6. **HACCP PLAN RECORDS**: Information on HACCP records not falsified.
7. **OTHER NCIMS REQUIREMENTS:** Including a Grade "A" milk supply from a an IMS listed source(s) with a SCR(s) of ninety percent (90%) or better and a drug residue control program implemented.
8. **HACCP SYSTEM AUDIT FOLLOW-UP ACTIONS:** A series of observations that lead to a finding of a potential NCIMS HACCP System failure that is likely to result in a compromise to Grade "A" milk and/or milk product safety.

3.) A NCIMS HACCP IMS listing of a milk plant that includes an aseptically processed and packaged Grade "A" low-acid milk and/or milk products and/or a retort processed after packaging Grade "A" low-acid milk and/or milk products milk plant and/or Grade "A" fermented high-acid, shelf-stable milk and/or milk products plant shall be requested to be withdrawn when any Critical Listing Element is identified as not being in compliance on FORM NCIMS 2359p and/or FORM NCIMS 2359q.
4.) When PHS/FDA NCIMS HACCP audit data indicates that the milk plant, receiving station and/or transfer station or attached supply of Grade "A" raw milk, if applicable, requires a withdrawal of their NCIMS HACCP IMS listing, the Rating Agency, upon written recommendation of the PHS/FDA, shall immediately withdraw the NCIMS HACCP IMS listing of the milk shipper and notify such milk shipper, the appropriate PHS/FDA MS or PHS/FDA MMPB for TPCs, and all known receiving States and/or TPCs thereof, in accordance with Section IV., B., 1.d. In case of withdrawal, a new listing 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 NCIMS HACCP audit within a lesser time period would result in an acceptable NCIMS HACCP IMS 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 by PHS/FDA.

NOTE: If a Grade "A" dairy farm(s) is included in an NCIMS HACCP IMS listing of a milk plant, receiving station or transfer station with an attached supply of Grade "A" raw milk, then the milk plant, receiving station or transfer station, respectively, shall be included in the new NCIMS HACCP audit conducted in accordance with the time period cited above. The Grade "A" dairy farm(s) shall achieve an SCR of ninety percent (90%) or higher and the individual milk plant, receiving station or transfer station, respectively, shall receive an acceptable NCIMS HACCP audit in order to be eligible for an NCIMS HACCP listing on the *IMS List*.

5.) If a Rating Agency fails to immediately notify all known receiving States and/or TPCs when the current NCIMS HACCP IMS listing of a milk 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 NCIMS HACCP audit

conclusion. The State or TPC which failed to take the required action shall be identified on the *IMS List* as not being in compliance with the provisions of this paragraph.

6.) If a Rating Agency indicates that it is not in a position to make a new NCIMS HACCP audit within the sixty (60) day period, or a re-audit when required, PHS/FDA shall identify those States or TPCs on the *IMS List* as not being in compliance with the provisions of this paragraph.

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

8.) If a Rating Agency fails to request removal of a milk plant, receiving station 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 known 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 Grade "A" milk and/or milk products until such hazard(s) has been eliminated. If such a violation results in a Grade "A" milk and/or milk product that presents a public health risk, the Regulatory Agency shall take immediate action against all Grade "A" milk and milk products produced and/or processed that have already entered the distribution system.

2.) The Regulatory Agency shall report in writing to PHS/FDA concerning actions taken within five (5) working days.

3.) If the Regulatory Agency fails to take immediate appropriate corrective action, PHS/FDA shall take any action necessary to protect the public health.

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 known 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:

a. Supervision of the Grade "A" milk supply, milk and milk products, condensed and dry milk products and whey and whey products to be NCIMS HACCP audited for an IMS listing shall be based on the criteria and procedures for Grade "A" standards set forth in Section VI., and in Section VI ., E., or regulations pertaining to supervision substantially equivalent thereto.

b. The milk shipper to be NCIMS HACCP audited shall be under the full-time supervision of a State or TPC Regulatory Agency.

2. Procedure for Requesting an NCIMS HACCP IMS Listing

A milk shipper desiring an NCIMS HACCP audit of their Grade "A" milk and/or milk products for the purpose of an IMS listing shall submit a request to the Rating Agency in their own State or to their TPC.

3. NCIMS HACCP IMS Listing

a. An acceptable NCIMS HACCP IMS listing shall be substituted for an acceptable SCR and ER for a milk plant, receiving station or transfer station participating in the voluntary NCIMS HACCP Program. FORM NCIMS 2359m and FORM NCIMS 2359n shall be completed as a part of all milk plant, receiving station or transfer station HACCP audits, re-audits and new audits. Provided that for NCIMS HACCP IMS listed milk plants producing aseptically processed and packaged Grade "A" low-acid milk and/or milk products, retort processed after packaging Grade "A" low-acid milk and/or milk products and/or Grade "A" fermented high-acid, shelf-stable milk and/or milk products, FORM NCIMS 2359p and/or FORM NCIMS 2359q shall be completed as a part of all NCIMS HACCP aseptic, NCIMS retort and/or NCIMS fermented high-acid, shelf-stable audits.

b. Milk plants, receiving stations or transfer stations participating in the voluntary NCIMS HACCP Program shall receive dairy ingredients, including Grade "A" raw milk and/or milk products, for use in IMS listed Grade "A" milk and/or milk products only from IMS listed milk shippers.

4. NCIMS HACCP IMS Listing Personnel

NCIMS HACCP IMS listings shall be conducted by certified SROs who:

a. Have been certified by PHS/FDA as an SRO and hold a valid certification to perform NCIMS HACCP IMS listing audits.

b. Have completed at least one (1) abbreviated approved training course in the auditing of milk plant NCIMS HACCP Systems and NCIMS HACCP IMS listings for the period of certification.

c. Have, during the three (3) year period for which certified, participated in at least one (1) 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 MMPB to be equivalent.

d. Do not have direct responsibility for the routine regulatory auditing and enforcement of the milk shipper to be NCIMS HACCP IMS listed.

5. Drug Residue Compliance

A milk shipper desiring a NCIMS HACCP IMS listing audit of their Grade "A" milk and/or milk products shall comply with Appendix N. of the *Grade "A" PMO.*

6. Food Safety Plan Compliance

An NCIMS HACCP IMS listed milk plant shall comply with the applicable Food Safety Plan requirements cited in Appendix T. of the *Grade "A" PMO* as determined on a PHS/FDA audit.

If, after consultation with and concurrence by FDA-CFSAN's MMPB, a milk plant is not in substantial compliance with Appendix T. of the *Grade "A" PMO*, then the milk plant shall develop and implement a written plan of correction, determined to be acceptable by the State and FDA.

7. Certification Procedure for SROs Who Will Conduct NCIMS HACCP IMS Listing Audits

a. Candidate Background

1.) Training and Experience

A.) The Candidate shall provide a statement describing their background and experience that qualifies them to perform this work.
B.) The Candidate is encouraged to gain practical milk plant experience in the application of HACCP and in conducting milk plant NCIMS HACCP IMS listing audits by working with SROs that are certified to perform NCIMS HACCP IMS listing audits whenever practical.
C.) The Candidate shall complete a basic HACCP training course that is acceptable to the NCIMS and PHS/FDA; NCIMS HACCP Orientation; as well as training in general auditing requirements for the auditing of milk plants, receiving stations and transfer stations under the voluntary NCIMS HACCP Program. The NCIMS HACCP orientation and training in general auditing requirements for auditing milk plants, receiving stations and transfer stations at a minimum consists of the Appendix T. training from the PHS/FDA MSs and the abbreviated training course approved and supplied by the HACCP Implementation Committee (HIC).
D.) Candidate shall be a certified SRO for milk plants.

b. Certification Process

1.) Knowledge of HACCP and NCIMS HACCP IMS Listing Auditing Standards and Requirements

A standardized PHS/FDA MS, certified to conduct PHS/FDA NCIMS HACCP Audits, shall accompany the Candidate during the course of one (1) mock-listing audit conducted separate from an official HACCP listing audit. The Candidate may be certified to conduct NCIMS HACCP listing audits after successfully completing one (1) mock-listing audit, with the certification valid for three (3) years. In the case of an original HACCP certification, the date of expiration of the other SRO certification shall be automatically extended to correspond with the original HACCP certification expiration date. The PHS/FDA MS shall evaluate the Candidate's HACCP knowledge and NCIMS HACCP IMS listing auditing skills. Particular attention shall be given to the Candidate's observations, evaluation, and decision making skills related to planning and conducting the mock-listing audit, identifying and recording the findings, communicating with industry representatives, and arriving at a NCIMS HACCP IMS

listing audit determination. The PHS/FDA MS shall categorize the Candidate's HACCP knowledge and NCIMS HACCP IMS listing auditing skills into one (1) of the following three (3) categories:

A.) The Candidate's work is acceptable; or
B.) The Candidate's work is acceptable with written recommendations identifying areas that need improvement; or
C.) The Candidate is not certified.

NOTE: If the Candidate is determined "not certified," the reasons for that determination shall be documented and provided to the Candidate and the Rating Agency.

c. Re-certification

After the initial NCIMS HACCP certification of an SRO to make NCIMS HACCP IMS listing audits, the SRO shall be re-certified once each three (3) years by a PHS/FDA MS.

1.) Milk Plant Technical Knowledge

The Candidate shall continue to meet the requirements for certification of an SRO for milk plants.

During the three (3) year certification period, the SRO, certified to conduct NCIMS HACCP listing audits, shall complete the minimum training requirements established to maintain proficiency regarding the voluntary NCIMS HACCP Program including having attended at least one (1) training course in the auditing of milk plant NCIMS HACCP Systems and NCIMS HACCP IMS listing audits. The NCIMS HIC has developed and accepted for this required training an abbreviated approved training course of individual instruction that may be presented to individuals or small groups by any of the HACCP Certified PHS/FDA MSs.

Small group training with practical exercises and other appropriate training that may include written examinations shall be used to evaluate the SRO's technical knowledge for re-certification.

2.) Knowledge of HACCP and NCIMS HACCP IMS Listing Auditing Standards and Requirements

During the three (3) year certification period, a PHS/FDA MS shall accompany the SRO during the course of at least one (1) re-certification NCIMS HACCP IMS listing audit. The re-certification NCIMS HACCP IMS listing audit can be done independent as a mock-listing audit or as part of an official NCIMS HACCP IMS listing audit, at the discretion of the PHS/FDA MS and SRO. This decision shall be made prior to the beginning of the re-certification NCIMS HACCP IMS listing audit. In the absence of an agreement, the re-certification NCIMS HACCP IMS listing audit shall be conducted during a mock listing audit. The certifying PHS/FDA MS shall accompany as a "silent observer" during this re-certification NCIMS HACCP IMS listing audit. The PHS/FDA MS shall evaluate the SRO's HACCP knowledge and NCIMS HACCP IMS listing

auditing skills. Particular attention shall be given to the SRO's observations, evaluation, and decision making skills related to planning and conducting the NCIMS HACCP IMS listing or mock-listing audit, identifying and recording the findings, communicating with industry representatives, and arriving at a NCIMS HACCP IMS listing audit or mock-listing audit determination. The PHS/FDA MS shall categorize the SRO's HACCP knowledge and NCIMS HACCP IMS listing auditing skills into one (1) of the following three (3) categories:

A.) The SRO is re-certified to conduct NCIMS HACCP Listing Audits, IMS listing audits; or
B.) The SRO is re-certified with written recommendations identifying areas that need improvement; or
C.) The SRO is not re-certified.

NOTE: If the Candidate is determined "not certified," the reasons for that determination shall be documented and provided to the SRO and the Rating Agency.

d. Paperwork Review

FORM NCIMS 2359m, with attachments, FORM NCIMS 2359n, and FORM NCIMS 2359o-PERMISSION FOR PUBLICATION (Interstate Milk Shipper's Listing) shall be completed and maintained on file by the Rating Agency and shall be reviewed as part of the check rating and/or Regulatory/Rating Agency Program Evaluation. FORM FDA 2359i shall be submitted for each NCIMS HACCP IMS Listing Audit to the appropriate PHS/FDA MS. Provided that for NCIMS HACCP IMS listed milk plants producing aseptically processed and packaged Grade "A" low-acid milk and/or milk products, retort processed after packaging Grade "A" low-acid milk and/or milk products and/or Grade "A" fermented high-acid, shelf-stable milk and/or milk products, FORM NCIMS 2359p and/or FORM NCIMS 2359q shall also be completed and maintained on file by the Rating Agency and shall be reviewed as part of the check rating and/or Regulatory/Rating Agency Program Evaluation.

8. Sampling Surveillance Personnel

Section V., G. shall apply as written.

9. Milk Laboratory Evaluation Personnel

Section V., H. shall apply as written.

10. Milk Plant, Receiving Station and Transfer Station NCIMS HACCP IMS Listings

a. Individual milk plants, receiving stations or transfer stations participating in the voluntary NCIMS HACCP Program shall be audited by a certified SRO for NCIMS HACCP for IMS listing at a frequency of not less than once every twenty-four (24) months plus the remaining days of the month.

11. New Audits

Whenever an NCIMS HACCP IMS listing audit results in the withdrawal of the NCIMS HACCP IMS listing of a milk shipper, the Rating Agency shall provide written notification to the NCIMS HACCP IMS listed milk shipper of their withdrawal from the IMS List. Such written notification shall be dated within five (5) working days following the earliest listing date of the NCIMS HACCP IMS listing audit. If an authorized representative of the milk shipper requests in writing a new audit stating that the milk shipper is in substantial compliance, the effective date for the new audit shall be determined from the date of the written notification from the milk shipper. A new audit shall be initiated in not more that fifteen (15) days~~,~~ from the date of receipt of the written notification from an authorized representative of the milk shipper, unless the Rating Agency has a reason to believe a new audit within a lesser time would result in an acceptable NCIMS HACCP IMS listing.

12. Denial of NCIMS HACCP IMS Listings

Requests for NCIMS HACCP IMS listings of milk shippers, which are not under supervision as described in E. 1. of this Section, shall be denied.

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

Grade "A" milk and/or milk products from points beyond the limits of routine inspection shall be acceptable under the principles of reciprocity, 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 NCIMS HACCP IMS listing by an SRO certified by PHS/FDA.

5. Milk Sanitation Standards

The current edition of the *Grade "A" PMO* shall be used as the basic sanitation standards in making NCIMS HACCP IMS listing audits of interstate milk shippers.

6. NCIMS HACCP IMS Listing Audit Procedures

The procedures outlined in the current edition of the *MMSR* shall be used in determining compliance with sanitation provisions and enforcement procedures contained in the applicable Standards specified in 1. through 5. above.

G. PROCEDURES GOVERNING A STATE'S OR TPC'S PARTICIPATION IN THE NCIMS VOLUNTARY HACCP PROGRAM FOR THE IMS LISTING OF SHIPPERS

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

1. Regulatory/Rating Agency Grade "A" Milk Safety Program Evaluations

a. PHS/FDA shall evaluate the inspection, supervisory, and voluntary NCIMS HACCP IMS work of Regulatory and Rating Agencies triennially to determine whether milk regulations are being interpreted and enforced in accordance with the provisions of the *Grade "A" PMO* and *Procedures*.

SECTION IX. PROCEDURES GOVERNING THE NCIMS VOLUNTARY INTERNATIONAL CERTIFICATION PROGRAM

In addition to complying with all of the other Sections of these *Procedures,* the following shall apply to the NCIMS voluntary 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 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 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 Grade "A" 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 LOU with the NCIMS as participants in the NCIMS voluntary ICP. This Section does not apply to NCIMS Member State and U.S. territory Regulatory/Rating Agency Grade "A" Milk Safety Programs that operate under the requirements of the NCIMS, nor does it apply to dairy facilities located within the geographic boundaries of those NCIMS 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 Grade "A" 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 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 MMPB.

h. PHS/FDA MMPB 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, 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 MMPB.

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 MMPB.

PHS/FDA MMPB, 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. **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. **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 MMPB. 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 these *Procedures*.

   b. **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 these *Procedures*.

   A signed and dated MOA shall be submitted to the ICP Committee Chair and PHS/FDA MMPB 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 MMPB and LPET to determine that it contains all the provisions set forth herein. PHS/FDA MMPB 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 MMPB.

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 MMPB. 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 MMPB in a manner acceptable to PHS/FDA MMPB. PHS/FDA MMPB 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 MMPB 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 regulatory inspections of Grade "A" dairy farms, milk plants, transfer and/or 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 these *Procedures*. SROs cannot have direct responsibility for the routine inspection and enforcement or regulatory auditing of the milk shipper to be rated or IMS listed.

c. Sampling Surveillance Personnel

TPC personnel conducting sampling surveillance activities shall meet the qualification and certification requirements set forth in Section V., G., and Section VIII., E. 8, if applicable, of these *Procedures*.

d. Milk Laboratory Evaluation Personnel

TPC personnel conducting milk laboratory evaluation activities shall meet the qualification and certification requirements set forth in Section V., H., and Section VIII., E. 9, if applicable, of these *Procedures* and those of the *EML*.

e. NCIMS Voluntary 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 voluntary 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 evaluation shall be a part of the required triennial Regulatory/Rating Agency Grade "A" Milk Safety Program evaluation completed by FDA.

f. NCIMS Aseptic/Retort Program Personnel

Before a milk plant may be regulated under the requirements of the NCIMS Aseptic Processing and Packaging Program, the Retort Processed after Packaging Program and/or Fermented High-Acid, Shelf-Stable Processing and Packaging Program, all relevant TPC regulatory and rating personnel shall successfully complete the mandatory NCIMS Aseptic Processing and Packaging Program, Retort Processed after Packaging Program or Fermented High-Acid, Shelf-Stable Processing and Packaging Program, respectively, 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 MMPB.

3. Code of Ethics

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

a. The TPC:

1.) Shall not be owned, operated or controlled by a manufacturer, supplier or vendor of Grade "A" milk and/or milk products regulated under the NCIMS;

2.) Shall not be financially affiliated with a manufacturer, supplier or vendor of Grade "A" milk and/or milk products regulated under the NCIMS;

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

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

b. The TPC and its Personnel:

1.) Shall act with honesty and integrity;

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

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

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

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

6.) 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;

7.) 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;

8.) 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;

9.) 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

10.) The TPC, TPC personnel, their spouses and dependents 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 non-performance 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 MMPB upon the completion of all ratings/listings conducted by the TPC.

D. **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. **LOI**

b. **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 Grade "A" milk and/or milk products and milk containers and/or closures, if applicable, and the required sampling of all applicable water system(s), including recirculated and reclaimed 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 MMPB, 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 ICP

1. TPC

Compliance with the requirements of the NCIMS voluntary ICP shall be determined by PHS/FDA MMPB 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 NCIMS documents by PHS/FDA MMPB 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 MMPB 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 MMPB 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 MMPB in a manner acceptable to PHS/FDA MMPB.

c. When there is evidence, found during PHS/FDA check ratings or a triennial Regulatory/Rating Agency NCIMS Grade "A" Milk Safety Program evaluation, that the TPC is in "substantial non-compliance" with the applicable requirements set forth in the NCIMS documents, the TPC shall be referred to the NCIMS Executive Board in accordance with Section IV, A. 3.d. of these *Procedure*s. The TPC and MC(s) listed by the TPC can be subject to withdrawal by PHS/FDA MMPB 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 MMPB 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 SCR to less than ninety percent (90%), the TPC shall immediately notify the PHS/FDA MMPB and all known receiving NCIMS Member States and/or TPCs. The MC's IMS listed milk shipper shall immediately be withdrawn from the *IMS List* by PHS/FDA MMPB.

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 MMPB 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 MMPB 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 MMPB in a manner acceptable to PHS/FDA MMPB.

c. When there is evidence that the MC or its 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 MMPB 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 MMPB and/or LPET, respectively. In the case that PHS/FDA MMPB 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 MMPB and/or LPET, is achieved. With this determination, PHS/FDA MMPB and/or LPET, respectively, shall notify all known receiving NCIMS 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 (FOIA) that may require disclosure of information related to a TPC and the rating and certification of MCs and their related facilities.

SECTION X. STATE PROGRAM EVALUATION REPORT GENERAL GUIDELINES AND FORMAT; MINIMUM STATE PROGRAM EVALUATION REQUIREMENTS AND CRITERIA; STATE PROGRAM EVALUATION RESOLUTION PROCESS

A. GENERAL GUIDELINES FOR STATE PROGRAM EVALUATIONS

1. The "Standard" for State Program Evaluations is the most current PMO or equivalent.

2. Prior to the review/visit(s) to the State, the MS shall provide to the State program manager a checklist of the information that they will review during this review(s)/visit(s). It is strongly recommended that the MS request and receive a copy of all applicable State laws, regulations, policies and procedures for their review prior to the initial review/visit.

3. State With Split Programs – States that have split regulatory and rating agencies shall have one final report issued, which will be sent to both agencies.

4. For "Compliance" with the State Laws and Regulations Section of the State Program Evaluation, the State must have the *Grade "A" PMO* adopted or equivalent regulations for not more than six (6) years prior to the most recent Conference.

5. If a section of the State Program Evaluation is not reviewed, it must be stated that this section was not covered and why it was not covered.

6. Action Regarding State Program Evaluations:

a. If after collecting and analyzing administrative and field data, FDA determines that there are substantial public health weaknesses in the state's milk safety program, the MS will provide comprehensive evaluations and documentation to the Office of Regulatory Affairs (ORA) Office of State Cooperative Programs (OSCP) Branch Director and develop a follow-up plan or strategy. This strategy is at the discretion of the ORA OSCP Branch Director.

   The MS is responsible for implementing and monitoring the follow-up action plan developed and mutually agreed upon at the joint FDA/state meeting concerning FDA's evaluation report. FDA's success in encouraging the state to correct substantial program weaknesses will depend in large part on the effectiveness of these follow-up efforts.

b. If FDA determines that there are no substantial public health weaknesses in the state milk safety program, the ORA OSCP Office Director should request a meeting with the state to advise them of this finding and plan how FDA can best continue to provide assistance to help the state preserve the public health.

7. Dissemination of State Evaluations and State Action:

   a. Within 60 days of the final field work/review/visit to the State by the MS, involving the gathering of information for the evaluation, a Draft version shall be sent to the State program manager.

b. This Draft evaluation report must be clearly marked "DRAFT."

c. The State shall have 30 days from receipt of the Draft to provide their comments to the MS.

d. Within 30 days of receipt of the State's comments, these comments shall be considered and incorporated, if appropriate: the final document with cover letter shall be routed to the OSCP Office Director for signature; and the final document sent to the head of the State Agency(ies), with signed copies to the State program manager and copies to OSCP and CFSAN Office of Food Safety (OFS) Division of Dairy, Egg and Meat Products (DDEMP), MMPB.

e. If necessary, within 90 days of receipt of the final report, the State may respond to the report. The State and FDA Branch should meet to develop a written action plan for major deficiencies, if necessary, which is acceptable to both parties.

8. Procedures

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

B. STATE PROGRAM EVALUATION REPORT/GENERAL FORMAT

I. EXECUTIVE SUMMARY:

One or two pages, stating the purpose and authority for the evaluation. Provide in bullet point format the significant observations (strengths and weakness) and a determination of program compliance or non-compliance. Also, provide any significant corrections or improvements from the last evaluation.

II. REPORT OF FINDINGS:

1. Review of organization, structure and significant changes since the last evaluation.

GENERAL INFORMATION TO INCLUDE, BUT NOT LIMITED TO:

- Organizational chart,
    - Include the laboratory section within the organizational structure and whom they report to.
- Certified Industry Inspection, if applicable,
- Contracts with Local Health Departments, if applicable,
- Number of staff:
    - Supervisors
    - Field Staff
    - Support Staff,
- If applicable, the milk plant HACCP portion of a State Milk Safety Program is reviewed; this format may be modified to accommodate the requirement of that review,
- Other responsibilities of program personnel (i.e., Retail food inspectors, food

manufacturing inspections, etc.),
- List State/FDA contracts, if applicable,
- # of Grade "A" dairy farms,
- # of listed BTU's,
- # of manufacturing grade dairy farms, if applicable,
- # of IMS listed plants,
- # of non-IMS listed Grade "A" plants, if applicable,
- # of manufacturing grade dairy plants, if applicable,
- # of IMS listed receiving stations and/or transfer stations, if applicable,
- # of non-IMS listed receiving stations and/or transfer stations, if applicable,
- # of listed single service facilities, if applicable,
- # of permitted milk tank truck wash facilities, if applicable,
- # of IMS Laboratories,
    - Central/Regulatory (State, County, Local, etc.),
    - Commercial
    - Industry,
- # of permitted milk tank trucks,
- # of permitted bulk milk haulers/samplers,
- # of industry samplers,
- # of dairy plant samplers (Regulatory),
- Brucellosis status, and
- Tuberculosis status

2. Regulatory Responsibilities

A. Inspection frequency and follow-up procedures
- Include pasteurization equipment testing

B. Sample procedures and follow-up

GENERAL INFORMATION TO INCLUDE, BUT NOT LIMITED TO:

- What samples Industry collects,
- What samples Industry analyzes,
- What samples the Regulatory Agency collects,
- What samples the Regulatory Agency analyzes,
- Are all required laboratory tests conducted (including Vitamin Assays) at the required frequency?

C. Enforcement procedures, as described in Section 3 of the *Grade "A" PMO*

GENERAL INFORMATION TO INCLUDE, BUT NOT LIMITED TO:
- Is the State Agency taking appropriate enforcement action when warranted?
- Is the enforcement that is being taken appropriate? (i.e., Using a monetary penalty in lieu of permit suspension and the milk is NOT allowed to be sold or offered for sale as Grade "A").
- Does the State Agency take immediate action when an imminent health

hazard is observed to prevent further movement of milk and milk products until such hazards have been eliminated?
- Does the State Agency conduct permit issuance, suspension, revocation, reinstatement, hearings, court actions and/or equivalent measures as required?
- Other *Grade "A" PMO* recommendations such as labeling requirements, etc.

3. State Laws and Regulations

Include a review of all applicable State laws, regulations policies and procedures with an explanation of any areas not compatible with the *Grade "A" PMO* and attendant documents (*MMSR/Procedures*). Address how the State Agency is taking enforcement action in regards to 3 out of 5 and repeat sanitation violations.

GENERAL INFORMATION TO INCLUDE, BUT NOT LIMITED TO:

- MS shall thoroughly review governing State Statutes regulations, policies and procedures, comparing them to the current *Grade "A" PMO* and related documents and describe any area(s) that are not equivalent.

- Has the State adopted the current *Grade "A" PMO* or does it have equivalent regulations in place that ensures the provisions of the IMS Program?

NOTE: For "Compliance" with the State Laws and Regulations Section of the State Program Evaluation, the State must have the *Grade "A" PMO* adopted or equivalent regulations for not more than six (6) years prior to the most recent Conference.

- Are the State laws regulations, policies and procedures substantially equivalent to the *Grade "A" PMO* requirements? (FDA should comment on areas which are not equivalent to the *Grade "A" PMO* and areas that exceed the *Grade "A" PMO*.)

- Does the State Agency follow the Provisions of the State Statues, regulations, policies and procedures? (FDA should comment on areas which are not followed and explain why.)

4. Identification of IMS Responsibilities

A. SROs or HACCP Listing Officers (if applicable),

B. LEOs,

C. SSOs and Sample Surveillance, and
   - List certification expiration date(s) for Items A, B and C.

D. Adherence to the *Grade "A" PMO* and attendant documents (*MMSR/Procedures*),

GENERAL INFORMATION TO INCLUDE, BUT NOT LIMITED TO:

- Is the State following the "*Procedures*" of the NCIMS?
- Are the listings (including Labs) being maintained and not allowed to expire?
- Are receiving States and FDA immediately notified when a listed shipper changes status because of degrading, permit revocation, SCR or ER of <90?
- Is the State Rating Agency certifying U.S. manufacturer of single service containers or closures?
- Is the State withdrawing certification of listings for IMS Listed Shippers and Labs when warranted?
- Is the shipping State responding to complaints received from receiving States?

E. Reciprocity, to include any milk and milk product labeling, coding and standards requirements, including imported milk and milk products from foreign sources, and

GENERAL INFORMATION TO INCLUDE, BUT NOT LIMITED TO:

- Has the State adopted any rules, policies, procedures or regulations which deny the movement of milk and milk products that originate from points beyond the limits of routine inspection that are produced and pasteurized under the Grade "A" IMS Program *Grade "A" PMO* or equivalent regulations?
- Has the State adopted any rules, policies, procedures or regulations, which will cause or require any action in excess of the requirements of the *Grade "A" PMO* and related documents of the NCIMS agreements?
    - Mandatory Pull (Sell-By) Date
    - Compositional Product Standards
    - Labeling

F. Summary and review of ratings and check ratings, including HACCP audits, if applicable.

GENERAL INFORMATION TO INCLUDE, BUT NOT LIMITED TO:

- Provide a summary of check rating results to include SCR and ER Scores, adverse action rates for BTU's, Plant (Receiving/Transfer Stations), Single Service audits (i.e., requested follow-ups).
- Summarize Items that were debited on check ratings, which were found in violation at 25% or more of the farms and plants.
- Summarize Items form the "Report of Enforcement Methods," which were not in 90% or higher compliance. (By beginning to calculate these overall adverse action rates, SCR and ER Scores (BTU's and Plants-Receiving/Transfer Stations) you are establishing a base line data base to be utilized to compare future State Program Evaluations).
- Single service listing, inspection and sampling responsibilities.

5. Regulatory Compliance with Appendix N. (See Section IV. A. 3. A.5. of the *Procedures* for details).

GENERAL INFORMATION TO INCLUDE, BUT NOT LIMITED TO:

- Compliance – Every milk tank truck tested prior to processing,
- Proper testing procedures followed,
- Acceptable laboratories,
- All analysts properly trained,
- Non-IMS Listed Plants – Availability of records on ratings and check ratings,
- Diversion of positive milk for animal feed (FDA acceptable protocol),
- Regulatory investigation following a positive producer result,
- # of producers with 3 positives in a 12 month period (Appropriate action initiated to revoke the permit),
- Quarterly Appendix N. review and 10% sampling program (Appropriate procedure or an acceptable alternative followed),
- % of industry dairy samplers evaluated at the required frequency, and
- Is the State submitting drug residue summary data to the Third Party Database?

6. Regulatory Compliance with Appendix B. (See Section IV. A. 3. A.6. of the *Procedures* for details).

GENERAL INFORMATION TO INCLUDE, BUT NOT LIMITED TO:

- % of Bulk Milk Hauler/Samplers evaluated at the required frequency,
- % of Dairy Plant Samplers (Regulatory) evaluated at the required frequency,
- % of Milk Tank Trucks inspected at the required frequency,
- Adequate training program for samplers, and
- Sampling Surveillance authority properly delegated to the field staff.

III. CONCLUSIONS AND RECOMMENDATIONS:

Summarize departures from FDA and *Grade "A" PMO* guidelines and procedures and guidance to strengthen and improve the program. Focus on broad problems (not isolated instances) and whether the State Program is effective in providing public health protection. Include a determination of compliance. Discuss program strengths as well as areas for improvement; this may include issues identified during check ratings and audits.

GENERAL INFORMATION TO INCLUDE, BUT NOT LIMITED TO:

- Does FDA check ratings indicate that the State's Milk Safety Program is effective in providing public health protection to consumers?
- Is there evidence through FDA/State received consumer complaints, recalls, check ratings, sampling surveillance programs or other means to show that State Program may fail to provide appropriate regulatory oversight? (MS shall document and comment on areas of concern.)

- MS will provide guidance to the State Program managers on how to strengthen and improve the State Program within the framework of the NCIMS Program.
- Identification of corrections or improvements from the previous State Program Evaluation.

IV. ATTACHMENTS:

- Comparison of check rating and state rating scores (SCR and ER scores from common rated listed shippers),
- Identify items debited more than 25% for both farms and plants,
- Identify enforcement rating measures not indicating 90% compliance, and
- Summary of check ratings that resulted in an adverse action, including action taken by state.

Include the following as needed to support conclusions and recommendations:
- Copies of State laws, regulations, policies and procedures, regulatory forms, sampler/hauler materials, and Appendix N. forms and SOP's.

C. CHECK LIST

MS's Visit to the State for Gathering of Information for the State Program Evaluation

(The following information may be asked for, but is not limited to:)

GENERAL INFORMATION

- CORRECTIONS and IMPROVEMENTS SINCE LAST EVALUATION
- ORGANIZATIONAL CHART
- CERTIFIED INDUSTRY INSPECTION PROGRAM, IF APPLICABLE
- CONTACTS WITH LOCAL HEALTH DEPARTMENTS, IF APPLICABLE
- STATE/FDA CONTRACTS, IF APPLICABLE
- DAIRY PLANT HACCP PROGRAM, IF APPLICABLE
- STAFF NUMBERS and BREAKDOWN
- # OF GRADE "A" DAIRY FARMS
- # OF LISTED BTU'S
- # OF MANUFACTURING GRADE DAIRY FARMS, IF APPLICABLE
- # OF IMS LISTED PLANTS
- # OF IMS LISTED RECEIVING/TRANSFER STATIONS, IF APPLICABLE
- # OF NON-IMS LISTED GRADE "A" PLANTS, IF APPLICABLE
- # OF NON -IMS LISTED RECEIVING STATIONS AND/OR TRANSFER STATIONS, IF APPLICABLE
- # OF MANUFACTURING GRADE DAIRY PLANTS, IF APPLICABLE
- # OF LISTED SINGLE SERVICE FACILITIES, IF APPLICABLE
- # OF PERMITTED MILK TANK TRUCK WASH FACILITIES, IF APPLICABLE
- # OF IMS LABORATORIES
    - CENTRAL/REGULATORY (State, County, Local, etc.)
    - COMMERCIAL
    - INDUSTRY

- # OF PERMITTED MILK TANK TRUCKS
- # OF PERMITTED BULK MILK HAULERS/SAMPLERS
- # OF INDUSTRY SAMPLERS
- # OF DAIRY PLANT SAMPLERS (Regulatory Personnel)
- BRUCELLOSIS STATUS DOCUMENTATION
- TUBERCULOSIS STATUS DOCUMENTATION

REGULATORY RESPONSIBILITIES

- INDIVIDUAL PLANT FILES
- INDIVIDUAL DAIRY FARM FILES
- INDIVIDUAL RECEIVING/TRANSFER STATION FILES, IF APPLICABLE
- RECALL FILES
- CONSUMER COMPLAINT FILES
- LABELING REQUIREMENT INFORMATION
- COPY OF ALL RELATED FORM, LETTER, MEMO's, etc.

STATE LAWS AND REGULATIONS (Copy to be provided prior to visit)

- COPY OF ALL APPLICABLE STATE LAWS AND REGULATIONS
- COPY OF ALL APPLICABLE STATE POLICIES AND PROCEDURES

APPENDIX N.

- APPENDIX N. PROTOCOL WITH INDIVIDUAL PLANTS, IF APPLICABLE
    - REPORTING
    - RETESTING
    - DIVERSION TO ANIMAL FEED
    - DISPOSITION
    - REGULATORY FOLLOW UP
- APPENDIX N. FILE OF POSITIVES WITH RELATED PAPERWORK
- INFORMATION ADDRESSING THE LABORATORY REQUIREMENTS
    - ACCEPTABLE LABORATORIES
    - TRAINING OF ANALYSTS
- QUARTERLY 10% AUDITING SAMPLING PROGRAM FILES
- INDUSTRY SAMPLER FILES
- % OF INDUSTRY SAMPLERS EVALUATED AT THE REQUIRED FREQUENCY
- COPY OF ALL RELATED FORMS, LETTERS, MEMO's, etc.

APPENDIX B.

- SAMPLING SURVEILLANCE PROGRAM
- DELEGATION OF SAMPLING SURVEILLANCE TO FIELD STAFF
- BULK MILK HAULER/SAMPLER TRAINING PROGRAM
- BULK MILK HAULER/SAMPLER EXAMINATION
- BULK MILK HAULER/SAMPLER FILES
- DAIRY PLANT SAMPLER FILES (Regulatory Personnel)
- MILK TANK TRUCK FILES
- % OF BULK MILK HAULERS/SAMPLERS EVALUATED AT THE REQUIRED

FREQUENCY
- % OF DAIRY PLANT SAMPLERS EVALUATED AT THE REQUIRED FREQUENCY
- % OF MILK TANK TRUCKS INSPECTED AT THE REQUIRED FREQUENCY
- COPY OF ALL RELATED FORMS, LETTER, MEMO's, etc.

D. SAMPLE SIZE ESTIMATES FOR THE NUMBER OF FILES TO BE REVIEWED BY THE TOTAL NUMBER OF FILES AND 95% CONFIDENCE LEVEL

(FARMS, RECEIVING STATIONS, TRANSFER STATIONS, MILK PLANTS, BULK MILK HAULER/SAMPLERS, INDUSTRY PLANT SAMPLERS, DAIRY PLANT SAMPLERS, MILK TANK TRUCKS, ETC.)

Number of Files	Number to be Reviewed	Number of Files	Number to be Reviewed	Number of Files	Number to be Reviewed
<12	All	66-70	32	181-200	45
13-15	12	71-75	33	201-220	46
16-20	15	76-80	34	221-240	47
21-25	18	81-81	35	241-280	48
26-30	20	86-95	36	281-310	49
31-35	22	96-100	37	311-360	50
36-40	24	101-110	38	361-420	51
41-45	26	111-120	40	421-500	52
46-50	27	121-140	41	501-1000	55
51-55	29	141-150	42	1001-1500	56
56-60	30	151-160	43	1501-3500	57
61-65	31	161-180	44	>3500	58

E. NCIMS Minimum State Program Evaluation Requirements and Criteria

1. **Regulatory Authority**
a. State regulations equivalent to *Grade "A" PMO* (Must have the *Grade "A" PMO* adopted or equivalent regulations for not more than six (6) years prior to the most recent Conference)*

2. **Dairy Farm Program** (All must be 90% Compliance or greater)
   a. Licenses/permits issued
   b. Inspection frequency maintained
   c. Producer milk sample frequency maintained
   d. Producer water sample frequency maintained

3. **Dairy Plant Program** (All must be 90% Compliance or greater) (b. and e.)*
   a. Licenses/permits issued
   b. Inspection frequency maintained
   c. Product sample frequency maintained
   d. Water sample frequency maintained
   e. HTST equipment testing frequency maintained

4. **Appendix N. Program**
a. Bulk milk pickup tankers sampled and tested as required (Must be 100% Compliance)*
b. 10% sampling program or equivalent maintained (Must be 90% Compliance ore greater)*

5. **Bulk Milk Hauler/Sampler Program and Industry Plant Sampler Program** (All must be 80% Compliance or greater)
a. Licenses/permits issued
b. Inspections/evaluation frequency maintained

6. **Milk Tank Truck Program** (All must be 80% Compliance or greater)
a. Licenses/permits issued
b. Inspection frequency maintained

7. **State Certification** (a., b., and d. – All must be 100% Compliance)
a. SRO(s) certified
b. SSO(s) certified
c. Sample surveillance authority properly delegated
aa. Bulk Milk Hauler/Samplers
bb. Dairy Plant Samplers evaluated at proper frequency
d. LEO(s) certified
e. Laboratories evaluated at proper frequency

8. **Records accurate, complete, current and systematically maintained as described in *MMSR***

9. **Compliance and Enforcement Actions Appropriate** (Use Enforcement Ratings from Check Ratings for farms and plants – 90% Compliance or greater.)*
a. State has established compliance and enforcement procedures for the above listed state program requirements and is following them

10. **Reciprocity**

*Triggers a Strategic Action Plan to be jointly developed by the FDA OSCP Branch and the State if the percent Compliance falls below the identified level. MSs would put the % compliance in the State Program Evaluation Report.

Other program requirements not meeting the minimum criteria should lead to a discussion of corrective action between the FDA OSCP Branch and the State, which may include the development and implementation of a Strategic Action Plan.

F. STATE PROGRAM EVALUATION RESOLUTION PROCESS

1. Using specific program evaluation criteria, the FDA MS will collect and analyze State milk program administrative and field data, and identify specific program strengths and/or weaknesses in accordance with established procedures to determine the strengths/weaknesses of the program. The DRAFT State Program Evaluation Report will be prepared and disseminated in accordance with Section X of the *Procedures*. The MS and the FDA Branch Director of the OSCP shall consult with MMPB and LPET on significant program weaknesses prior to completion of the State Program Evaluation Report. The determination of the final program evaluation (a & b below) is made by the ORA OSCP Branch Director.

a. Using the predefined Minimum State Program Requirements and Criteria, if the final determination is that:

1. There are no public health weaknesses that could realistically lead to a potential health hazard, and
2. There has not been a departure from FDA and NCIMS State program requirements.

b. Using the predefined Minimum State Program Requirements and Criteria, if the final determination is that:

1. There are public health weaknesses that could realistically lead to a potential health hazard, or
2. There is a departure from FDA and NCIMS State Program Requirements.

2. If a. above is determined the MS shall finalize and submit the report to the ORS OSCP Branch Director for concurrence, signature and distribution to the head of the responsible State Agency(s), [split States-Regulatory and Rating], with copies to the State dairy Program Manager or, if applicable, the State Rating Program Manager, and copies to MMPB. The State Agency should respond to the report with their proposed solution to correct the deficiencies noted in the report.

If b. above is determined, the MS shall finalize and submit the report to the ORA OSCP Branch Director for review and signature. Prior to distributing the signed final report to the head of the responsible State Agency(s), [split States-Regulatory and Rating], with copies to the State Dairy Program Manager or, if applicable, the State Rating Program Manager, and copies to MMPB, the ORA OSCP Branch Director shall attach a cover letter requesting that the MS, State Dairy Program Manager, and State Rating Program Manager, if applicable, and other high ranking State Regulatory Officials, meet, discuss, and develop a mutually agreed upon written Strategic Action Plan.

The Strategic Action Plan shall be designed to:

- Strengthen the State program,
- Address/correct identified program weaknesses,
- Provide a means to easily track progress,
- Identify specific State and FDA areas of responsibility,
- Identify areas where FDA can assist the State in achieving program objectives, and
- Identify clear time frame and milestones for the implementation of the plan.

The Strategic Action Plan, once developed, will be forwarded to the ORA OSCP Branch Director from the head of the responsible State Agency, referencing the State Program Evaluation. If a mutually agreed upon Strategic Action Plan cannot be developed, FDA shall request that the NCIMS Executive Board provide both the State Program Officials and FDA an opportunity to present position statements at the next and any subsequent Executive Board meeting(s).

3. The Strategic Action Plan shall be implemented within ninety (90) days of the date of the cover letter. Thereafter, State Program Officials, the ORA OSCP Branch Director and the MS(s)

shall periodically meet and discuss the progress of the Strategic Action Plan.

4. The MS shall be responsible for monitoring the Strategic Action Plan and provide written status reports to State Program Officials, the ORA OSCP Branch Director, and the ORA OSCP Director. Status reports shall be provided at agreed upon intervals and shall continue until such time that the objectives of the Strategic Action Plan have been met and the identified program weakness(es) are corrected.

5. If at any time (a) a determination is made that established, documented and agreed upon commitments are not being met, or (b) that the Strategic Action Plan has failed to correct the identified weakness(es), and as a result the weakness(es) are identified in the next triennial State Program Evaluation, the MS shall immediately begin providing copies of all status reports to MMPB, LPET, and the NCIMS Executive Board.

6. As a result of #5, the State must immediately develop a mutually agreed upon Revised Strategic Action Plant with Specific timelines for correction. If those revised timelines are NOT adhered to; or, if an identified program weakness previously corrected under a Strategic Action Plan, is identified in two subsequent consecutive triennial State Program Evaluation reports, FDA shall request that the NCIMS Executive Board provide both the State Program Officials and FDA an opportunity to present position statements at the next and any subsequent Executive Board meeting(s).

7. Within 120 days from the date of the initial Executive Board meeting, the Chair of the NCIMS Executive Board shall provide both the State Program Officials and FDA an opportunity to re-address the Board to determine if the Revised Strategic Action Plan has been adhered to. If at that time the NCIMS Executive Board and FDA mutually agree that because the Revised Strategic Action Plan has not been complied with, the NCIMS Executive Board Chair and FDA shall jointly notify the State Agency in writing that they are not in compliance with the *Procedures* and that until such time that satisfactory compliance can be achieved, the State cannot actively participate in future NCIMS conferences.

SECTION XI. APPLICATION OF NCIMS CONFERENCE AGREEMENTS

A. IMPLEMENTATION OF CHANGES TO NCIMS DOCUMENTS

Unless explicitly specified otherwise by a vote of the voting delegates, changes in the *Procedures* and recommended changes in Standards, found in Section VI. of these *Procedures*, shall be implemented in accordance with the following schedule:

1. The transcript of the second voting day shall be forwarded to PHS/FDA within forty-five (45) days of the close of the NCIMS Conference.

2. PHS/FDA shall review the transcript and within ninety (90) days of receipt, notify the NCIMS 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 NCIMS documents or notification to the NCIMS Member States

and TPCs by IMS-a, following the NCIMS Conference at which the changes were passed and concurred with.

3. Those issues with which PHS/FDA does not concur 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 NCIMS documents or notification to the States and TPCs by IMS-a, following the NCIMS Conference at which the changes were passed and concurred with, unless otherwise mutually agreed upon by PHS/FDA and the NCIMS Executive Board.

4. If mutual concurrence cannot be reached, the matter shall be referred to the next NCIMS 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 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.

B. EDITORIAL CHANGES TO NCIMS CONFERENCE DOCUMENTS

Editorial changes may be made to the *Procedures* and other NCIMS conference documents (excluding the *Constitution* and *Bylaws*) for the purposes of:

1. Incorporating language from Proposals adopted by the voting delegates into their respective NCIMS documents;

2. Incorporating language from any Proposal that does not include the exact language to be incorporated but does provide some direction for determining the text to be incorporated in the NCIMS document. **For Example**: Section IV., A. 6. shall apply as written except that, for purposes of this Section the word "rating" shall be replaced with "listing".;

3. Correcting misspelled words;

4. Correcting capitalization of words;

5. Correcting the use of punctuation within NCIMS documents;

6. Correcting paragraph or Section numbering schemes;

7. Correcting incorrect citations or other references within a NCIMS document;

8. Correcting the incorrect use of terms used in any Proposal. **For Example**: Using the term "rating" instead of "listing".;

9. Correcting the inconsistent use of defined terms when referencing facilities, persons or equipment subject to any requirement contained in any of the NCIMS documents. **For Example**: Adding "receiving station and transfer station" after "milk plant" if the Section requirements were intended to be applicable to all three (3).;

10. Changing incomplete sentences into complete sentences without changing the meaning or intent of the original language passed by the voting delegates;

11. Consistently using acronyms within NCIMS documents after they have been cited where the term or phrase first occurs in each NCIMS document;

12. Deleting or changing references within NCIMS documents if a document is deleted or combined with another document to ensure accurate references;

13. Deleting any language that would extend the regulatory oversight to products outside the scope of the NCIMS Grade "A" Milk Safety Program;

14. Modifying any definition that is in conflict with a previously established definition in any NCIMS document to be consistent with the established definition and limited to the extent that the editorial changes do not alter the meaning or intent of the original language passed by the voting delegates; or

15. Providing consistent references to NCIMS document titles, Committee names, Agency names, Agency identifications, position names/titles, reporting forms, citations of NCIMS documents and other documents and citations of Sections within NCIMS documents and other documents.

Limited editorial changes may be made to the *Constitution* and *Bylaws* for the purposes of incorporating language from Proposals amending the *Constitution* or *Bylaws* adopted by the voting delegates and to correct misspelled words, capitalization, punctuation, formatting and paragraph or Section numbering schemes.

C. REVIEW AND APPROVAL OF EDITORIAL CHANGES

1. After receipt of the transcript of the second voting day PHS/FDA shall prepare an IMS-a document detailing the Actions of the NCIMS Conference and shall incorporate the language from all Proposals passed by the voting delegates into the appropriate NCIMS documents.

2. PHS/FDA shall prepare an electronic version of each IMS-a and NCIMS document detailing the Actions of the NCIMS Conference for review by the NCIMS DRC that strikes out text to be deleted and underlines text to be inserted. The NCIMS DRC shall have a minimum of ten (10) business days to review the changes and respond back to PHS/FDA with any concerns. Review of each IMS-a and NCIMS document detailing the Actions of the NCIMS Conference shall continue until both the NCIMS DRC and PHS/FDA concur on the IMS-a and NCIMS document or concurrence cannot be reached.

3. Those issues on which the NCIMS DRC and PHS/FDA do not concur shall be referred to the NCIMS Executive Board for further discussion. If the NCIMS Executive Board and PHS/FDA reach agreement on a proposed solution, the IMS-a or NCIMS document being considered shall require approval by a minimum of two-thirds (2/3) affirmative vote of the NCIMS Executive Board voting members before being released for publication.

4. The NCIMS Executive Board shall review and approve all editorial changes to NCIMS documents by a minimum of two-thirds (2/3) affirmative vote of the NCIMS Executive Board

voting members. Editorial changes that did not raise any concerns of the NCIMS DRC may be combined and voted on as one (1) motion by the NCIMS Executive Board.

D. **TRAINING COURSE DEVELOPMENT**

NCIMS and/or PHS/FDA may determine the need to develop and conduct training courses for regulatory and industry personnel.

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" 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 (Grade "A" 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 (Grade "A" 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 (Grade "A" 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 (Grade "A" 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, aseptically processed and packaged milk and/or milk products, retort processed after packaging milk and/or milk products and/or fermented high-acid, shelf-stable processed and packaged 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 and the Certifications/Listings of Single-Service Containers and Closures for Milk and/or Milk Products Manufacturers* (*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*)).

In addition, because Grade "A" milk and/or milk products will be imported into the United States, the TPC shall make the Milk Company (MC) aware of the requirements of the U. S. Federal Import Milk Act (FIMA) and help the MC determine which if any of their Grade "A" milk and/or milk products to be imported would be covered under FIMA.

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 MMPB and Laboratory Proficiency Evaluation Team (FDA MMPB 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 *Grade "A" PMO* and U.S. Department of Agriculture (USDA) regulations for tuberculosis and brucellosis testing and control.

In addition, the MC shall apply for a FIMA Permit for any Grade "A" milk and/or milk products covered under FIMA that they wish to import into the United States.

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 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 MMPB and shall be reviewed by the NCIMS ICP Committee and FDA MMPB 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 MMPB 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 NCIMS documents by PHS/FDA MMPB 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 MMPB 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 MMPB 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 MMPB in a manner acceptable to PHS/FDA MMPB.

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 MMPB 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 MMPB 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 MMPB in a manner acceptable to PHS/FDA MMPB.

d. When there is evidence, found during PHS/FDA check ratings or a triennial Regulatory/Rating Agency Program Evaluation, that the TPC is in "substantial non-compliance" with the applicable requirements set forth in the NCIMS documents, the TPC shall be referred to the NCIMS Executive Board in accordance with Section IV., A. 3.d. of the *Procedures*. The TPC and MC(s) listed by the TPC can be subject to withdrawal by PHS/FDA MMPB 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 SCR to less than ninety percent (90%), the TPC shall immediately notify the PHS/FDA MMPB and all known receiving NCIMS Member States and/or TPCs. The MC's IMS listed milk shipper shall immediately be withdrawn from the *IMS List* by PHS/FDA MMPB.

f. When there is evidence that the MC or its 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 MMPB 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 MMPB and/or LPET, respectively. In the case that PHS/FDA MMPB 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 MMPB and/or LPET, is achieved. With this determination, PHS/FDA MMPB and/or LPET, respectively, shall notify all known receiving NCIMS 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 MMPB. 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 MMPB in a manner acceptable to FDA MMPB. FDA MMPB 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 MMPB 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 NCIMS 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)

Most Responsible Person:

Signature: _____

Name: _____

Title: _____

Date: _____

Expiration Date: _____

For the MC: (Name of MC)

Most Responsible Person:

Signature: _____

Name: _____

Title: _____

Date: _____

CONSTITUTION OF THE NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

ARTICLE I ------ ORGANIZATION

SECTION 1. The name of the entity shall be "The National Conference On Interstate Milk Shipments", hereinafter referred to as the Conference.

SECTION 2. The Conference shall be directed by and shall be in the control of the various States who join together to stipulate the Conference's Procedures.

SECTION 3. The Conference shall meet at least biennially during odd numbered years with additional meetings as the need arises.

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 Rating and Regulatory Agencies.

SECTION 2. Promoting mutual respect and trust between Rating and 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 Rating and Regulatory Agencies for the objective of promoting uniformity among the States and 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, Rating and Regulatory Agencies and other groups that are willing to assist in the dissemination of such information.

ARTICLE III ------ AFFILIATION AND REGISTRATION

SECTION 1. Any person, who is interested in promoting the unrestricted availability of safe milk, thus encouraging its greater consumption, may become affiliated with the Conference by:

Subd. 1. Registering at the biennial or special meeting of the Conference; or

Subd. 2. Applying to the Executive Secretary for affiliation on forms provided and paying the annual affiliation fee.

SECTION 2. Persons may not attend and/or take part in the biennial or special meeting of the Conference until they have registered their name, address, company, or Agency with the Executive Secretary and paid the registration fee.

SECTION 3. Payment of registration fees as are required in Article I, Section 9. of the *Bylaws* shall be a part of registration.

SECTION 4. All persons affiliated with the Conference as prescribed in this Article are entitled to be on an official list to receive copies of the Conference proceedings and other Conference matters determined by the Board to be of interest to all persons affiliated with the Conference.

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 Rating Agencies, State 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 2. An individual must be affiliated with the Conference to be eligible to serve as an Officer of the Conference, on the Board, on Committees or Councils or as Program Chair. Individuals must be in attendance and registered at the Conference at which they are appointed or elected or shall have been registered or attended the Conference immediately preceding the one at which they are appointed or elected. The requirement in respect to the consumer representative, Committees and Councils may be waived by the unanimous consent of the Board.

SECTION 3. The voting delegates of the biennial meeting of the Conference shall elect its Executive Board, hereinafter called the Board.

SECTION 4. The Board shall be composed up to twenty-seven (27) 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) or, in the case of a vacancy between Conferences, as appointed by the Chair and confirmed by the Board; 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, Chair of the NCIMS Laboratory 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, Chair of the NCIMS Laboratory 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.

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 Rating Agency, one (1) member from industry, one (1) member from a State Regulatory Agency, plus one (1) member from either a State Rating or State 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 Rating Agency, one (1) member from industry, one (1) member from a State Regulatory Agency, plus one (1) member from either a State Rating or State 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.

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 Rating Agency, one (1) member from industry, one (1) member from a State Regulatory Agency, plus one (1) member from either a State Rating Agency or State Regulatory Agency), plus one (1)

member (at-large) from USDA to be appointed by the Secretary of Agriculture.

Subd. 4. Other Membership

In the case of participating U.S. Trust Territories, non-U.S. countries or political subdivision thereof, each U.S. Trust Territory, non-U.S. country or subdivision thereof shall be assigned to Group I, Group II, or Group III by the Board.

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 a vote on the Board 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 7. The immediate Past Chair of the Board shall continue to serve on the Board until replaced by the next retiring Chair. If the immediate Past Chair of the Board is unable for any reason to continue to serve on the Board, the position shall remain vacant until filled by the next retiring Chair. The immediate Past Chair shall serve on the Board as a non-voting member, provided that the Past Chair shall be a voting member if elected by the voting delegates to serve on the Board, in a capacity other than as immediate Past Chair.

SECTION 8. Elected members of the Board who retire or change disciplines from which elected (such as becoming consultants) may no longer continue to serve on the Board in their current position. Should the Conference Chair retire or change positions, the Chair may continue to serve as Past Chair.

SECTION 9. There shall exist three (3) Councils in the Conference to provide continuity in carrying out the mission of the Conference. Councils shall be known as Council I, Council II, and Council III.

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 Rating and/or Regulatory Agencies and ten (10) representatives from industry.

Subd. 2. Industry Council members shall be equally divided between producer and processor representatives.

Subd. 3. Each Council member shall be eligible to serve on a specific Council through no more than five (5) consecutive biennial meetings of the

Conference. On an individual basis, when a new member is not available to serve, the term limit may be waived by the unanimous consent of the Board.

SECTION 11. Each Council shall have a Council Chair and a Vice Chair who are appointed by the Chair and confirmed by the Board. The Council Chairs and Vice Chairs shall serve on the Councils as non-voting members. After each biennial meeting of the Conference, each Council Chair shall select twenty (20) Council members from qualified Conference registrants and offer their names for Chair appointment and Board confirmation. Careful attention must be given by the Council Chair in the selection of Council members to achieve the discipline balance required in Article IV, Section 10. of this *Constitution*.

Subd. 1. Council Chairs and Vice Chairs shall after appointment serve through two (2) consecutive biennial meetings of the Conference. Council Chairs and Vice Chairs may exceed the limit of five (5) consecutive biennial meetings cited in Article IV, Section 10. of this *Constitution* only to fulfill their terms as Chair and/or Vice Chair.

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

Subd. 3. At the end of the Council Chair's term of office, the Vice Chair will become Council Chair and a new Vice Chair will be appointed from that Council and represent the same segment of the Conference as the outgoing Council Chair.

SECTION 12. PHS/FDA may provide a consultant for each of the Councils.

SECTION 13. Each Standing, Study and Ad hoc Committee shall have a Committee Chair and Committee Vice Chair who are appointed by the Conference Chair and confirmed by the Board after each biennial meeting of the Conference.

Subd. 1. If the Committee Chair represents a Rating and/or Regulatory Agency, the Committee Vice Chair may represent industry. If the Committee Chair represents industry, the Committee Vice Chair may represent a Rating and/or Regulatory Agency.

Subd. 2. Committee Vice Chairs shall perform the duties of the Committee Chair whenever the Committee Chair is unable to attend.

Subd. 3. Unless fulfilling the role of Committee Chair, the Committee Vice Chair shall serve as a voting member of the Committee.

ARTICLE V ------ AMENDMENTS TO THE CONSTITUTION

SECTION 1. This *Constitution* may be amended at a duly called biennial meeting of the Conference with the delegates having had forty-five (45) days notice from

the Executive Board or its designee of such proposed amendments. Two-thirds (2/3) affirmative vote of the delegate quorum shall be necessary to adopt amendments to the *Constitution.*

SECTION 2. Amendments to the *Constitution* shall be deliberated by Council III. Council III's actions on Constitutional amendments shall be reviewed by the delegate body. Council III or the delegate body may recommend changes to proposed Constitutional amendments. Adoption of such changes shall be as required in Section 1. of this Article.

SECTION 3. Amendments to the *Constitution* shall become effective at the close of the Conference at which they are adopted.

BYLAWS OF THE NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

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

SECTION 1. The Board shall manage the affairs of the Conference, and act for the Conference on emergency matters deemed appropriate by the Public Health Service/Food and Drug Administration (PHS/FDA) and/or the Board using one of the following procedures:

Subd. 1. Call a special meeting of the Conference.

Subd. 2. Poll the States to determine majority support or non-support of those States responding to the Board's proposed action.

SECTION 2. The Board shall meet prior to and after each Conference. The Chair shall call special meetings of the Board, at any time, at the request of two-thirds (2/3) of its members. In addition to the required meetings of the Board prior to and after the Conference, and special meetings of the Board called at the request of two-thirds (2/3) of the Board members, the Chair is empowered to call special meetings of the Board at any time, as the need arises, with the concurrence of two-thirds (2/3) of the Board members. With the concurrence of two-thirds (2/3) of the Board members, special Board meetings may be conducted by using telephone conference calls and electronic mail (FAX or e-mail) ballots.

SECTION 3. The Board shall direct the Chair, Executive Secretary, and Program Chair in the preparation of the programs for each Conference.

SECTION 4. The Board shall set the time and place of each required odd numbered year Conference. Additional meetings of the Conference may be called and arranged by the Board at any time the need arises.

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 Rating and State Regulatory Agencies in each of the three (3) geographical groups of States.

SECTION 6. If any voting member of the Board is unable to attend a Board meeting, the voting member may not conduct business in absentia or send a substitute, but may forward by mail, FAX or e-mail information for consideration by the attending members of the Board.

SECTION 7. Voting Board members who fail to attend two (2) consecutive Board meetings and who fail to show cause why absent, may have their position declared vacant by the Chair.

SECTION 8. An elected Board membership vacancy occurring between Conferences shall be filled by the Chair and confirmed by the Board, to serve until the next biennial or special meeting of the Conference. The vacancy shall be filled by a qualified registrant from the most recent biennial or special meeting of the Conference. At the next biennial or special meeting of the Conference, the vacancy shall be filled for the balance of the term by a qualified registrant who is nominated by the Nominating Committee or from the floor in General Assembly and is elected by the voting delegates.

SECTION 9. The Board shall direct the Executive Secretary to collect registration and affiliation fees as necessary to defray the costs of the operation of the Conference. The Board shall cause an annual audit to be made of the Executive Secretary's records, which are a part of the Board's records.

SECTION 10. The Board shall, after consideration of Council III recommendations, rule on matters of reciprocity as it shall affect listings in the *IMS LIST-Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers*, as required in Section IV., A. 5.c. of the *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments*.

SECTION 11. The Board shall authorize the form used to tally votes in Board meetings and in General Assembly.

SECTION 12. The Board shall establish the registration and annual affiliation fees.

SECTION 13. The Board shall approve an annual budget for the fiscal year established by the Board.

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

SECTION 15. The Executive Board or its designee shall notify the voting delegates at least forty-five (45) days prior to the Conference of any proposed *Constitution* or *Bylaws* changes.

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

SECTION 1. The Chair shall preside at all meetings of the Board and during all business sessions of the Conference, except as provided for in Article III, Section 1. of the *Bylaws*.

SECTION 2. The Chair shall assist the Executive Secretary in arranging all Conferences.

SECTION 3. The Chair, with the approval of the Board, shall appoint qualified Conference registrants to Standing Committees, including the Appendix N.

Modification Committee, 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, Other Species and International Certification Program Committees, and Councils as is necessary to carry out the mission of the Conference. From among the members of each Standing Committee, the Conference Chair, with the approval of the Board, shall appoint a Committee Chair and Committee Vice-Chair as outlined in Article IV, Section 13, of the *Constitution*.

SECTION 4. The Chair shall appoint Study and Ad hoc Committees as directed by the voting delegates or the Board. From among the members of each Study and Ad hoc Committee, the Conference Chair, with the approval of the Board, shall appoint a Committee Chair and Committee Vice-Chair as outlined in Article IV, Section 13. of the *Constitution*.

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 Rating and Regulatory Agencies, provided the membership of the Nominating Committee, Resolutions Committee and Constitution and Bylaws Committee shall consist in whole from State Rating and State Regulatory Agencies. The Nominating Committee shall be composed as set forth in Article I, Section 5. of the *Bylaws*.

SECTION 6. The Chair shall assure that PHS/FDA may provide a non-voting consultant to Standing committees, Ad hoc committees or Study committees, provided PHS/FDA shall not provide any consultant to the Nominating Committee, Resolutions Committee, NCIMS Liaison Committee and Constitution and Bylaws Committee.

SECTION 7. The Chair with the approval of the Board shall appoint Council Chairs and Vice Chairs as outlined in Article IV, Section 11. of the *Constitution*.

SECTION 8. The Chair shall appoint Council consultants as required in Article II, Section 13. of the *Bylaws*.

SECTION 9. The Chair shall appoint a Local Arrangements Committee to assist in planning the physical facilities for the next Conference.

SECTION 10. The Chair may retain the services of a Parliamentarian to rule on Parliamentary Procedures at Board meetings, Council meetings and during the delegate business meetings of the Conference, employing Roberts Rules of Order Modern Edition.

SECTION 11. The Chair, with Board approval, may retain clerical assistance for the Conference.

SECTION 12. The Chair shall appoint a Program Chair.

SECTION 13. The Chair shall appoint a consultant for each Council from the Board. These consultants shall have no voting rights in Council, but will attend Council deliberations to offer advice when needed.

ARTICLE III ------ DUTIES OF THE VICE CHAIR

SECTION 1. In the event the Chair is unable to attend any meeting of the Conference or Board, the Vice Chair shall act as Chair at the meeting.

SECTION 2. When acting as Chair, as provided for in Section 1. of this Article, the Vice Chair shall perform all the necessary duties required in Article II of the *Bylaws*.

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

SECTION 1. The Executive Secretary shall record the minutes of each meeting of the Board and each delegate business meeting.

SECTION 2. The Executive Secretary shall tally and record all voting of the Board and each delegate business meeting on forms authorized by the Board.

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 Rating and/or 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.

SECTION 4. The Executive Secretary shall collect registration and affiliation fees and shall pay all bills as directed by the Board. The Executive Secretary shall obtain a receipt for all disbursements and shall make all such receipts a part of the Board records.

SECTION 5. The Executive Secretary shall accomplish the duties outlined in Article VII, Section 3., Subdivisions 2., 3., and 4., and Article VII, Section 4., Subdivision 4., of the *Bylaws*.

SECTION 6. At least ninety (90) days prior to the Conference, the Executive Secretary shall provide each registrant of the preceding Conference with forms on which Proposals may be submitted to the Program Chair for assignment to Councils.

SECTION 7. The Executive Secretary shall act as Treasurer of the Conference and handle all financial matters of the Conference as directed by the Board.

ARTICLE V ------ DUTIES OF THE PROGRAM CHAIR AND COMMITTEE

SECTION 1. The Program Chair shall assist the Executive Secretary and Chair in planning and arranging for all sessions of the Conference.

SECTION 2. The Program Chair shall assist the Executive Secretary in the preparation and distribution of programs for each Conference.

SECTION 3. The Program Committee shall review and assign all Proposals received for Council and voting delegate deliberation. Proposal assignments shall be made in accordance with the subject matter outlined in Article VI, Sections 1., 2. and 3. of the *Bylaws* unless this will result in one Council being assigned more than 38% of all Proposals; in which case, the Program Committee may assign Proposals to the Councils without considering their subject matter for purposes of equalizing the distribution of Proposals between the three Councils.

SECTION 4. The Program Chair shall serve as a non-voting member on the Board.

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

SECTION 1. Council I shall deal with Proposals submitted to the Conference regarding Sections 7, 8, 9, 10, 12, 13, and 14 and Appendices A, C, D, H, I, J, M, O and Q of the *Grade "A" Pasteurized Milk Ordinance;* and Proposals assigned by the Program Committee to or originating from the Single-Service Container and Closure Committee or Technical Engineering Review Committee.

SECTION 2. Council II shall deal with Proposals submitted to the Conference regarding Sections 1, 2, 3, 4, 5, 6, 15, and 16 and Appendices B, E, F, G, L, N, P and R of the *Grade "A" Pasteurized Milk Ordinance*; the *Evaluation of Milk Laboratories* document; and Proposals assigned by the Program Committee to or originating from the Methods of Making Sanitation Ratings Committee.

SECTION 3. Council III shall deal with Proposals submitted to the Conference regarding Sections 11, 17, and 18 and Appendices K, S and T 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.

SECTION 4. Each Council shall deliberate all assigned Proposals and each Council Chair shall report the actions of the Council to the certified voting delegates in General Assembly for final delegate action.

SECTION 5. The Chair of each Council shall appoint a minimum of four (4), but not more than eight (8), alternate Council members representing one (1) or two (2) dairy processors, one (1) or two (2) dairy producers, one (1) or two (2) Regulatory Agencies and one (1) or two (2) Rating Agencies 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. Alternates must be affiliated with the current Conference and meet the same eligibility requirements to serve on a Council as the member for whom they will temporarily replace. Alternates shall be required to be in attendance at the Conference and be present at each Council meeting, even if not called upon by the Council Chair to temporarily replace an existing Council member. Alternates are only eligible to replace existing Council members from the same stakeholder group and shall be seated for the entire Conference as a temporary replacement for the original Council member. Council Chairs are encouraged to consider Council alternates when recommending permanent Council replacements to the Board for approval.

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

SECTION 1. All Conferences shall be at least two (2) days' duration and shall not adjourn until all business matters have been dispensed with. Each day's session shall be recessed until a specified time the following day, whereas the end of business at the conclusion of the Conference shall be adjourned until the next biennial or special meeting of the Conference.

SECTION 2. Except for additional meetings as provided for in Article I, Section 4. of the *Bylaws*, the Conference will convene each odd numbered year.

SECTION 3. Order of business, of the delegate business meetings, shall include the following:

Subd. 1. Call to order by the Chair.

Subd. 2. Roll call of States and the announcement of the names of the delegates who will vote for each State in General Assembly.

Subd. 3. Report of the Executive Secretary.

Subd. 4. Unfinished business.

Subd. 5. Appointment of the Nominating Committee.

Subd. 6. Conference program, PHS/FDA report, Council Chair reports, the annual audit report and other new business.

Subd. 7. Report of the Nominating Committee at least four (4) hours before voting.

Subd. 8. Election of Board Members. In addition to the nominees selected by the Nominating Committee, nominations may be made from the floor of the delegate business meeting, if nominees qualify for the position to be filled.

Subd. 9. Report of the Resolutions Committee.

Subd. 10. Authorization by the voting delegates for the Board to conclude and implement any current unfinished action requiring PHS/FDA concurrence not specifically obtained during the Conference.

Subd. 11. Adjourn.

SECTION 4. Rules of the delegate business meeting.

Subd. 1. Roberts Rules of Order Modern Edition shall prevail, unless provisions of the *Constitution*, *By-Laws* or historic practice exist which shall take precedence.

Subd. 2. Each State or other entity listed in Subdivision 3. of this Section, shall be entitled to one (1) full vote or two (2) one-half (1/2) votes in the delegate business meeting.

Subd. 3. Only a registrant at the Conference, who is a representative of a State Rating Agency or a State 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 Rating and 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 Rating and 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. When any State is represented by only one (1) Agency, the voting delegate at the Conference may cast a full vote for that State. Each voting delegate at the Conference may cast a vote only for the voting delegate's own State. Delegates and/or alternates will not be allowed to vote at the Conference from a State, which fails to honor the reciprocity provisions set forth in Section VI., paragraphs A. and B. of the *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments*.

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 Rating or State 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 Rating Agency only, or as State Regulatory Agency only, or both as identified in Article VII, Section 4., Subdivision 3. of the Bylaws.

b. The name of the delegate and the alternate and the authority they represent.

c. Designation of the vote to which they are entitled, whether one-half (1/2) vote or one (1) vote.

In the event two (2) delegates are designated by two (2) State Agencies to represent the same responsibility, either Rating or Regulatory, or, the sum of the votes designated for the delegates is greater than one (1), the Executive Secretary shall reject, void, and return the reports to the Agencies for correction and to be in compliance with Article VII, Section 4., Subdivision 3. of the *Bylaws*.

Subd. 5. State delegates shall record their names with the Executive Secretary, and shall cast their votes in the General Assembly when their State's name is called by announcing "yes" or "no" one (1) vote, or "yes" or "no" one-half (1/2) vote.

Subd. 6. Voting in General Assembly shall be recorded as "yes" or “no”.

Subd. 7. A delegate may pass when the State's name is called for the purpose of caucusing and then shall vote when the second roll is called.

Subd. 8. To adopt in General Assembly:

a. A delegate quorum must be present.

b. A delegate quorum is defined as the registered voting delegates from at least two-thirds (2/3) of the States which have designated official delegates for the Conference, as identified in Section 4., Subdivisions 3. and 4. of this Article.

c. Adoption of motions involving actions not otherwise covered in this Constitution and Bylaws shall require a simple majority vote of the delegate quorum.

d. Adoption of a motion involving a new procedure in the Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments shall require a simple majority vote of the delegate quorum with the vote to be taken on the second delegate voting day of the biennial or special meeting of the Conference; and

e. In order to change a procedure in the Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments, adopted at any previous biennial or special meeting of the Conference, two (2) ballots are required on the motion for change. The first ballot shall be made on the first delegate voting day of the Conference, and shall require a majority vote of the delegate quorum. If the motion for change carries on the first ballot, the second consideration shall then be made on the second delegate voting day of the Conference. For the proposed change in procedure of the Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments to be finally adopted, the second ballot shall require at least a two-thirds (2/3) affirmative vote of the delegate quorum.

ARTICLE VIII ------ AMENDMENTS TO THE BYLAWS

SECTION 1. These *Bylaws* may be amended at a duly called biennial meeting of the Conference, with the delegates having had forty-five (45) days notice from the Executive Board or its designee of such proposed amendments. Two-thirds (2/3) affirmative vote of the delegate quorum shall be necessary to adopt amendments to these *Bylaws*.

SECTION 2. Amendments to the *Bylaws* shall be deliberated by Council III. Council III's actions on *Bylaws* amendments shall be reviewed by the delegate body. Council III or the delegate body may recommend changes to proposed *Bylaws* amendments. Adoption of such changes shall be as required in Section 1. of this Article.

SECTION 3. Amendments to the *Bylaws* shall become effective at the close of the Conference at which they are adopted.

MEMORANDUM OF UNDERSTANDING BETWEEN THE U.S. FOOD AND DRUG ADMINISTRATION AND THE NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

BACKGROUND

The Food and Drug Administration (FDA) is the federal agency responsible for enforcing the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 301 et seq. Included within the FDA's responsibilities under the Act is the responsibility for regulation of foods shipped in interstate commerce including milk and milk products.

The National Conference on Interstate Milk Shipments (NCIMS) is a voluntary organization directed and controlled by the member States and open to all persons interested in its objective of promoting the availability of a high quality milk supply. It is governed by an Executive Board whose members include representatives from state departments of health and agriculture, the FDA, the U.S. Department of Agriculture and industry.

Through their collaborative efforts, the FDA and the NCIMS have developed a cooperative, federal-state program (the Interstate Milk Shipper Program) to ensure the sanitary quality of milk and milk products shipped interstate. The Program is operated primarily by the States, with FDA providing varying degrees of scientific, technical and inspection assistance as provided by FDA Publication No. 72-2022, Procedures Governing the Cooperative Federal-State Program for Certification of Interstate Milk Shippers ("Procedures Manual")*. The result has been the establishment of a viable and effective certification and enforcement program which has been of significant benefit to consumers.

The Interstate Milk Shippers Program relies upon the Grade “A” Pasteurized Milk Ordinance and related technical documents referred to in the Procedures Manual for the sanitary standards, requirements and procedures it follows to ensure the safety and wholesomeness of Grade "A" milk and milk products. FDA considers these standards, requirements and procedures to be adequate for the protection of the health and safety of the consumer. Sources of Grade “A” milk and milk products intended for use on interstate conveyances and subject to the Interstate Conveyance Sanitation Regulations (21 CFR 1250 et seq.) promulgated pursuant to the Public Health Service Act (42 U.S.C. 264) are considered approved sources for purposes of 21 CFR 1250.26 if they have a State or local permit, are under the routine inspection of a State or local regulatory agency and meet the provisions of the Procedures Manual.

PURPOSE

The purpose of this Memorandum is to strengthen the Interstate Milk Shippers Program by stating the responsibilities of the FDA and the NCIMS for execution of the Program, the means for resolving questions of interpretation that may arise in the execution of the Program, and the means for making modifications in the Program.

AGREEMENT

The FDA and NCIMS have agreed upon the following principles:

A. The Interstate Milk Shippers Program shall be governed by the provisions of the current FDA Publication No. 72-2022, Procedures Governing the Cooperative Federal-State Program for Certification of Interstate Milk Shippers*, and by the documents referenced therein. Copies of all governing documents are available for review in the office of the Food and Drug Administration, Hearing Clerk.

B. The responsibilities of the NCIMS, the participating States, and FDA for execution of the Interstate Milk Shippers Program shall be as stated in the above referenced Procedures Manual.

C. Failure on the part of any certified state milk sanitation rating officer, state milk laboratory survey officer, or state sampling surveillance officer to comply with the provisions of this Memorandum or the Procedures Manual shall be sufficient cause for FDA to proceed to a hearing to provide said rating officer, laboratory survey officer, or sampling surveillance officer an opportunity to show cause why his/her certification or approval should not be revoked.

D. It shall be the right of the NCIMS and each participating State to request and receive consultation with the appropriate representative of the FDA to discuss the provisions of this Memorandum or problems encountered in the execution of the provisions of the Procedures Manual. The initial contact office at FDA for all inquiries pertaining to the Program is Bureau of Foods (HFF-415)**, FDA, 200 C Street, S.W., Washington, D.C. 20204.

E. It shall be the right of the FDA to request and receive consultation with appropriate officials of the NCIMS or any of its member States to discuss the provisions of this Memorandum or problems encountered in the execution of the provisions of the Procedures Manual. The Executive Board of NCIMS can be contacted by FDA personnel through the Bureau of Foods (HFF-415)** at the address indicated in paragraph D, above.

F. Problems of interpretation regarding provisions of the Procedures Manual and the documents referenced therein, or their application, shall be subject to resolution by mutual agreement of the parties.

G. Changes in the provisions of the Procedures Manual and the documents referred to therein shall be mutually concurred in by NCIMS and FDA.

H. This Memorandum of Understanding may be modified by mutual consent of the parties and may be terminated by either party upon a thirty (30) day advance written notice to the other. Any modification or notice of termination will be published in the Federal Register.

For the FDA.

Dated: August 5, 1977.

Donald Kennedy,
Commissioner of
Food and Drugs.

For the NCIMS.

Dated: June 28, 1977.

H. H. Vaux
Chairman, NCIMS.

Effective date: This Memorandum of Understanding became effective August 5, 1977.

Dated: September 12, 1977.

Joseph P. Hile
Associate Commissioner
for Compliance

(FR Doc. 77-37071 Filed 9/19/77; 8:45 a.m.)

* Current document is titled: Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments.
**Note: HFF-415 mail symbol for Dairy and Lipid Technology Branch, DFT, Bureau of Foods is now HFS-316, Center for Food Safety and Applied Nutrition, Milk and Milk Products Branch, 5001 Campus Drive, College Park, MD 20740.

RELATED DOCUMENTS

Grade "A" Pasteurized Milk Ordinance, Current Edition.

Methods of Making Sanitation Ratings of Milk Shippers and the Certifications/Listings of Single-Service Containers and/or Closures for Milk and/or Milk Products Manufacturers, Current Edition.

Evaluation of Milk Laboratories, Current Edition.

IMS LIST-Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers *(an electronic publication).*

Bacteriological Analytical Manual, AOAC International, Gaithersburg, MD 20877, Current Edition.

Code of Federal Regulations, Title 21, U.S. Government Printing Office, Washington, DC, Current Edition.

Federal Food, Drug, and Cosmetic Act, *as Amended*, U.S. Government Printing Office, Washington, DC, 1996.

Standard Methods for the Examination of Dairy Products, American Public Health Association, Washington, DC 20001-3710, Current Edition.

Official Methods of Analysis, AOAC International, Gaithersburg, MD 20877, Current Edition.

Pesticide Analytical Manual of the Food and Drug Administration, available from the Association of Official Analytical Chemists, Box 540, Benjamin Franklin Station, Washington, DC 20044.

Standard Methods for the Examination of Water and Wastewater, American Public Health Association, Washington, DC 20001-3710, Current Edition.

NCIMS 2400 Forms, Current Edition.