



NCIMS
National Conference on Interstate Milk Shipments

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

2025 Revision



PREFACE

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

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

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ABBREVIATIONS AND ACRONYMS

ACLE (Aseptic Critical Listing Element)
APPS (Aseptic Processing and Packaging System)
AQFPSS (Aseptic-Qualified Filler and Product Sterilizer System)
AR (Audit Report)

BTU (Bulk Tank Unit)

CCP (Critical Control Point)
CFR (*Code of Federal Regulations*)
CIP (Clean-in-Place)
CL (Critical Limit)
CLE (Critical Listing Element)
cwt. (100 Pounds Weight Unit)

dSSO (delegated Sampling Surveillance Regulatory Agency Official)

EML (*Evaluation of Milk Laboratories*)
EPA (Environmental Protection Agency)
ER (Enforcement Rating)

FDA (Food and Drug Administration)
FFD&CA (*Federal Food, Drug, and Cosmetic Act*)

FHA (Fermented High-Acid)

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

ICP (International Certification Program)
IMS (Interstate Milk Shipper)

LACF (Low-Acid Canned Food)
LEO (Laboratory Evaluation Officer)
LOI (Letter of Intent)
LOU (Letter of Understanding)

M-a (Memorandum of Interpretation)
MC (Milk Company)
M-I (Memorandum of Information)
MS (Milk Specialist)
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)

NCIMS (National Conference on Interstate Milk Shipments)

PCQI (Preventive Controls Qualified Individual)

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*)

PP (Prerequisite Program)

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)

SCR (Sanitation Compliance Rating)

SMEDP (*Standard Methods for the Examination of Dairy Products*)

SRO (Sanitation Rating Officer)

SSC (Single-Service Consultant)

SSO (Sampling Surveillance Officer)

TPC (Third-Party Certifier)

USDA (United States Department of Agriculture)

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

A. DEFINITIONS

Terms used in this document 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.

1. **AREA RATING:** An area rating, if used, shall apply to Grade “A” raw milk for pasteurization, aseptic processing and packaging and/or retort processed after 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-Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers (IMS List)*. An individual Grade “A” dairy farm shall only be included in one (1) IMS listing.

2. **ASEPTIC CRITICAL LISTING ELEMENT (ACLE):** An Item on FORM NCIMS 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND/OR RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS (Grade “A” Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products). The identification of any ACLE by a Milk Sanitation Rating Officer (SRO) or PHS/FDA Milk Specialist (MS) as not being in compliance, whereby an IMS listing shall be immediately denied or withdrawn.

3. **ASEPTIC, RETORT OR FERMENTED HIGH-ACID, SHELF-STABLE MILK PLANT RATING:** A rating of a Grade “A” milk plant or portion of a Grade “A” milk plant that produces 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 Grade “A” fermented high-acid, shelf-stable milk and/or milk products that is rated separately from the rating of pasteurized Grade “A” milk and/or milk products produced in the milk plant. This rating shall be made for all Grade “A” milk plants producing 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 Grade “A” fermented high-acid, shelf-stable milk and/or milk products as defined in the *Grade “A” PMO*. A National Conference on Interstate Milk Shipments (NCIMS) Hazard Analysis Critical Control Point (HACCP) milk plant that produces 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 Grade “A” fermented high-acid, shelf-stable milk and/or milk products shall have only an NCIMS HACCP listing.

NOTE: The Grade “A” raw milk receiving area may be rated with the aseptic or retort milk plant, or with a separately IMS listed pasteurized Grade “A” milk plant, or separately as a receiving station.

4. ASEPTIC PROCESSING AND PACKAGING SYSTEM (APPS): For the purposes of this *MMSR*, the APPS in a milk plant is comprised of the processes and equipment used to process and package aseptic Grade "A" low-acid milk and/or milk products. The 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 aseptically processed and packaged Grade “A” low-acid milk and/or milk product.

5. 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/Center for Food Safety and Applied Nutrition (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.

6. 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 and the Retort Processed after Packaging System (RPPS) for retort processed after packaging Grade “A” milk plants, respectively.

7. BULK TANK UNIT (BTU): A Grade “A” dairy farm or group of Grade “A” dairy farms from which Grade “A” raw milk for pasteurization, aseptic processing and packaging and/or retort processed after 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.

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

9. 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 SROs. An SRO may be certified to make NCIMS HACCP milk plant, aseptic milk plant, milk plant, BTU, single-service facility, receiving station or transfer station IMS listing ratings.

10. 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, SROs, LEOs, etc. may be certified as SSOs.

11. CERTIFIED SINGLE-SERVICE CONSULTANT (SSC): An individual who has been certified by the PHS/FDA, has a valid certificate of qualification to conduct the certification and 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.

12. 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.

13. 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 element 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.

14. 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.

15. ENFORCEMENT RATING (ER): This is a measure of the degree to which enforcement provisions of the *Grade “A” PMO* are being applied by the Regulatory Agency.

16. FERMENTED HIGH-ACID, SHELF-STABLE CRITICAL LISTING ELEMENT: An Item 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 identification of any Fermented High-Acid, Shelf-Stable Critical Listing Element by an SRO or PHS/FDA MS as not being in compliance shall cause a listing to be immediately denied or withdrawn.

17. IMS LISTED MILK SHIPPER: An interstate milk shipper (BTU, receiving station, transfer station, milk plant or a milk plant, receiving station or transfer station with an attached supply of

Grade “A” raw milk), which has been rated by an 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 this *MMSR*. For milk plants that produce aseptically processed and packaged Grade “A” low-acid milk and/or milk products, and/or retort processed after packaged Grade “A” low-acid milk and/or milk products, and/or Grade “A” fermented high-acid, shelf-stable 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 Grade “A” Fermented High-Acid, Shelf-Stable Milk and/or Milk Products 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 and/or Grade “A” fermented high-acid, shelf-stable milk and/or milk products Program. An individual Grade “A” dairy farm shall only be included in one (1) IMS listing.

18. INDIVIDUAL RATING: An individual rating is the rating of a single producer group, Grade “A” dairy farm, milk plant, receiving station, transfer station or a 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 milk products and/or Grade “A” condensed or dry whey and whey products may be rated separately from the same milk plant producing other Grade “A” milk and/or milk products, provided each IMS listing holds a separate permit. 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 Grade “A” fermented high-acid, shelf-stable milk and/or milk products, and pasteurized Grade “A” milk and/or milk products shall be rated separately. Provided, that an NCIMS HACCP IMS listing for milk plants that produces 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 Grade “A” fermented-high acid, shelf-stable 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.

19. INTERNATIONAL CERTIFICATION PROGRAM (ICP): The International Certification Program (ICP) is 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 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.

20. LETTER OF INTENT (LOI): A formal written signed agreement between a TPC, authorized under the NCIMS voluntary ICP, and an 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.

21. 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 voluntary 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.

22. 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.

23. MILK COMPANY (MC): An 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, dairy plant samplers, industry plant samplers, milk distributors, 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.

24. 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.

25. NCIMS HACCP LISTING: An inclusion on the *IMS List* based on an SRO's evaluation of a milk plant's, receiving station's or transfer station's NCIMS voluntary HACCP Program and other applicable NCIMS requirements.

26. 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 and the RPPS for retort processed after packaging Grade "A" milk plants, respectively.

27. PHS/FDA AUDIT: An evaluation conducted by PHS/FDA of the entire milk plant, receiving station, or transfer station facility to ensure compliance with the NCIMS HACCP System and other NCIMS regulatory requirements, with the exception of the APPS for aseptic processing and packaging milk plants, the RPPS for retort processed after packaging milk plants and the AQFPSS for Fermented High-Acid, Shelf-Stable plants, respectively.

28. PREVENTIVE CONTROLS QUALIFIED INDIVIDUAL (PCQI): A qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.

29. 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 this *MMSR*. Ratings are conducted by PHS/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.

30. 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.

31. RECIPROCITY: For the purposes of the NCIMS agreements, reciprocity shall mean any action or requirements on the part of any Regulatory Agency will not cause or require any action in excess of the requirements of the current edition of the *Grade "A" PMO* and NCIMS related documents of the NCIMS agreements.

32. 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 this *MMSR* shall also mean the appropriate TPC having jurisdiction and control over the applicable matters cited within this *MMSR*.

33. RETORT PROCESSED AFTER PACKAGING SYSTEM (RPPS): For the purposes of this *MMSR*, 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" milk and/or milk product.

34. 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*.

35. SINGLE-SERVICE CONTAINERS AND/OR CLOSURES MANUFACTURER AUDIT: The designated PHS/FDA and NCIMS *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.

36. SINGLE-SERVICE CONTAINERS AND/OR CLOSURES MANUFACTURER CERTIFICATION IMS LISTING: This is the certification listing conducted by an SRO for U.S. manufacturers of single-service containers and/or closures for milk and/or milk products; or a TPC's SRO; or an 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/or 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*.

37. 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. The TPC provides the means for the rating and IMS listing of Grade "A" milk plants, receiving stations, transfer stations and their related Grade "A" 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.

38. 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.

B. RATING METHODS FOR GRADE “A” RAW MILK FOR PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING, RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING

1. DRUG RESIDUE COMPLIANCE - PROCEDURE FOR DETERMINING BTU OR ATTACHED SUPPLY COMPLIANCE WITH APPENDIX N. OF THE GRADE “A” PMO

During an IMS rating or PHS/FDA check rating, it is necessary to determine compliance of the BTU or attached supply of Grade “A” raw milk with the requirements of Appendix N. Drug Residue Testing and Farm Surveillance of the *Grade “A” PMO*. The following criteria are to be used in making that determination. If the BTU or attached supply of Grade “A” raw milk is not in substantial compliance, a rating or PHS/FDA check rating is not to be completed and the Rating Agency shall either deny an initial IMS listing or immediately notify the appropriate PHS/FDA MS or PHS/FDA for TPCs to withdraw the IMS listing.

a. Record Review

Determine from records that are stored in a manner acceptable to the Rating Agency that all milk pick-up tankers and/or all Grade “A” raw milk supplies that have not been transported in bulk milk pickup tankers, regardless of final use, are screened daily, prior to processing, for *Beta lactams* with an approved test method. As necessary, determine that all dairy farms are randomly tested four (4) times in any consecutive six (6) months for other drug residues, if directed by Section 6. The Examination Of Milk And/Or Milk Products of the *Grade “A” PMO*.

Compliance with the above Item would be satisfied in the following manner:

- 1.) Records indicating that Grade “A” raw milk that is shipped in bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers were always received by an IMS listed milk shipper shall suffice for actual test results.
- 2.) If Grade “A” raw milk that is shipped in bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers is received by a non-IMS listed milk plant, receiving station and/or transfer station, records indicating actual testing shall be provided or available for review. When the Regulatory Agency has determined adequate documentation for compliance with this Section exists, the Rating Agency may accept this documentation. SROs and PHS/FDA MSs may at their discretion request records on the testing of loads of Grade “A” raw milk and/or all raw milk supplies that have not been transported in bulk milk pickup tankers, that is received by non-IMS listed milk plants, receiving stations and/or transfer stations. If records are requested, the SRO or PHS/FDA MS should choose and request to review records for not more than fifteen (15) days, unless these selected records indicate a problem.

b. Regulatory Notification and Disposition

If a Grade “A” raw milk sample from a milk tank truck load of milk; and/or a sample from all raw milk supplies that have not been transported in bulk milk pickup; or a sample of raw milk from an individual dairy farm is positive for a drug residue, determine if the Regulatory Agency was immediately notified, including the method of proper disposition to keep the contaminated milk out of the food chain.

c. Reinstatement

Determine if the violative dairy farm was not allowed to ship milk until the milk no longer tested positive, using the same or equivalent (M-I-96-10, latest revision) test method as used when the producer was initially found to be violative for drug residues.

2. COLLECTION OF DATA

Data from which ratings and PHS/FDA check ratings are determined, are obtained by SROs or PHS/FDA MSs, respectively, from the Regulatory Agency’s official records on file and from the evaluation of sanitary practices and facilities at the Grade “A” dairy farms. It is not necessary, except on very small BTUs or attached supplies of Grade “A” raw milk, to inspect every dairy farm, since a sufficiently accurate determination of the percentage compliance with the sanitation requirements can be determined by rating statistically selected dairy farms.

a. Number of Dairy Farms to be Rated

1.) The minimum number of dairy farms to be included in the rating depends upon the number in the area rating, BTU or attached supply of Grade “A” raw milk to be rated and the accuracy desired. To attain accuracy such that the probable error in the individual percentages of compliance with the various items of sanitation will be less than five percent (5%), the minimum number of dairy farms selected at random for inspection during the rating shall be determined from TABLE 1.

TABLE 1

**MINIMUM NUMBER OF DAIRY FARMS TO BE SELECTED AT RANDOM
FOR INCLUSION IN A RATING**

Number in the BTU or Attached Supply	Number to be Rated
1 to 25	All
25 to 54	25
55 to 59	26
60 to 64	27
65 to 71	28
72 to 78	29
79 to 86	30
87 to 94	31
95 to 105	32
106 to 116	33
117 to 130	34
131 to 147	35

148 to 167	36
168 to 191	37
192 to 222	38
223 to 262	39
263 to 316	40
317 to 394	41
395 to 514	42
515 to 725	43
726 to 1,192	44
1,193 to 5,000	50
5,001 to 10,000	100

2.) TABLE 1 is used to determine separately the number of dairy farms to be included in the rating. The probable error is not applicable to small samples. If the total number is twenty-five (25) or less, the entire number of dairy farms shall be rated.

b. Random Selection of Dairy Farms to be Rated

The individual dairy farms included in the rating or PHS/FDA check rating shall be representative to reflect conditions throughout the BTU or attached supply of Grade “A” raw milk. It is important that the selection method excludes elements of pre-selection and pre-notification and provides a truly random sample. The selection of dairy farms for a rating should be made from a current listing of dairy farms making up the BTU or attached supply of Grade “A” raw milk and may be compared to a list for the previous sixty (60) days to determine if an appreciable shifting of dairy farms has taken place. Random selections, once made, should be deviated from only in cases of emergencies. Replacements, where necessary, should also be selected at random. Whenever possible, random selection or announcements of such selections for only one (1) day's work at a time should be made.

Examples of methods, which are satisfactory for the random selection of dairy farms, include the following:

- 1.) The name of each dairy farm in the BTU or attached supply of Grade “A” raw milk is written on a small card, one (1) name per card. These cards are then thoroughly shuffled and the number of dairy farms to be included in the rating, as determined from TABLE 1, are selected.
- 2.) The selection of dairy farms is made at intervals from a complete card index, ledger record, or other list. When this method is used, the sequence interval chosen shall be such that the entire card index, ledger record, or other list is subject to the sampling method. The sequence interval may be determined by dividing the total number of dairy farms by the number of dairy farms required for the rating or PHS/FDA check rating.

For Example: If there were 280 dairy farms in the BTU or attached supply of Grade “A” raw milk, TABLE 1 indicates that forty (40) dairy farms shall be included in the rating and the sequence interval in this case would be every seventh (7th) dairy farm. The first dairy farm in sequence is picked at random from the complete card index, ledger record or other lists in order that chance alone determines the selection of individual dairy farms.

3.) Immediately prior to the initial random drawing of dairy farms to be selected for inclusion in a rating, every dairy farm, which produces forty percent (40%) or more of the volume of milk in a BTU, or attached supply of Grade "A" raw milk, which consists of five (5) dairy farms or more, shall be removed from the existing BTU or attached supply of Grade "A" raw milk and rated as a separate BTU.

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

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

d. Recording of Inspection Data

1.) During a rating or PHS/FDA check rating, inspection data are recorded on FORM NCIMS 2359a-DAIRY FARM INSPECTION REPORT, the Items of which correspond to the Items of sanitation in Section 7. Standards For Grade "A" Milk And/Or Milk Products of the *Grade "A" PMO*.

2.) Sanitary conditions are evaluated in terms of the requirements of Section 7. of the *Grade "A" PMO*. Professional judgment alone shall dictate whether an observed deficiency is representative of significant day-to-day sanitary conditions or is an anomaly. When significant violations of any given requirement are noted, the corresponding Item(s) or sub-item(s) on the individual FORM NCIMS 2359a are debited with an "X". Each sub-item found in violation should be carefully debited, as this affects the computation of the SCR.

3.) The average number of pounds of milk sold daily is needed for computing the rating and is entered in the appropriate place at the top of FORM NCIMS 2359a.

NOTE: A deficiency should not be based entirely on a discussion held with a dairy farm employee. Confirmation of a deficiency should be made with the responsible owner or manager in charge.

e. Recording of Laboratory and Other Test Data

1.) The Regulatory Agency's official records are utilized in determining compliance with bacterial, drug residue, somatic cell and cooling temperature requirements. The acceptance of data from Official and/or Officially Designated Laboratories is contingent upon the utilization of standard procedures by the laboratories concerned. Accordingly, it is necessary for the SRO or PHS/FDA MS to determine from the Regulatory Agency or Milk Laboratory Control Agency that both sampling and laboratory procedures have been approved in accordance with the methods of the current edition of the *Grade "A" PMO* and *EML*, respectively. Ratings and PHS/FDA check ratings shall not be conducted when an approved laboratory has not been utilized by the Regulatory Agency for the necessary tests and the Rating Agency shall immediately notify the appropriate PHS/FDA personnel for TPCs to withdraw the IMS listing.

2.) Compliance with bacterial, drug residue, somatic cell and cooling temperature requirements is based on whether, at the time of the rating or PHS/FDA check rating, a dairy farm's Grade "A" raw milk meets the standards of Section 7. of the *Grade "A" PMO*. Credit for bacterial, somatic cell and cooling temperature requirements shall be given if no more than two (2) of the last four (4) sample results exceed the limit(s), provided that the last sample result is within the limit(s). Individual dairy farms that are in violation of having two (2) of the last four (4) sample results exceeding the limit(s) and the last sample exceeds the limit(s) shall not be given credit (debited) for the specific bacterial, somatic cell and/or cooling temperature limit(s) that was exceeded. No credit shall be given (debited) for compliance with bacterial, drug residue, somatic cell and cooling temperature requirements when less than the required number of samples have been examined during the preceding six (6) months. For rating and PHS/FDA check rating purposes, the preceding six (6) months is considered to be the elapsed period of time, prior to the earliest rating date in which the rating or PHS/FDA check rating was conducted, in addition to the preceding six (6) months. Dairy farms, which have had a permit for less than six (6) months at the time of the rating or PHS/FDA check rating and for which the Regulatory Agency has not yet examined the required number of Grade "A" raw milk samples, shall be given credit, provided that the last sample result is within the limit(s). Individual dairy farms that have had a permit for less than six (6) months and their last sample results exceed the limit(s) shall not be given credit (debited) for the specific bacterial, somatic cell and/or cooling temperature limit(s) that was exceeded.

3.) The SRO and PHS/FDA MS shall utilize the Regulatory Agency's official records in determining compliance with those Items of sanitation which require laboratory tests to complete the rating or PHS/FDA check rating, respectively.

NOTE: All Grade "A" raw milk required sampling and testing is to be conducted only when there are test methods available that are evaluated by FDA and accepted by the NCIMS. Grade "A" raw milk that does not have evaluated and accepted test methods are not required to be tested. (Refer to M-a-98, latest revision, for the specific Grade "A" milk and/or milk products that have FDA evaluated and NCIMS accepted test methods.)

3. COMPUTATION OF SANITATION COMPLIANCE RATINGS

a. Rating or PHS/FDA check rating results are transferred to FORM NCIMS 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING, RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING. This Form may be obtained from a PHS/FDA MS or at the following FDA website: <https://ncims.org/forms>. The FORM is sufficiently flexible to permit various combinations of pages to be used for reporting ratings or PHS/FDA check ratings of area or individual IMS listed BTUs.

b. The identity of each dairy farm, included in the rating or PHS/FDA check rating, and the total pounds of milk sold daily, expressed to the nearest 100 pound unit (cwt.), are entered in the first, "Name of Dairy Farm", and second, "Pounds Sold Daily (100# Units)", columns, respectively, of FORM NCIMS 2359k.

For Example: 3,760 pounds of milk sold per day shall result in an entry of thirty-eight (38) in the "Pounds Sold Daily (100# Units)" column.

Violations of Items or sub-items are indicated by an "X" or by inserting the point value of the violation in the appropriate column(s). The sum of the weights of all Items and sub-items found violated at each dairy farm is entered in the "Total Debits" column. This figure is then multiplied by the number in the "Pounds Sold Daily (100# Units)" column, and the results are entered in the "Pounds Sold Daily (100# Units) X Total Debits" column. When all entries have been made, the figures entered in the "Pounds Sold Daily (100# Units) X Total Debits" column are totaled as are the figures in the "Pounds Sold Daily (100# Units)" column from all the dairy farms rated. (Refer to Section K., Number 13, of this *MMSR* for an example.)

NOTE: Item 8-Water Supply on FORM NCIMS 2359a has been divided into two (2) point and five (5) point violations/debits. The maximum point value for the entire Item 8r-WATER SUPPLY of the *Grade "A" PMO* cannot exceed five (5) points on FORM NCIMS 2359k. (Refer to APPENDIX B. TABLE OF DAIRY FARM WATER SUPPLY VIOLATIONS of this *MMSR*, which provides guidance that may be used to differentiate between two (2) point (minor) and five (5) point (major) violations of Section 7., Item 8r of the *Grade "A" PMO* during ratings and PHS/FDA check ratings.)

Non-compliance with Item 15r-DRUG AND CHEMICAL CONTROL, ADMINISTRATIVE PROCEDURES, Numbers 5, 6 and 7 of the *Grade "A" PMO* (debited under Item 15r(d) and (e) on FORM NCIMS 2359a), would constitute a five (5) point debit, not to exceed a total of seven (7) points for the entire Item 15- Drug and Chemical Control on FORM NCIMS 2359k.

Non-compliance with Item 18r-RAW MILK COOLING, ADMINISTRATIVE PROCEDURES, Number 3 of the *Grade "A" PMO*, would constitute a one (1) point debit, not to exceed a total of five (5) points for the entire Item 18-Cooling on FORM NCIMS 2359k.

c. The SCR is derived from the following formula:

$$\text{SCR} = 100 - \left(\frac{\text{The Sum of the "Pounds Sold Daily (100\# Units) X Total Debits" column}}{\text{The Sum of the "Pounds Sold Daily (100\# Units)" column}} \right)$$

This SCR calculation is entered in the appropriate space in the upper right-hand corner of FORM NCIMS 2359k. It is also entered on FORM NCIMS 2359j-MILK SANITATION RATING REPORT-SECTION A. REPORT OF THE MILK SANITATION RATING (PAGE 1), in the appropriate location.

d. Provision is also made on FORM NCIMS 2359k for computing the percentage of dairy farms violating individual Items of sanitation. The number of dairy farms violating each Item shall be totaled and the percentage computed by dividing this number by the total number of dairy farms rated or PHS/FDA check rated and then multiplying by 100. The percentage of dairy farms violating an Item may also be determined by using the "TABLE FOR COMPUTING PERCENT VIOLATION" of this *MMSR*.

C. RATING METHODS FOR GRADE “A” MILK PLANTS, RECEIVING STATIONS AND TRANSFER STATIONS

1. DRUG RESIDUE COMPLIANCE - PROCEDURE FOR DETERMINING GRADE “A” MILK PLANT, RECEIVING STATION AND TRANSFER STATION COMPLIANCE WITH APPENDIX N. OF THE *GRADE “A” PMO*

During an IMS rating/NCIMS HACCP listing audit or PHS/FDA check rating/NCIMS HACCP audit, it is necessary to determine compliance of the Grade “A” milk plant, receiving station and/or transfer station with the requirements of Appendix N. of the *Grade “A” PMO*. The following criteria are to be used in making that determination. If the Grade “A” milk plant, receiving station or transfer station is not in substantial compliance, a rating/NCIMS HACCP listing audit or PHS/FDA check rating/NCIMS HACCP audit is not to be completed and the Rating Agency shall either deny the initial IMS listing or immediately notify the appropriate PHS/FDA personnel for TPCs to withdraw the IMS listing.

a. Record Review

Determine from records that are stored in a manner acceptable to the Rating/Listing Agency that all milk pick-up tankers and/or all Grade “A” raw milk supplies that have not been transported in bulk milk pickup tankers are screened daily, prior to processing, for *Beta lactams* with an approved test method. If the Grade “A” milk plant, receiving station and/or transfer station has an attached supply of Grade “A” raw milk, determine that all dairy farms are randomly tested four (4) times in any consecutive six (6) months for other drug residues, if directed by Section 6. The Examination Of Milk And/Or Milk Products of the *Grade “A” PMO*.

Grade “A” milk plants, receiving stations and/or transfer stations having an attached supply of Grade “A” raw milk with raw milk tank truck loads that occasionally are diverted by direct dairy farm shipment to a milk plant, receiving station and/or transfer station shall be deemed in compliance if the following criteria are met:

- 1.) Records indicating that Grade “A” raw milk that was shipped in bulk milk pickup tanker and/or all raw milk supplies that have not been transported in bulk milk pickup tankers are always being received by an IMS listed milk shipper shall suffice for actual test results.
- 2.) If Grade “A” raw milk that is shipped in bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers is received by a non-IMS listed milk plant, receiving station and/or transfer station, records indicating official testing shall be provided or available for review. When the Regulatory Agency has determined adequate documentation for compliance with this Section exists, the Rating Agency may accept this documentation. SROs and PHS/FDA MSs may at their discretion request records on the testing of loads of Grade “A” raw milk and/or all raw milk supplies that have not been transported in bulk milk pickup tankers that are received by non-IMS listed milk plants, receiving stations and/or transfer stations. If official testing records are requested, the SRO or PHS/FDA MS should choose and request to review records for not more than fifteen (15) days, unless these selected records indicate a problem.

b. Regulatory Notification

If a Grade “A” raw milk sample from a milk tank truck load of milk and/or a sample from all raw milk supplies that have not been transported in bulk milk pickup tankers was positive for a drug residue, determine if the Regulatory Agency was immediately notified of the results and the ultimate disposition of the raw milk.

c. Industry Notification

If a Grade “A” raw milk sample from a milk tank truck load of milk and/or a sample from all raw milk supplies that have not been transported in bulk milk pickup tankers was positive for a drug residue, determine if a representative of the BTU or attached supply of Grade “A” raw milk that the dairy farms are attached to was properly notified.

2. APPENDIX T. COMPLIANCE – PROCEDURES FOR DETERMINING MILK PLANT COMPLIANCE

During a PHS/FDA Check Rating or, upon written agreement between FDA and the State Rating/Dairy Regulatory Agency, and in consultation with FDA, during a State Rating Agency Individual Rating or a State Regulatory Inspection it is necessary to determine compliance of the milk plant with the applicable requirements of Appendix T. Preventive Controls for Human Food Requirements for Grade “A” Milk and Milk Products of the *Grade “A” PMO* at least once every thirty-six (36) months.

To determine compliance, a broad assessment will be conducted, consisting of review of the milk plant’s sanitation controls, food allergen controls, and process controls, as appropriate. This broad assessment shall not include the conducting of a hazard analysis by FDA/Regulatory Agency personnel or a review of the facility’s written food safety plans, hazard analysis, preventive control programs, supply-chain programs, or recall plan. During the broad assessment, if conditions are not observed pertaining to the lack of control of significant hazards, the milk plant shall be determined to be in compliance with Appendix T. of the *Grade “A” PMO*.

During the broad assessment, if conditions are observed pertaining to the lack of control of significant hazards relative to compliance with Appendix T. of the *Grade “A” PMO*, and after consultation with and concurrence by FDA, the following process shall be used in making the determination of substantial compliance:

a. Record Review

Determine from records stored in a manner as required in the *Grade “A” PMO* that the milk plant’s food safety plan is in compliance. Milk plants shall be deemed in compliance if the following criteria are met:

- 1.) The milk plant’s food safety plan is in writing and was prepared, or its preparation overseen by one (1) or more PCQIs.
- 2.) The milk plant’s written food safety plan and its contents included the following:
 - A.) The written Recall Plan;
 - B.) The written Hazard Analysis;

- C.) The written food allergen control plan;
 - D.) The written Preventive Controls, as appropriate, for hazards not addressed by the *Grade "A" PMO*;
 - E.) The written Supply-Chain Program, as appropriate, for hazards not addressed by the *Grade "A" PMO*;
 - F.) The written Procedures for Monitoring the Implementation of the Preventive Controls, as appropriate, for hazards not addressed by the *Grade "A" PMO*;
 - G.) The written Corrective Action Procedures, as appropriate, for hazards not addressed by the *Grade "A" PMO*; and
 - H.) The written Verification Procedures, as appropriate, for hazards not addressed by the *Grade "A" PMO*.
- 3.) A reanalysis of the milk plant's food safety plan, as a whole, or portion of the food safety plan, was conducted as required and was performed, or overseen, by a PCQI.
 - 4.) The milk plant has a written Hazard Analysis for each kind or group of Grade "A" milk and/or milk products processed. A milk plant may group similar types of Grade "A" milk and milk products, or similar types of production methods together, if the hazards and procedures are essentially identical.
 - 5.) The milk plant has controls at identified critical control points (CCPs)/process preventive controls and other preventive controls, as appropriate to the Grade "A" milk plant and the milk and/or milk products, for hazards not addressed by the *Grade "A" PMO*.
 - 6.) The milk plant has established and implemented adequate written procedures, including the frequency with which they are to be performed, for monitoring the preventive control and at an adequate frequency to provide assurance that they are consistently performed, for controlling hazards not addressed by the *Grade "A" PMO*.
 - 7.) The milk plant has established and implemented written corrective action procedures that shall be taken if preventive controls are not properly implemented, for hazards not addressed by the *Grade "A" PMO*.
 - 8.) The milk plant is verifying that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards, for hazards not addressed by the *Grade "A" PMO*.
 - 9.) The milk plant has validated the process preventive controls are adequate to control the hazard as appropriate to the nature of the process preventive control and its role in the milk plant's food safety system, for hazards not addressed by the *Grade "A" PMO*.
 - 10.) The milk plant has established and is maintaining the required records documenting the implementation of the food safety plan for hazards not addressed by the *Grade "A" PMO* and that these records have not been falsified.

If, after consultation with and concurrence by FDA, 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.

3. COLLECTION OF DATA

Data from which ratings and PHS/FDA check ratings are determined are obtained by SROs or PHS/FDA MSs, respectively, from the Regulatory Agency's official records on file and from the evaluation of sanitary practices and facilities at the Grade "A" milk plants, receiving stations and transfer stations. For receiving stations and transfer stations operated by the milk plant; under the

same routine supervision of the milk plant; and shipping to the milk plant, they may be considered as an integral part of the Grade “A” milk plant to which milk is shipped and may be IMS listed with the milk plant. Therefore, all such receiving stations and transfer stations not having an individual IMS listing and supplying Grade “A” milk to the milk plant shall be included in the milk plant’s IMS listing. Receiving stations and transfer stations, which are not an integral part of a milk plant or are not IMS listed with the milk plant, shall have an individual rating and may be IMS listed separate from their BTUs.

a. Recording of Inspection Data

1.) During a rating or PHS/FDA check rating, inspection data are recorded on FORM NCIMS 2359-MILK PLANT INSPECTION REPORT (Includes Dry Milk/Condensing Plants, Blending Plants, Receiving Stations, Transfer Stations, and Milk Tank Truck Cleaning Facilities), the Items of which correspond to the Items of sanitation in Section 7. of the *Grade “A” PMO*.

2.) Sanitary conditions are evaluated in terms of the requirements of Section 7. of the *Grade “A” PMO*. Professional judgment alone shall dictate whether an observed deficiency is representative of significant day-to-day sanitary conditions or is an anomaly. When significant violations of any given requirement are noted, the corresponding Item(s) or sub-item(s) on the individual FORM NCIMS 2359 are debited with an "X". Each sub-item found in violation should be carefully debited, as this affects the computation of the SCR.

3.) The average number of pounds of Grade “A” milk and milk products processed daily is required for computing the SCR and is entered in the appropriate place at the top of FORM NCIMS 2359. When a deficiency in a milk plant affects only one (1) type of packaging, i.e., paper, glass, single-service plastics, multi-use plastics, dispenser, cottage cheese, sour cream or yogurt containers; or the capping of these containers; or an individual pasteurization unit used, i.e., vat, high-temperature-short-time (HTST), higher-heat-shorter-time (HHST); or a Grade “A” milk and/or milk product(s) that has not been pasteurized at minimum pasteurization times and temperatures; only the quantity of all Grade “A” milk and/or milk products affected by the deficiency, rather than the entire milk plant’s Grade “A” milk and/or milk products production, is recorded for use in the computation of the milk plant’s SCR. Only violations of Items 16p-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING, AND RETORT PROCESSED AFTER PACKAGING, 18p-BOTTLING, PACKAGING AND CONTAINER FILLING and 19p-CAPPING, CONTAINER CLOSURE AND SEALING AND DRY MILK PRODUCT STORAGE of the *Grade “A” PMO* are to receive partial debits. Provided, that bacterial count, coliform count and cooling temperature may be partially debited for the particular Grade “A” milk and/or milk product involved. All other violations shall be considered as affecting the entire Grade “A” milk and/or milk products production of the milk plant.

b. Recording of Laboratory and Other Test Data

1.) The Regulatory Agency’s official records are utilized in determining compliance with bacterial, coliform, phosphatase, drug residue, and cooling temperature requirements. The acceptance of data from Official and/or Officially Designated Laboratories is contingent upon the utilization of standard procedures by the laboratories concerned. Accordingly, it is necessary for the SRO or PHS/FDA MS to determine from Regulatory Agency or the

Milk Laboratory Control Agency that both sampling and laboratory procedures have been approved in accordance with the methods of the current edition of the *Grade "A" PMO* and *EML*, respectively. Ratings/NCIMS HACCP listing audits and PHS/FDA check ratings/NCIMS HACCP audits shall not be conducted when an approved laboratory has not been utilized by the Regulatory Agency for the necessary tests and the Rating Agency shall immediately notify the appropriate PHS/FDA personnel for TPCs to withdraw the IMS listing.

2.) Compliance with bacterial, coliform and cooling temperature requirements is based on whether, at the time of the rating or PHS/FDA check rating, a milk plant's Grade "A" milk and/or milk products meet the standards of Section 7. of the *Grade "A" PMO*. Credit for bacterial, coliform, and cooling temperature requirements for each Grade "A" milk and/or milk product, including bacterial and cooling temperature requirements for commingled raw milk prior to pasteurization, aseptic processing and packaging, retort processed after packaging and fermented high-acid, shelf-stable processing and packaging shall be given if no more than two (2) of the last four (4) sample results exceed the limit(s), provided, that the last sample result is within the limit(s). Individual Grade "A" milk and/or milk products that are in violation of having two (2) of the last four (4) sample results exceeding the limit(s) and the last sample exceeds the limit(s) shall not be given credit (debited) for the specific bacterial, coliform and/or cooling limit(s) that was exceeded. No credit shall be given (debited) for compliance with bacterial, coliform, and cooling temperature requirements when less than the required number of samples has been examined during the preceding six (6) months. For rating or PHS/FDA check rating purposes, the preceding six (6) months is considered to be the elapsed period of the month, prior to the earliest rating date in which the rating or PHS/FDA check rating is conducted and the preceding six (6) months. Grade "A" milk plants which have had a permit for less than six (6) months at the time of the rating or PHS/FDA check rating or which do not operate on a year-round basis and for which the Regulatory Agency has not yet examined the required number of Grade "A" milk and/or milk product samples shall be given credit, provided that the last sample result is within the limit(s). Milk plants that have had a permit for less than six (6) months and their last sample results exceed the limit(s) shall not be given credit (debited) for the specific bacterial, coliform, and/or cooling temperature limit(s) that was exceeded.

3.) The SRO or PHS/FDA MS shall utilize the Regulatory Agency's official records in determining compliance with those items of sanitation, which require laboratory tests to complete the rating or PHS/FDA check rating, respectively. The Regulatory Agency's official records of pasteurization equipment tests may also be used in lieu of performing such pasteurization equipment tests during the rating or PHS/FDA check rating. Provided, that the SRO or PHS/FDA MS is satisfied as to the competency of the Regulatory Agency's personnel to perform these pasteurization equipment tests as described in Appendix I. Pasteurization Equipment And Controls - Tests of the *Grade "A" PMO*.

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

The sampling and testing of aseptically processed and packaged Grade “A” low-acid milk and/or milk products, retort processed after packaged Grade “A” low-acid milk and/or milk products, and Grade “A” fermented high-acid, shelf-stable milk and/or milk products is not required, with the exception of the annual vitamin assay analysis to which vitamin(s) A and/or D have been added for fortification purposes. The sampling and testing requirements of Section 6. of the *Grade “A” PMO* for Grade “A” raw milk for aseptic processing and packaging and retort processed after packaging is required.

c. Recording of Data for Grade “A” Milk Plants, Receiving Stations and Transfer Stations Being IMS Listed Under the NCIMS Voluntary HACCP Program IMS Listing Procedure

1.) Prior to conducting the initial NCIMS HACCP listing audit, there shall be a Regulatory audit conducted of the Grade “A” milk plant, receiving station, or transfer station and the milk plant, receiving station, or transfer station shall have a minimum of sixty (60) days of NCIMS HACCP System records prior to a NCIMS HACCP IMS listing audit.

2.) The NCIMS HACCP IMS listing audit may be announced at the discretion of the auditor under limited circumstances, such as, the initial audit or a re-audit in response to an PHS/FDA NCIMS HACCP audit. When unannounced audits are conducted, the audits shall not be completed until appropriate milk plant personnel have had an opportunity to make all pertinent records available for review by the auditor.

3.) NCIMS HACCP IMS Listing Audit Procedures

A.) Pre-Audit Management Interview: Review and discuss the milk plant’s, receiving station’s or transfer station’s NCIMS HACCP System including:

- (i) The management structure;
- (ii) The Hazard Analysis: Ensure that all Grade “A” milk and/or milk product hazards are addressed;
- (iii) The HACCP Plan;
- (iv) The Prerequisite Programs (PPs);
- (v) The flow diagrams; and
- (vi) The products/processes.

B.) Review past Regulatory Agency Audit Reports (ARs) and corrections of deficiencies and non-conformities if any.

C.) In the milk plant review of the implementation and verification of the NCIMS HACCP System.

D.) Review records of the NCIMS HACCP System.

E.) Review compliance with other applicable NCIMS regulatory requirements*.

F.) Discuss findings and observations.

G.) Prepare and issue an AR based on findings of deficiencies and non-conformities.

H.) Conduct the exit interview.

*Examples of Other Applicable NCIMS Requirements:

- 1. Grade “A” Raw Milk Supply Source;
- 2. Labeling Compliance;
- 3. Adulteration;
- 4. Licensing Requirements;
- 5. Drug Residue Testing and Trace Back Requirements;
- 6. Regulatory Grade “A” Milk and/or Milk Product Samples in Compliance;
- 7. Approved Laboratory Utilized for the Required Regulatory Tests; and

8. Pasteurization Equipment Design, Construction, and Installation.

4.) Criteria and Procedures for Denial or Withdrawal of a NCIMS HACCP IMS Listing

A.) An NCIMS HACCP IMS Listing under the NCIMS voluntary HACCP Program may be denied or withdrawn when CLEs have been noted indicating that the Grade “A” milk plant, receiving station or transfer station has failed to recognize or correct a deficiency(ies) or nonconformity(ies) indicating:

(i) A major NCIMS HACCP System dysfunction that is reasonably likely to result in a Grade “A” milk or milk product safety hazard or an adverse health consequence(s).*

*A Grade “A” milk and/or milk product safety hazard that is reasonably likely to occur is one (1) for which a prudent milk plant, receiving station or transfer station operator would establish controls because experience, illness data, scientific reports, or other information provides 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) A series of observations that lead to a finding of a potential HACCP System failure that is likely to result in a compromise to milk or milk product safety.

(iii) Drug residue testing and trace back requirements are not met.

(iv) Milk is received from a supply other than an IMS listed milk shipper or from a listed source with a Sanitation Compliance Rating below 90 percent (90%).

B.) Significant deficiencies involving one (1) or more CLEs constitute grounds for denial or withdrawal of a milk plant’s, receiving station’s or transfer station’s 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 audited and/or the Regulatory Agency but not debited on the AR as a CLE or used to justify the denial or 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.

CLEs are noted on FORM NCIMS 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT with a double star (**) and cover the following areas of the NCIMS voluntary HACCP Program:

(i) **HAZARD ANALYSIS:** Flow Diagram and Hazard Analysis conducted and written for each kind or group of Grade “A” milk and/or milk products processed.

(ii) **HACCP PLAN:** HACCP Plan prepared for each kind or group of Grade “A” milk or milk products processed.

(iii) **HACCP PLAN CRITICAL LIMITS (CLs):** CLs are adequate to control the hazard identified.

(iv) **HACCP PLAN CORRECTIVE ACTION:** Corrective action taken for Grade “A” milk or milk products produced during a deviation from CLs defined in the HACCP Plan.

(v) **HACCP PLAN VERIFICATION AND VALIDATION:** Calibration of CCP process monitoring instruments performed as required and at the frequency defined in the HACCP Plan.

(vi) **NCIMS HACCP SYSTEM RECORDS:** Information on NCIMS HACCP records not falsified.

(vii) **OTHER NCIMS REQUIREMENTS:** Incoming milk supply from a NCIMS listed source(s) with a Sanitation Compliance Rating(s) of 90 percent (90%) or above and a drug residue control program implemented.

(viii) **NCIMS HACCP SYSTEM AUDIT FOLLOW-UP ACTION:** 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.

NOTE: In the case of an NCIMS listed HACCP aseptic milk plant, HACCP retort listed milk plant, and/or HACCP fermented high-acid, shelf-stable milk plant, the identification of any CLE on FORM NCIMS 2359p-NCIMS ASEPTIC PROCESSING AND/OR PACKAGING PROGRAM AND RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products) or Fermented High-Acid, Shelf-Stable CLE 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 by a SRO or PHS/FDA MS as not being in compliance shall also constitute an CLE deficiency under the NCIMS HACCP System, whereby an IMS listing shall be immediately denied or withdrawn.

d. Recording of Data for Grade “A” Milk Plants and Receiving Stations Being IMS Listed Under the NCIMS Aseptic Processing and Packaging Program and/or the Fermented High-Acid, Shelf-Stable Processing and Packaging Program.

1.) Inspection Criteria

A.) The NCIMS Aseptic Processing and Packaging Program includes all aseptically processed and packaged Grade “A” low-acid milk and/or milk products as defined in the *Grade “A” PMO*.

B.) The NCIMS Retort Processed after Packaging Program includes all retort processed after packaging Grade “A” low-acid milk and/or milk products as defined in the *Grade “A” PMO*.

C.) The NCIMS Fermented High-Acid, Shelf-Stable Processing and Packaging Program includes all Grade “A” fermented high-acid, shelf-stable milk and/or milk products as defined in the *Grade “A” PMO*.

NOTE: Retort processed after packaging Grade “A” low-acid milk and/or milk products as addressed in the definition of Milk Products as cited in the *Grade “A” PMO* shall be considered to be Grade “A” milk and/or milk products if they are used as an ingredient to produce any Grade “A” milk and/or milk product defined in the

definition of Milk Products as cited in Section 1. Definitions of the *Grade "A" PMO*; or if they are labeled as Grade "A" as described in Section 4. Labeling of the *Grade "A" PMO*.

D.) Regulatory Agency inspections of a Grade "A" milk plant or portion of a Grade "A" milk plant that is IMS listed to 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 shall be conducted in accordance with the *Grade "A" PMO* at least once every six (6) months. The Grade "A" milk plant's APPS, RPPS and/or AQFPSS, respectively, as defined by the *Grade "A" PMO*, shall be inspected by FDA, or a Regulatory Agency designated by FDA under the FDA Low-Acid Canned Foods (LACF), in accordance with the applicable requirements of 21 CFR Parts 108, 113 and 117 at a frequency determined by FDA.

E.) For Grade "A" milk plants or portions of Grade "A" milk plants that are listed to 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, the APPS, RPPS and/or AQFPSS, respectively, as defined by the *Grade "A" PMO*, shall be exempt from Items 7p, 10p, 11p, 12p, 13p, 15p, 16p, 17p, 18p, and 19p of the *Grade "A" PMO*. These Items, which are dedicated only to the APPS or RPPS, respectively, shall comply with the applicable portions of 21 CFR Parts 108, 113 and 117. The rest of the Grade "A" milk plant, including the receiving area, shall be inspected in accordance with the *Grade "A" PMO* and rated and IMS listed in accordance with the current NCIMS requirements. (Refer to Appendix S. Aseptic Processing And Packaging Program And Retort Processed After Packaging Program of the *Grade "A" PMO*.)

F.) When the APPS is utilized to produce aseptically processed and packaged Grade "A" milk and/or milk products and pasteurized Grade "A" milk and/or milk products, the APPS shall be inspected and tested by the Regulatory Agency in accordance with the requirements cited in Section 7. of the *Grade "A" PMO*.

G.) NCIMS HACCP IMS listed aseptic, retort and/or fermented high-acid, shelf-stable milk plants shall be inspected/audited and regulated under the NCIMS voluntary HACCP Program with the exception of the APPS, RPPS or AQFPSS respectively, which shall be inspected and regulated under the NCIMS Aseptic Processing and Packaging Program, Retort Processed after Packaging Program, and or Fermented High-Acid, Shelf-Stable Processing and Packaging Program respectively. Provided that FORM NCIMS 2359p and/or FORM NCIMS 2359q shall also be completed.

2.) Criteria and Procedures for Denial or Withdrawal of an IMS Listing

In addition to the current NCIMS requirements for an IMS listing, the identification of any CLE on FORM NCIMS 2359p or FORM NCIMS 2359q by an SRO or PHS/FDA MS as not being in compliance, requires that a listing shall be immediately denied or withdrawn.

4. COMPUTATION OF SCRs

The criteria and procedures for actions following a NCIMS HACCP IMS listing audit are found in Section C., 3., c. of this *MMSR*. SCRs shall be made of Grade “A” dairy farms that are attached supplies of Grade “A” raw milk of Grade “A” milk plants, receiving stations, or transfer stations IMS listed under the NCIMS voluntary HACCP Program IMS listing procedure.

a. Rating and PHS/FDA check rating results are transferred to FORM NCIMS 2359L-STATUS OF MILK PLANTS (Including Drying and Condensing, Blending, Milk and Milk Products Plants, Receiving Stations and Transfer Stations). This FORM may be obtained from a PHS/FDA MS or at the following NCIMS website: <https://ncims.org/forms>.

b. The name of the Grade “A” milk plant and the average total pounds of Grade “A” milk and/or milk products processed daily, expressed to the nearest 100-pound unit (cwt.), are entered in the first, "Name of Plant", and second, "Pounds Processed Daily (100# Units)", columns, respectively, of FORM NCIMS 2359L.

For Example: 86,340 pounds processed per day shall result in an entry of 863 in the "Pounds Processed Daily (100# Units)" column.

The recorded production quantity is the daily average, based on actual operating days, for the week preceding the rating or PHS/FDA check rating.

c. Violations of Items or sub-items are indicated by an "X" or by inserting the point value of the violation in the appropriate column(s) of FORM NCIMS 2359L. When a deficiency in a Grade “A” milk plant affects only one (1) type of packaging, i.e., paper, glass, single-service plastics, multi-use plastics, dispenser, cottage cheese, sour cream or yogurt containers, etc.; or capping of these containers; or individual pasteurization unit including: vat, HTST, HHST, the number of pounds of all Grade “A” milk and/or milk products so packaged, capped, or pasteurized are debited. In such cases, entries are made on separate lines below the name of the Grade “A” milk plant. The identity of the individual packaging and/or capping machine(s) affected by the violation(s) of Items 18p and/or 19p; or the identity of the individual pasteurization unit(s) used, i.e., vat, HTST or HHST affected by the violation(s) of Item 16p is entered in the "Name of Plant" column, together with a parenthetical entry of the total volume in 100 pound units (cwt.) of the Grade “A” milk and/or milk product(s) involved. The name or names of the Grade “A” milk and/or milk product(s) affected by the violation(s) of bacterial, coliform, or cooling temperature standards of the *Grade “A” PMO* is entered in the “Name of Plant” column, together with a parenthetical entry of the total volume in 100 pound units (cwt.) of the Grade “A” milk and milk product(s) involved. Care shall be taken not to enter this quantity in the "Pounds Processed Daily (100# Units)" column where it would again be included in the average total pounds of Grade “A” milk and/or milk products processed daily. (Refer to Section K., Numbers 14 and 15 of this *MMSR* for examples.)

d. For Grade “A” receiving and/or transfer stations operated by the Grade “A” milk plant and under the same routine supervision as the milk plant and shipping to the milk plant, the name of the receiving and transfer station is entered in the "Name of Plant" column, together with a parenthetical entry of the average hundredweight (cwt.) of Grade “A” milk shipped daily. An entry is not made in the "Pounds Processed Daily (100# Units)" column.

The recorded production quantity is the daily average, based on actual operating days, of the shipments of Grade "A" milk for the week preceding the rating or PHS/FDA check rating. Violations of Items or sub-items are indicated by an "X" or by inserting the point value of the violation in the appropriate column(s).

To facilitate the SCR computations, receiving station's and/or transfer station's entries follow the entries for the milk plant. If the SCR of the receiving station and/or transfer station is equal to, or greater than the SCR of the milk plant, or equal to ninety percent (90%) or greater, the milk plant SCR is considered as being inclusive of the receiving station's and/or transfer station's violation(s); therefore, an entry is not made in the "Total Debits" column, for the receiving and/or transfer station(s). However, if the receiving station's and/or transfer station's SCR is less than ninety percent (90%) and lower than the milk plant's SCR, it is subtracted from the SCR of the milk plant, which it supplies, and the difference is entered in the "Total Debits" column. This difference is then multiplied by the number of pounds of milk shipped daily by the receiving and/or transfer station to the milk plant and entered in the "Pounds Processed Daily X Total Debits" column. (Refer to Section K., Number 15 of this *MMSR* for an example.)

e. The SCR computation procedure for a Grade "A" milk plant is similar to that for Grade "A" dairy farms, except that a modified procedure is necessary in computing debits for violations involving only one (1) type of packaging, i.e., paper, glass, single-service plastics, multi-use plastics, dispenser, cottage cheese, sour cream or yogurt containers; or capping of these containers; or individual pasteurization unit used, i.e., vat, HTST, HHST or individual Grade "A" milk and/or milk product(s) violating the bacterial, coliform or cooling temperature standards; and for violations involving receiving or transfer stations that are IMS listed with the milk plant. The latter is explained in the preceding paragraph. For such violations, the entry in the "Total Debits" column is multiplied by the actual number of pounds of Grade "A" milk and/or milk product involved, as entered parenthetically in the "Name of Plant" column, rather than by the milk plant's entire Grade "A" milk and/or milk products production from the "Pounds Processed Daily (100# Units)" column. This figure is entered in the "Pounds Processed Daily (100# Units) X Total Debits" column.

The SCR for the milk plant is derived from the following formula:

SCR= 100 - (The Sum of the "Pounds Processed Daily (100# Units) X Total Debits" column) divided by (The Sum of the "Pounds Processed Daily (100# Units)" column)

This SCR calculation is entered in the appropriate space in the upper right-hand corner of FORM NCIMS 2359L. It is also entered on FORM NCIMS 2359j-SECTION A. REPORT OF MILK SANITATION RATING (PAGE 1) and FORM FDA 2359i, in the appropriate location.

D. CERTIFICATION IMS LISTING METHODS FOR SINGLE-SERVICE CONTAINERS AND/OR CLOSURES FOR MILK AND/OR MILK PRODUCTS MANUFACTURERS

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. Standards For The Fabrication Of Single-Service Containers And/Or Closures For Milk And/Or Milk Products of the *Grade "A" PMO* and in accordance with this *MMSR* for inclusion on the *IMS List*.

A TPC's SRO or an 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 this *MMSR* for inclusion on the *IMS List*.

1. COLLECTION OF DATA

Data from which IMS certification listings for U.S. manufacturers of single-service containers and/or closures for milk and/or milk products are determined shall be obtained by State Rating Agency SROs from the Regulatory Agency's official records or single-service containers and/or closures manufacturer, respectively, and from the evaluation of sanitary practices and facilities at the single-service containers and/or closures manufacturer.

Data from which IMS certification listings for foreign manufacturers of single-service containers and/or closures for milk and/or milk products are determined shall be obtained by a TPC's SRO or a SSC from the Regulatory Agency's records, SSC, or single-service containers and/or closures manufacturer, respectively, and from the evaluation of sanitary practices and facilities at the single-service containers and/or closures manufacturer.

a. Recording of Inspection Data

1.) During IMS certification listing, inspection data are recorded on FORM NCIMS 2359c-MANUFACTURING PLANT INSPECTION REPORT (*Single-Service Containers and/or Closures for Milk and/or Milk Products*), the Items of which correspond to the Items of sanitation in Appendix J. of the *Grade "A" PMO*.

2.) Sanitary conditions are evaluated in terms of the requirements of Appendix J. of the *Grade "A" PMO*. Professional judgment alone shall dictate whether an observed deficiency is representative of significant day-to-day sanitary conditions or is an anomaly. When significant violations of any given requirement are noted, the corresponding Item(s) or sub-item(s) on the FORM NCIMS 2359c are debited with an "X". Each item or sub-item found in violation should be carefully considered before debiting with an "X", as this affects the computation of the SCR.

b. Recording of Laboratory and Other Test Data

1.) As applicable, the Regulatory Agency's official records or records from the SSC and/or single-service containers and/or closures manufacturers are utilized in determining compliance with bacterial, coliform and chemical, as applicable, requirements. The acceptance of data from Official and/or Officially Designated Laboratories is contingent

upon the utilization of standard procedures by the laboratories concerned. Accordingly, it is necessary for the SRO or PHS/FDA MS to determine from the official Milk Laboratory Control Agency or for the SSC that certified and IMS listed the single-service containers and/or closures manufacturer that both sampling and laboratory procedures have been approved in accordance with the methods of the current edition of the *Grade "A" PMO* and *EML*. Certification IMS listings shall not be conducted when an approved laboratory has not been utilized by the Regulatory Agency, SSC or single-service containers and/or closures manufacturers, as applicable, for the necessary tests and the Rating Agency or SSC, respectively, shall immediately notify the appropriate PHS/FDA personnel for TPCs to either deny or withdraw the IMS certification listing.

2.) Compliance with bacterial and coliform requirements is based on whether, at the time of the certification of the IMS listing, a single-service manufacturer's containers and/or closures meet the standards of Appendix J. of the *Grade "A" PMO*. Each manufacturing line of containers and/or closures for each of the above applicable requirements, credit shall be given if no more than two (2) of the last four (4) sample set results exceed the limit(s), provided that the last sample set result is within the limit(s). Individual sample sets that are in violation of having two (2) of the last four (4) sample results exceeding the limit(s) and the last sample set exceeds the limit(s) shall not be given credit (debited) for the specific bacterial and/or coliform limit(s) that was exceeded. No credit shall be given (debited) for compliance with bacterial or coliform requirements when less than the required number of sample sets has been examined during the preceding six (6) months. For certification listing purposes, the preceding six (6) months is considered to be the *minimum* elapsed period of time prior to the earliest certification in which the IMS listing was conducted. Single-service containers and/or closures manufacturers which have had a permit, if applicable, for less than six (6) months at the time of the certification or which do not operate on a year round basis and for which the Regulatory Agency, SSC and/or single-service containers and/or closures manufacturer, as applicable, has not yet examined the required number of sample sets shall be given credit, provided that the last sample set result is within the limit(s). Single-service containers and/or closures manufacturers that have had a permit, if applicable, for less than six (6) months or do not operate on a year-round basis and their last sample results exceed the limit(s) shall not be given credit (debited) for the specific bacterial and/or coliform limit(s) that was exceeded.

2. COMPUTATION OF SCRs

SCRs shall be made of single-service containers and/or closures for milk and/or milk products manufacturers.

- a. Certification IMS listing and PHS/FA audit results are transferred to FORM NCIMS 2359e-STATUS OF MANUFACTURING PLANTS (*Single-Service Containers and/or Closures for Milk and/or Milk Products*). This FORM may be obtained from a PHS/FDA MS or at the following NCIMS website: <https://ncims.org/forms>.
- b. The identity of each single-service containers and/or closures manufacturer is entered in the first column, "Name of Plant" on FORM NCIMS 2359e.

Violations of Items are indicated by an "X" or by inserting the point value of the violation in the appropriate column(s). The sum of the weights of all Items found violated at the single-

service containers and/or closures manufacturer is entered in the "Total Debits" column. (Refer to Section K., Number 24, of this *MMSR*, for an example.)

c. The SCR is Derived from the Following Formula:

$$\text{SCR} = 100 - (\text{The Sum of the "Total Debits"})$$

This SCR is entered in the appropriate space in the upper right-hand corner of FORM NCIMS 2359e and on FORM FDA 2359d-REPORT OF CERTIFICATION (*Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products*). (Refer to Section K., Number 26 of this *MMSR*, for an example.)

E. COMPUTATION OF ENFORCEMENT RATINGS

For all NCIMS HACCP IMS listings, including aseptic, retort and/or fermented high-acid, shelf-stable Grade "A" milk plants, complete FORM NCIMS 2359n-NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT. (Refer to Section K., Number 18 of this *MMSR*, for an example.) ERs shall be made for Grade "A" dairy farms that are IMS listed with Grade "A" milk plants, receiving stations, or transfer stations that are IMS listed under the NCIMS voluntary HACCP IMS listing procedure. These ERs shall be made using the procedures for Grade "A" raw milk for pasteurization, aseptic processed and packaging, retort processed after packaging and fermented high-acid, shelf-stable processing and packaging addressed in 2. of this Section.

1. PURPOSE

a. FORM NCIMS 2359j consists of five (5) parts: SECTION A. REPORT OF THE MILK SANITATION RATING is on PAGE 1, SECTION B. REPORT OF ENFORCEMENT METHODS is on PAGE 2, SECTION C. EVALUATION OF SAMPLING PROCEDURES is on PAGE 3, SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS is on PAGE 4 and SECTION E. MILK PLANT ENFORCEMENT ACTION AND RECORDS EVALUATIONS is on PAGE 5. (Refer to Section J., Numbers 1, 2, 3, 4 and 5 of this *MMSR* for an example of this FORM.) This FORM provides a means of measuring the degree to which the enforcement provisions of the *Grade "A" PMO* are being applied by the Regulatory Agency. It serves to delineate specific areas where a Grade "A" milk sanitation program needs strengthening.

The rating procedures provide for separate appraisals of these provisions as they are applied to Grade "A" dairy farms, milk plants, receiving stations and transfer stations. In some cases, the ER is derived by combining these appraisals with an appraisal of other regulatory actions for which the Regulatory Agency is responsible.

b. Appraisal of Items is based on the SRO's or PHS/FDA MS's observations made during the rating or PHS/FDA check rating, respectively, and their review of the Regulatory Agency's official records for one (1) of the following periods:

1.) Back to the beginning of the month in which the previous rating was conducted; or

For Example: The previous rating was conducted 10/21/2018 and the earliest rating date for the next rating or PHS/FDA check rating was 6/14/2020. The period for the Regulatory Agency's official records review for this or PHS/FDA check rating, respectively, would cover 10/1/2018 to 6/13/2020.

- 2.) Back to the beginning of the month in which the previous rating was conducted. If the last rating was conducted within the preceding six (6) months, for rating or PHS/FDA check rating purposes, the preceding six (6) months is considered to be the elapsed period of the month prior to the earliest rating date in which the PHS/FDA check rating was conducted and the preceding six (6) months.

For Example: The previous rating was conducted 12/21/2018 and the earliest rating date for the next rating or PHS/FDA check rating was 5/14/2019. The period for the Regulatory Agency's official record review for this rating or PHS/FDA check rating, respectively, would cover 11/1/2018 to 5/13/2019.

c. ERs shall be computed utilizing the GUIDELINES FOR COMPUTING ENFORCEMENT RATINGS, contained in Appendix A. of this *MMSR*.

d. The ER applies directly to the individual Regulatory Agency; therefore, there are not any provisions for combining the ERs of two (2) or more Regulatory Agencies. ERs shall be made in accordance with the procedures in the following Sections.

e. For ER purposes, to determine if inspections, sampling, and evaluations have been conducted at the required frequency, the interval shall include the designated period, plus the remaining days of the month in which the inspection, equipment tests or sample(s) is due:

- Dairy Farms: at least once every six (6) month period or prescribed by Appendix P.
- Transfer Stations: at least once every six (6) month period
- Milk Plants and Receiving Stations: at least once every three (3) month period or every six (6) months for Aseptic, Retort or Fermented High-Acid, shelf-stable or HACCP listed milk plants
- Milk Pasteurization equipment tests: at least once every three (3) month period and the holding time testing at least once every six (6) month period
- Grade "A" milk and/or milk product sampling and testing: during any consecutive six (6) months, at least four (4) samples of each Grade "A" milk and milk product, as defined in Sections 1. and 6. of the *Grade "A" PMO* shall be collected in four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days
- Dairy Farm individual water supplies: at least once every three (3) year period
- Milk plants, receiving stations and transfer stations individual water supplies: at least once every six (6) month period
- Reclaim and recirculated cooling water samples: at least once every six (6) month period
- Hauled Water: during any consecutive six (6) months, at least four (4) samples in four (4) separate months
- Sampler evaluations: at least once every twenty-four (24) month period

2. GRADE "A" RAW MILK FOR PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING, RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING ONLY

- a. When an individual milk shipper offers for sale only Grade "A" raw milk for pasteurization, aseptic processing, retort processed after packaging or fermented high-acid, shelf-stable processing and packaging directly from Grade "A" dairy farms, known as a BTU, and there is not a Grade "A" milk plant, receiving and/or transfer station included with their IMS listing, all Items in DAIRY FARMS-PART I, FORM NCIMS 2359j-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2) shall be evaluated. The TOTAL CREDIT, PART I shall be the ER and shall be recorded on of this FORM, in the appropriate location. (Refer to Section K., Numbers 1, 9 and 11 of this *MMSR* for examples.)
- b. When an Item requires separate action on the part of the Regulatory Agency with respect to each Grade "A" dairy farm, compliance is prorated on the proportion of Grade "A" dairy farms included in the rating or PHS/FDA check rating for which the Regulatory Agency's official records that were reviewed during the appropriate time period back to the previous rating indicate the Item to have been satisfied.
- c. When an Item requires an action by the Regulatory Agency that affects the entire Grade "A" milk sanitation program, quantitative estimates of compliance by the above-described procedure are not applicable. These Items have the "Percent Complying" column blocked out and the full weight of the Item is debited or credited, depending upon whether the Grade "A" milk sanitation program is satisfying the pertinent provisions of the *Grade "A" PMO*. In appraising these Items, the SRO's or PHS/FDA MS's judgment should be based on the attainment of objectives toward which the provisions of the appropriate Sections are directed and not on occasional circumstances or insignificant deviations in procedure. (Refer to Section K., Numbers 5, 9 and 11 of this *MMSR*, for examples.)
- d. For rating and PHS/FDA check rating purposes, to determine if tests, as applicable, have been made at the required frequency, the interval shall include the designated period, plus the remaining days of the month in which the test(s) is due.
- e. For Grade "A" dairy farms inspected under the provisions of Appendix P. Performance-Based Dairy Farm Inspection System of the *Grade "A" PMO*, the following rating criteria applies:
 - 1.) At each three (3) month categorization during the rating period, the previous twelve (12) month Regulatory Agency's official dairy farm records were used to determine the proper categorization of individual Grade "A" dairy farms into twelve (12), six (6), four (4) and three (3) month inspection intervals.
 - 2.) Grade "A" dairy farms were re-categorized properly every three (3) months.
 - 3.) The due date for the next routine regulatory inspection is calculated from the date of the last routine regulatory inspection, unless the due date was scheduled to occur before the re-categorization. However, the due date may be extended up to thirty (30) days after the re-categorization date for Grade "A" dairy farms assigned to a six (6), four (4) or three (3) month inspection frequency, if the due date was scheduled to occur before the re-categorization date.

3. GRADE "A" RECEIVING STATION OR TRANSFER STATION

a. When an individual milk shipper offers for sale Grade "A" raw milk for pasteurization, aseptic processing and packaging, retort processed after packaging or fermented high-acid, shelf-stable processing and packaging, which is shipped from a receiving station or transfer station, with one (1) or more Grade "A" dairy farms rated with it, all Items in MILK PLANT-PART II, except Numbers 5 and 7, and all Items on INDIVIDUAL SHIPPER RATING-PART III on FORM NCIMS 2359j-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), shall be evaluated. When a Grade "A" receiving station and/or transfer station receives and transports Grade "A" raw milk for pasteurization, aseptic processing and packaging, retort processed after packaging or fermented high-acid, shelf-stable processing and packaging from one (1) or more IMS listed BTUs and wishes a separate IMS listing for its facilities, all Items in MILK PLANT-PART II, except Numbers 5 and 7, and all Items in INDIVIDUAL SHIPPER RATING-PART III, except Number 1 shall be evaluated. The procedures outlined in E., 3., b and E., 4., b.3.), 4.) and 5.) shall be followed in computing the ER of the receiving station and/or transfer station.

b. The total credit, which can be earned in MILK PLANT-PART II, is seventy-five (75). Therefore, the sum of the credits earned in MILK PLANT-PART II should be divided by seventy-five (75) and multiplied by 100 to arrive at the TOTAL CREDIT, PART II.

For Example: Assume that the addition of all credits, omitting Numbers 5 and 7 under MILK PLANT-PART II, equals 67.7. Then 67.7 divided by seventy-five (75), multiplied by 100 equals 90.3 percent. Fractions of 0.5 or higher are increased to the next whole number and fractions of less than 0.5 are dropped. Under these rules, 90.3 percent would equal ninety percent (90%). The TOTAL CREDIT from DAIRY FARMS-PART I and MILK PLANT-PART II are transferred to INDIVIDUAL SHIPPER RATING-PART III. The sum of the credits in INDIVIDUAL SHIPPER RATING-PART III shall be the ER of the Regulatory Agency. (Refer to Section K., Number 5 of this *MMSR*, for an example.)

c. When an Item requires separate action on the part of the Regulatory Agency with respect to each Grade "A" receiving station or transfer station, compliance is based on the proportion of Grade "A" receiving stations or transfer stations that are included in the rating for which Regulatory Agency's official records show the Item to have been satisfied. If an Item requires more than one (1) test or determination, i.e., MILK PLANT-PART II, Numbers 2, 4, 6, 8, 9, and 10, then compliance is also based on the proportion of tests or determinations, which according to the Regulatory Agency's official records, were made at the required frequency.

For Example: If only six (6) of the required eight (8) routine regulatory inspections were conducted since the last rating, the compliance would be 6/8 or seventy-five percent (75%).

d. When an Item requires an action by the Regulatory Agency, which affects the entire Grade "A" milk sanitation program, quantitative estimates of compliance by the procedure described in the preceding paragraph are not applicable. These Items have the "Percent Complying" column blocked out and the full weight of the Item is debited or credited, depending upon whether the Grade "A" milk sanitation program being rated is satisfying the pertinent provisions of the *Grade "A" PMO*. In appraising these Items, the SRO's or PHS/FDA MS's

judgment should be based on the attainment of objectives toward which the milk sanitation regulations are directed and not on occasional circumstances or insignificant deviations in procedure.

4. GRADE “A” MILK PLANTS

a. For IMS listed Grade “A” aseptic milk plants, retort milk plants and fermented high-acid, shelf-stable milk plants, all Items in MILK PLANT-PART II, except Number 5, and all Items on INDIVIDUAL SHIPPER RATING-PART III on FORM NCIMS 2359j-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), shall be evaluated. The total credit, which can be earned in MILK PLANT-PART II, is eighty-five (85). Therefore, the sum of the credits earned in MILK PLANT-PART II shall be divided by eighty-five (85) and multiplied by 100 to arrive at the TOTAL CREDIT, PART II.

b. Milk Plant with an Unattached Supply of Raw Milk

1.) When an individual shipper of pasteurized milk and/or milk products imports all raw milk for pasteurization, aseptic processing and packaging, retort processed after packaging or fermented high-acid, shelf-stable processing and packaging from outside the jurisdiction of the Regulatory Agency in which the milk plant is located, only Parts II and III of FORM NCIMS 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), shall be evaluated. If an Item requires more than one (1) test or determination, i.e., Part II, Numbers 2, 4, 5, 6, 7, 8, 9, and 10, then compliance is also based on the proportion of tests or determinations, which according to the Regulatory Agency’s records, were made at the required frequency.

For Example: For ERs, all required pasteurization equipment tests, including the test(s) required following regulatory seal(s) being broken, shall be performed on each individual pasteurizer and/or pasteurization system(s) (unit) used to receive credit. Compliance is determined by multiplying the number of pasteurization systems (units) by the number of three (3) month periods (quarters), plus the number of regulatory seal(s) being broken in the rating period, and less the number of broken seals or required quarterly pasteurization equipment tests where the testing was not done in compliance to the requirements set forth of Appendix I. of the *Grade “A” PMO*. If a milk plant utilizes four (4) pasteurization systems (units) and was last rated two (2) years ago and one (1) pasteurization system (unit) does not have all of the required tests properly completed during one (1) quarter; plus there were four (4) milk plant notifications to the Regulatory Agency of a regulatory seal(s) being broken, of which one (1) did not have the required test(s) conducted before being re-sealed by the Regulatory Agency, then compliance is calculated as follows:

4 (Units) X 8 (Quarters) = 32 Required Unit Tests = Plus Four (4) Milk Plant Notifications due to broken regulatory seals = 36 Required Unit Tests, Less One (1) Non-Complying Re-seal Unit Test and Less One (1) Non-Complying Quarter Unit Test for a Total of Thirty-four (34) of Thirty-six (36) in Compliance.

$$34/36 = 94.4\% \times 15 \text{ Weight} = 14.17 \text{ Credits.}$$

NOTE: For rating purposes, to determine if the required quarterly and semi-annual pasteurization equipment tests have been performed at the required frequency, the interval shall include the designated period plus the remaining days of the month in which the quarterly and semi-annual pasteurization equipment tests are due.

2.) When an Item requires an action by the Regulatory Agency, which affects the entire Grade "A" milk sanitation program, quantitative estimates of compliance by the procedure described in the preceding paragraph are not applicable. These Items have the "Percent Complying" column of the schedule blocked out, and the full weight of the Item is debited or credited, depending upon whether the Grade "A" milk sanitation program being rated is satisfying the pertinent provision of the *Grade "A" PMO*. In appraising these Items, the SRO's or PHS/FDA MS's judgment should be based on the attainment of objectives toward which the milk sanitation regulations are directed and not on occasional circumstances or insignificant deviations in procedure.

3.) The utilization of Grade "A" milk and/or milk products from a separate IMS listed milk shipper, which has an SCR, which is less than ninety percent (90%), or is from an unlisted source, would initiate an immediate withdrawal of the milk shipper from the *IMS List*.

4.) The utilization of Grade "A" milk and/or milk products from a separate IMS listed milk shipper, which has an ER of less than ninety percent (90%) for longer than six (6) months, or which has been re-rated and received an ER of less than ninety percent (90%) following a rating with an ER of less than ninety percent (90%), is considered a violation of Section 11. MILK AND MILK PRODUCTS FROM POINTS BEYOND THE LIMITS OF ROUTINE INSPECTION of the *Grade "A" PMO* and would initiate an immediate withdrawal of the shipper from the *IMS List*.

5.) When computing INDIVIDUAL SHIPPER RATING-PART III of FORM NCIMS 2359j-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), there shall be zero (0) credit in Item 1-Enter TOTAL CREDIT from PART 1 under Percent Complying. It will be necessary to increase the weight for Item 2-Enter TOTAL CREDIT from MILK PLANT-PART II under Percent Complying to .94 to negate the zero (0) credit in Item 1. (Refer to Section K., Number 2 of this *MMSR*, for an example.)

For Example: TOTAL CREDIT in MILK PLANT-PART II is 88.7 and Item 3-All milk and milk products properly labeled in INDIVIDUAL SHIPPER RATING-PART III has a credit of 4.8, the calculations shall be as follows:

$$(88.7 \times .94) = 83.4 + 4.8 = 88.2 = \mathbf{88\% \text{ ER}}$$

c. Milk Plant with an Attached Supply of Raw Milk

1.) When an individual milk shipper of Grade "A" pasteurized milk and/or milk products receives Grade "A" raw milk for pasteurization, aseptic processing and packaging, retort processed after packaging or fermented high-acid, shelf-stable processing and packaging from an attached supply(ies) within the jurisdiction of the Regulatory Agency in which the Grade "A" milk plant is located, DAIRY FARMS-PART I, MILK PLANT-PART II, and INDIVIDUAL SHIPPER RATING-PART III, on FORM NCIMS 2359j-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2) shall be evaluated. If Grade "A" raw milk for pasteurization, aseptic processing and packaging, retort processed after packaging or fermented high-acid, shelf-stable processing and packaging is received from

both attached and unattached supplies, only those sources from attached supplies shall be evaluated in DAIRY FARMS-PART I. If an Item requires more than one (1) test or determination, i.e., MILK PLANT-PART II, Numbers 2, 4, 5, 6, 7, 8, 9, and 10, then compliance is also based on the proportion of tests or determinations, which according to the Regulatory Agency's official records, were made at the required frequency.

For Example: For an ER of a milk plant, if only eight (8) of the required ten (10) individual Grade "A" milk and/or milk products had been sampled at the required frequency during the rating period back to the last rating, the compliance would be 8/10 or eighty percent (80%) under MILK PLANT-PART II, Number 7.

2.) When an Item requires an action by the Regulatory Agency, which affects the entire Grade "A" milk sanitation program, quantitative estimates of compliance by the procedure described in the preceding paragraph are not applicable. These Items have the "Percent Complying" column blocked out and the full weight of the Item is debited or credited, depending upon whether the Grade "A" milk sanitation program being rated is satisfying the pertinent provisions of the *Grade "A" PMO*. In appraising these Items, the SRO's or PHS/FDA MS's judgment should be based on the attainment of objectives toward which the milk sanitation regulations are directed and not on occasional circumstances or insignificant deviations in procedure.

3.) The utilization of Grade "A" milk and/or milk products from a separate IMS listed milk shipper, which has an SCR, which is less than ninety percent (90%), or is from an unlisted source, would initiate an immediate withdrawal of the milk shipper from the *IMS List*.

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

F. PREPARATION OF THE SRO's REPORT FOR MILK SHIPPERS

1. PURPOSE

Ratings made by the methods described measure the degree to which the milk shipper and enforcement practices of a Regulatory Agency conform to the standards and procedures contained in the *Grade "A" PMO*. Space is provided on FORM NCIMS 2359j-SECTION A. REPORT OF MILK SANITATION RATING (PAGE 1) to present a summary of the rating results and recommendations of the SRO.

2. SUMMARY OF RATING RESULTS

SCRs computed in accordance with procedures previously described and other data pertinent to the milk shipper are entered in the SUMMARY OF RATING RESULTS on FORM NCIMS 2359j-SECTION A. REPORT OF MILK SANITATION RATING (PAGE 1). When the SCR of Grade "A" raw milk for pasteurization, aseptic processing and packaging, retort processed after

packaging or fermented high-acid, shelf-stable processing and packaging has been combined with the rating(s) of unattached supplies in accordance with the conditions and procedures found under H. PUBLICATION OF THE "INTERSTATE MILK SHIPPER'S REPORTS", Sections 2., c., 2.) or 2., c., 3.) B.) of this *MMSR*; the combined rating, rather than the rating of the attached supply is entered in the summary.

3. SUPPLEMENTARY NARRATIVE REPORT

In the course of conducting a rating and computing the SCR and ER, additional facts may become apparent which, if presented, would be of value to the Regulatory Agency in directing the NCIMS Grade "A" Milk Safety Program so as to be more effective. SROs are urged to prepare a supplementary narrative report of their rating findings and document conclusions. This report should include, but not be limited to, the following:

- a. A statement regarding the general status of the NCIMS Grade "A" Milk Safety Program, including both strengths and weaknesses.
- b. Discussion of needs for greater NCIMS Grade "A" Milk Safety Program emphasis as indicated by the compliance levels of sanitation Items and enforcement practices found during the rating.

4. RECOMMENDATIONS OF THE SRO

A summary of the narrative report, including the specific measures recommended for NCIMS Grade "A" Milk Safety Program improvement, is entered on FORM NCIMS 2359j -SECTION A. REPORT OF THE MILK SANITATION RATING (PAGE 1), under the heading "Recommendations of the Milk Sanitation Rating Officer". The full report should be discussed in detail with the appropriate officials of the Regulatory Agency. Such discussions contribute to a better understanding of the problems involved and provide the Regulatory Agency authorities an opportunity to discuss means of implementing the SRO's recommendations. (Refer to Section K., Number 1 of this *MMSR* for an example.)

For all NCIMS HACCP IMS listings, including aseptic, retort and/or fermented high-acid, shelf-stable Grade "A" milk plants, complete FORM NCIMS 2359n, which includes an evaluation of the following: (Refer to Section K., Number 18 for an example.)

- a. Milk plant, receiving station or transfer station holds a valid permit;
- b. Milk plant, receiving station or transfer station audited by a HACCP trained Regulatory Agency auditor at the minimum required frequency and follow-up conducted as required;
- c. Requirements interpreted in accordance with the *Grade "A" PMO* as indicated by past audits;
- d. Pasteurization equipment tested at required frequency (Not applicable to receiving stations, transfer stations, aseptic milk plants and retort milk plants);
- e. Individual and cooling water samples tested and reports on file as required;
- f. Samples of milk plant's milk and/or milk products collected at the required frequency and all necessary laboratory examinations made (Not applicable to receiving stations/transfer stations);
- g. Sampling procedures approved by PHS/FDA evaluation methods;

- h. Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required; and
- i. Records systematically maintained and current.

G. PREPARATION OF THE SRO's OR SSC's REPORT FOR SINGLE-SERVICE CONTAINERS AND/OR CLOSURES MANUFACTURERS

1. PURPOSE

Certification listing conducted by the methods described measure the degree to which the single-service containers and/or closures manufacturer conforms to the standards and procedures contained in Appendix J. of the *Grade "A" PMO*.

2. SUMMARY OF CERTIFICATION OF IMS LISTING RESULTS

The following FORMS shall be provided in the summary report provided to the Regulatory Agency and/or single-service containers and/or closures manufacturer, as applicable:

- a. FORM NCIMS 2359c shall be used. Under "REMARKS," an explanation of the observations per debited Item shall be included. During the certification listing, additional facts may become apparent. These facts, if provided, would be valuable information to the Regulatory Agency and/or single-service containers and/or closures manufacturer in directing the Regulatory Agency program and/or single-service containers and/or closures manufacturer to be utilized for improvement. Specific measures that give guidance on how improvements may be made shall be included. The full report shall be discussed in detail with the appropriate officials of the Regulatory Agency and/or the appropriate personnel responsible for the management of the single-service containers and/or closures manufacturer. These discussions will contribute to a better understanding of the problems present and provide an opportunity for communicating a means of implementing the SRO's or SSC's recommendations.
- b. FORM NCIMS 2359e shall also be included in the summary report.

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

1. PURPOSE

- a. The *IMS List* is an electronic publication of the Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740-3835. This is a part of the activities of the PHS/FDA in cooperation with the Regulatory Agencies in the cooperative program for the IMS listing of milk shippers.
- b. FORM FDA 2359i shall be submitted by the SRO to the appropriate PHS/FDA personnel for TPCs for milk shippers who desire to be listed on the *IMS List*. (Refer to Section J., Numbers 8 and 9 of this *MMSR* for a copy of the FORM.)

A signed copy of FORM NCIMS 2359o-PERMISSION FOR PUBLICATION - Interstate Milk Shipper's Listing shall be maintained on file by the Rating Agency for publication on the *IMS List* and shall be reviewed as part of the PHS/FDA check rating and/or Regulatory/Rating Agency Program Evaluation. Once a milk shipper has been IMS listed, all ratings, re-ratings and new ratings and NCIMS HACCP listing audits, re-audits and new audits shall be submitted to the appropriate PHS/FDA personnel for TPCs even though the milk shipper has refused to sign FORM NCIMS 2359o Interstate Milk Shipper's Listing. Supporting sampling and laboratory accreditation reports, as specified in the *Procedures*, are also necessary for inclusion and retention of the milk shipper on the *IMS List*. (Refer to Section J., Number 11 of this *MMSR* for a copy of the FORM.)

The SCR of a milk shipper is not published on the *IMS List* unless FORM NCIMS 2359o is signed by an authorized representative of the milk shipper included in the IMS listing and has been received by the Rating Agency. BTUs, Grade "A" milk plants, receiving stations and transfer stations shall achieve an SCR of ninety percent (90%) or greater in order to be eligible for a listing on the *IMS List*. The SCR for Grade "A" milk plants, receiving stations and transfer stations will not be printed on the *IMS List*.

2. PREPARATION OF THE "INTERSTATE MILK SHIPPER'S REPORT"

a. Individual Shipper of Raw Milk for Pasteurization, Aseptic Processing and Packaging, Retort Processed after Packaging or Fermented High-Acid, Shelf-Stable Processing and Packaging.

This milk shipper is commonly referred to as a BTU. Following the computation of the SCR on FORM NCIMS 2359k and the ER from DAIRY FARMS-PART I on FORM NCIMS 2359j-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), the SCR and ER shall be transferred to FORM FDA 2359i. The earliest rating date shall be the date of the first day of the BTU rating. (Refer to Section K., Number 16 of this *MMSR* for examples.)

NOTE: If the ER for the IMS listed milk shipper is less than ninety percent (<90%), then the IMS listing is valid for a period not to exceed six (6) months plus the remaining days of the month and shall have an expiration date six (6) months from the earliest rating date plus the remaining days of the month. For example, the earliest rating date is 6/15/2020; therefore, the expiration date would be 12/31/2020.

b. Grade "A" Receiving Station or Transfer Station

Following the computation of the SCR on FORM NCIMS 2359k and FORM NCIMS 2359L, and the ER from DAIRY FARMS-PART I, MILK PLANT-PART II, and INDIVIDUAL SHIPPER RATING-PART III on FORM NCIMS 2359j-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), the SCR and ER shall be transferred to FORM FDA 2359i. The earliest rating date shall be the date of the first day of the rating of either the dairy farms (BTU), receiving station or transfer station, whichever is earliest in time. When receiving and/or transfer stations wish a separate listing and receive raw milk for pasteurization, aseptic processing and packaging, retort processed after packaging or fermented high-acid, shelf-stable processing and packaging from one (1) or more rated and listed BTUs for trans-shipment, the procedures to be followed shall be that of Section H. PUBLICATION OF THE "INTERSTATE MILK SHIPPER'S REPORT, 2., c.2) or 2., c.3).

NOTE: If the ER for the IMS Listed Shipper is less than ninety percent (<90%), then the IMS Listing is valid for a period not to exceed six (6) months plus the remaining days of the month and shall have an expiration date six (6) months from the earliest rating date plus the remaining days of the month. For example, the earliest rating date is 6/15/2020; therefore, the expiration date would be 12/31/2020.

c. Grade “A” Milk Plant

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

Following the computation of the SCR on FORM NCIMS 2359k and FORM NCIMS 2359L, and Parts I, II and III of FORM NCIMS 2359j-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), the SCR and ER shall be transferred to FORM FDA 2359i. The earliest rating date shall be the date of the first day of the rating of either the dairy farms (BTU) or milk plant, whichever is earliest in time. Both the milk plant and the attached supply of Grade “A” raw milk shall have attained an acceptable SCR and ER necessary for inclusion on the *IMS list*.

NOTE: If the ER for the IMS Listed Shipper is less than ninety percent (<90%), then the IMS Listing is valid for a period not to exceed six (6) months plus the remaining days of the month and shall have an expiration date six (6) months from the earliest rating date plus the remaining days of the month. For example, the earliest rating date is 6/15/2020; therefore, the expiration date would be 12/31/2020.

2.) Attached Grade “A” Supply and Grade “A” Unattached Supplies: A Grade “A” milk plant with a source of Grade “A” raw milk under the jurisdiction of the same Regulatory Agency as the milk plant and one (1) or more sources of Grade “A” raw milk from other IMS listed sources.

The Grade “A” raw milk SCR and earliest rating date shall be reported in the following manner: The SCR of the attached supply of Grade “A” raw milk shall be reported as the raw milk SCR for the shared IMS listing. The earliest rating date shall be the date of the first day of the rating of either the dairy farm(s) (BTU) or milk plant, whichever is earliest in time. Both the milk plant and the attached supply of Grade “A” raw milk shall have attained an acceptable SCR and ER necessary for inclusion on the *IMS List*. All unattached Grade “A” raw milk supplies shall have an IMS listing. If Grade “A” raw milk is received from a source that is not IMS listed, the appropriate PHS/FDA personnel for TPCs shall be immediately notified and the milk plant and the attached supply of Grade “A” raw milk included in the shared IMS listing shall be withdrawn from the *IMS list*.

Following the computation of the SCR on FORM NCIMS 2359k and FORM NCIMS 2359L, and the ER from DAIRY FARMS-PART I, MILK PLANT-PART II and INDIVIDUAL SHIPPER RATING-PART III on FORM NCIMS 2359j SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), the SCR and ER shall be transferred to FORM FDA 2359i. The earliest rating date shall be reported on FORM FDA 2359i. In addition, the name of each unattached IMS listed Grade “A” raw milk shipper,

during the thirty (30) days preceding the rating, along with the SCR and the Expiration Rating Date of each IMS listed Grade “A” raw milk shipper shall be listed on the reverse side of FORM FDA 2359i.

NOTE: If the ER for the IMS Listed Shipper is less than ninety percent (<90%), then the IMS Listing is valid for a period not to exceed six (6) months plus the remaining days of the month and shall have an expiration date six (6) months from the earliest rating date plus the remaining days of the month. For example, the earliest rating date is 6/15/2020; therefore, the expiration date would be 12/31/2020.

3.) Unattached Grade “A” Raw Milk Supplies Only: A Grade “A” milk plant with one (1) or more sources of raw milk received from other IMS listed sources.

The milk plant’s SCR and earliest rating date shall be reported in the following manner: The calculated SCR of the milk plant shall be reported as the milk plant’s SCR for the IMS listing. The earliest rating date shall be the date of the first day of the rating. The milk plant shall have attained an acceptable SCR and ER necessary for inclusion on the *IMS List*. All unattached Grade “A” raw milk supplies shall have an IMS listing. If Grade “A” raw milk is received from a source that is not IMS listed, the appropriate PHS/FDA personnel for TPCs shall be immediately notified and the milk plant shall be withdrawn from the *IMS List*.

Following the computation of the milk plant’s SCR on FORM NCIMS 2359L and the milk plant’s ER from MILK PLANT-PART II and INDIVIDUAL SHIPPER RATING-PART III on FORM NCIMS 2359j-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), the SCR and ER shall be transferred to FORM FDA 2359i.

NOTE: For all the ratings identified under this Item, if the ER for the IMS listed milk shipper is less than ninety percent (<90%), then the IMS listing is valid for a period not to exceed six (6) months plus the remaining days of the month and shall have an expiration date six (6) months from the earliest rating date plus the remaining days of the month. For example, the earliest rating date is 6/15/2020; therefore, the expiration date would be 12/31/2020.

The raw milk SCR shall be reported as ninety percent (90%), or ninety percent (90%)-Outside Sources or listed with an asterisk (*), which denotes all Grade “A” raw milk supplies IMS listed on Form FDA 2359i. In addition, the name of each unattached IMS listed Grade “A” raw milk shipper during the thirty (30) days preceding the rating along with the SCR and the Expiration Rating Date of each unattached IMS listed Grade “A” raw milk shipper shall be listed on the reverse side of FORM FDA 2359i.

NOTE: For all ratings identified under this Item, if the ER for the IMS listed milk shipper is less than ninety percent (<90%), then the IMS listing is valid for a period not to exceed six (6) months plus the remaining days of the month and shall have an expiration date six (6) months from the earliest rating date plus the remaining days of the month. For example, the earliest rating date is 6/15/2020; therefore, the expiration date would be 12/31/2020.

The acceptance of Grade “A” milk from a source that is not IMS listed is considered a violation of the agreed upon provisions of Section 11. of the *Grade “A” PMO*. The appropriate PHS/FDA personnel for TPCs shall be immediately notified and the milk shipper shall be withdrawn from the *IMS List*.

The utilization of Grade “A” milk from an IMS listed source which has an ER of less than ninety percent (90%) for longer than six (6) months, or which has been re-rated and received an ER of less than ninety percent (90%), following a rating with an ER of less than ninety percent (90%), is considered a violation of Section 11. of the *Grade “A” PMO* and the appropriate PHS/FDA personnel for TPCs shall be immediately notified and the milk shipper shall be withdrawn from the *IMS List*.

3 PREPARATION OF THE “INTERSTATE MILK SHIPPER’S REPORT” FOR NCIMS HACCP LISTINGS

The provisions of this Section apply to Grade “A” milk plants, receiving stations, and transfer stations listed under the NCIMS HACCP listing procedure, except that:

- a. A statement regarding the acceptability, or unacceptability of the NCIMS HACCP System shall be substituted on FORM FDA 2359i for the SCR and ER; and
- b. FORM NCIMS 2359m and FORM NCIMS 2359n 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.

4 PREPARATION OF THE “INTERSTATE MILK SHIPPER’S REPORT” FOR ASEPTIC PROCESSING AND PACKAGING PROGRAM, RETORT PROCESSED AFTER PACKAGING PROGRAM AND/OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING PROGRAM IMS LISTINGS

The provisions of this Section apply to Grade “A” milk plants and receiving stations listed under the NCIMS Aseptic Processing and Packaging Program, Retort Processed after Packaging Program, and/or Fermented High-Acid, Shelf-Stable Processing and Packaging Program listing procedure, except that FORM NCIMS 2359p and/or FORM NCIMS 2359q shall be completed and maintained on file by the Rating Agency for publication on the *IMS List* and shall be reviewed as part of the check rating and/or Regulatory/Rating Agency Program Evaluation.

I. PUBLICATION OF THE “REPORT OF CERTIFICATION (*Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products*)” FOR IMS LISTING

1. PURPOSE

- a. Criteria for the Certification and Listing of Single-Service Containers and/or Closures Manufacturers on the *IMS List*

The following criteria have been developed to allow Rating and/or Regulatory Agencies flexibility in evaluating, certifying and listing single-service containers and/or closures manufacturing plants. Rating and/or Regulatory Agencies shall choose from the following list of criteria for the certification and listing of single-service containers and/or closures manufacturers:

- 1.) Single-service containers and/or closures manufacturers that operate in conjunction with an IMS listed milk plant may be listed for twenty-four (24) months plus the remaining days of the month, if the single-service containers and/or closures manufacturing plant is inspected at least every six (6) months plus the remaining days of the month in which the inspection is due, using FORM NCIMS 2359c, and Regulatory Agency's official records of such inspections and all required tests are maintained by the Regulatory Agency. Provided that, single-service containers and/or closures manufacturers that operate in conjunction with an NCIMS HACCP IMS listed milk plant may be listed for twenty-four (24) months plus the remaining days of the month in which the rating is due, if the single-service containers and/or closures manufacturing plant is integrated into the milk plant's NCIMS HACCP System and if the single-service containers and/or closures manufacturing plant is inspected at the minimum milk plant audit frequency specified in Appendix K. of the *Grade "A" PMO*, using FORM NCIMS, and records of such inspections and all required tests are maintained by the Regulatory Agency. The permit for the milk plant shall also include the inspection of the single-service containers and/or closures manufacturing areas.
- 2.) Single-service containers and/or closures manufacturers that operate in conjunction with an IMS listed milk plant and are not inspected at least quarterly and/or are not included under a permit system may be optionally IMS listed for twelve (12) months plus the remaining days of the month in which the rating is due.
- 3.) Single-service containers and/or closures manufacturers that operate as a separate entity may be IMS listed for twenty-four (24) months plus the remaining days of the month, if the Regulatory Agency has a permit system and inspects the single-service containers and/or closures manufacturing plant using FORM NCIMS 2359c at least every six (6) months plus the remaining days of the month in which the inspection is due. All testing of containers, closures and individual water supplies shall be under the direction of the Regulatory Agency and kept on file.
- 4.) Single-service containers and/or closures manufacturers that operate as a separate entity and are not inspected by Regulatory Agency personnel and do not have a permit system may be optionally IMS listed for twelve (12) months plus the remaining days of the month in which the rating is due.

NOTE: This criterion is the only option available for use by an SSC when certifying foreign manufacturers of single-service containers and/or closures for milk and/or milk products.

- 5.) Certification of single-service containers and/or closures manufacturing plants may be valid for a period not to exceed one (1) or two (2) years from the earliest certification listing date plus the remaining days of the month, based on the criteria above. The expiration date is one (1) or two (2) years from the earliest certification date plus the remaining days of the month. In the case of a one (1) year certification listing with the earliest certification date of 6/15/2019, the expiration date would be 6/30/2020.

b. Procedures for the Certification and Listing of Single-Service Containers and/or Closures Manufacturers.

The following procedures shall be followed for the certification and listing of single-service containers and/or closures manufacturers on the *IMS List*:

- 1.) For domestic firms the PHS/FDA's electronic version (transmitted via computer) of FORM NCIMS 2359c, FORM NCIMS 2359e and FORM FDA 2359d shall be submitted by the SRO to the appropriate PHS/FDA MS for single-service containers and/or closures manufacturers who desire to be certified and listed on the *IMS List*.
- 2.) For foreign firms, the PHS/FDA's electronic version (transmitted via computer) of FORM NCIMS 2359c, FORM NCIMS 2359e and FORM FDA 2359d shall be submitted by the TPC or SSC conducting the certification to PHS/FDA, Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740-3835 for single-service containers and/or closures manufacturers who desire to be certified and listed on the *IMS List*.
- 3.) A single-service containers and/or closures manufacturer is not certified and listed on the *IMS List* unless the "PERMISSION TO PUBLISH" SECTION of FORM FDA 2359d is signed by an officer of the firm authorizing the release and received by the Rating Agency, TPC or SSC, respectively.
 - A.) For the submission of PHS/FDA's electronic version, a signed copy of FORM FDA 2359d, including Section 12, shall be maintained on file by the Rating Agency and shall be reviewed as part of the single-service containers and/or closures manufacturer's PHS/FDA audit and/or the Regulatory/Rating Agency NCIMS Grade "A" Milk Safety Program evaluation.
 - B.) For the submission of PHS/FDA's electronic version, a signed copy of FORM FDA 2359d, including Section 12, shall be maintained on file by the SSC.
- 4.) The single-service containers and/or closures manufacturer may be certified and listed on the *IMS List* as a "PARTIAL" listing. A "PARTIAL" listing shall mean that only specific production rooms, or fabrication lines or machines have been evaluated in regard to specific containers and/or closures or specific size of containers and/or closures and conform to the specifications contained within Appendix J. of the *Grade "A" PMO*.

2. PREPARATION OF THE "REPORT OF CERTIFICATION" FOR IMS LISTING

Following the computation of the SCR on FORM NCIMS 2359e, the SCR shall be transferred to FORM FDA 2359d. The earliest certification date shall be the date of the first day of the certification listing.

NOTE: The certification for IMS listing of single-service containers and/or closures for milk and/or milk products manufacturers conducted by SSCs may be valid for a period of one (1) year from the earliest certification listing date. The expiration date is one (1) year from the earliest certification listing date plus the remaining days of the month. For this one (1) year certification and listing, with the earliest certification listing date of 6/15/2019, the expiration date would be 6/30/2020.

J. EXAMPLES OF RATING, NCIMS IMS HACCP LISTING, ASEPTIC PROCESSING AND PACKAGING PROGRAM, RETORT PROCESSED AFTER PACKAGING PROGRAM, AND FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING PROGRAM LISTING FORMS AND SINGLE-SERVICE CONTAINERS AND/OR CLOSURES FOR MILK AND/OR MILK PRODUCTS MANUFACTURERS CERTIFICATION IMS LISTING FORMS

The following pages contain examples of FORMS used in IMS ratings/listing audits and PHS/FDA check ratings/FDA audits. These FORMS include:

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7. FORM NCIMS 2359L-STATUS OF MILK PLANTS (INCLUDING DRYING AND CONDENSING MILK PRODUCTS PLANTS, RECEIVING STATIONS AND TRANSFER STATIONS).....	51
8. FORM FDA 2359i-INTERSTATE MILK SHIPPER’S REPORT.....	52
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NOTE: These FORMS may be obtained at the following FDA and NCIMS websites:
<https://www.fda.gov/about-fda/reports-manuals-forms/forms> and <https://ncims.org/forms>.

1. FORM NCIMS 2359j-MILK SANITATION RATING REPORT-SECTION A. REPORT OF THE MILK SANITATION RATING

National Conference on Interstate Milk Shipments		MILK SANITATION RATING REPORT		SECTION A. REPORT OF THE MILK SANITATION RATING	
Of _____ (Shipper's Name and Address)			As of _____ (Date)		
REGULATORY AGENCY		MILK SANITARIAN		ORDINANCE IN EFFECT	
				Edition	Date Adopted
RATED BY		DATE CERTIFIED BY PHS/FDA		RATING BASED ON	
NAME				_____ Edition of the Pasteurized Milk Ordinance	
TITLE					
AGENCY					
				APPROVED LABORATORY (Name or #)	
				DATE	

SUMMARY OF RATING RESULTS																	
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 80%;">Number of Dairy Farms</td><td style="width: 20%;"></td></tr> <tr><td>Number of Dairy Farms Inspected</td><td></td></tr> <tr><td>Number of Milk Plants, Receiving Stations or Transfer Stations</td><td></td></tr> <tr><td>Number of Milk Plants, Receiving Stations or Transfer Stations Inspected</td><td></td></tr> <tr><td>Total Pounds of Pasteurized Milk Produced Daily</td><td></td></tr> </table>	Number of Dairy Farms		Number of Dairy Farms Inspected		Number of Milk Plants, Receiving Stations or Transfer Stations		Number of Milk Plants, Receiving Stations or Transfer Stations Inspected		Total Pounds of Pasteurized Milk Produced Daily		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 80%;">Sanitation Compliance Rating of Raw Milk for Pasteurization</td><td style="width: 20%;"></td></tr> <tr><td>Sanitation Compliance Rating of Milk Plant, Receiving Station or Transfer Station</td><td></td></tr> <tr><td>Enforcement Rating</td><td></td></tr> </table>	Sanitation Compliance Rating of Raw Milk for Pasteurization		Sanitation Compliance Rating of Milk Plant, Receiving Station or Transfer Station		Enforcement Rating	
Number of Dairy Farms																	
Number of Dairy Farms Inspected																	
Number of Milk Plants, Receiving Stations or Transfer Stations																	
Number of Milk Plants, Receiving Stations or Transfer Stations Inspected																	
Total Pounds of Pasteurized Milk Produced Daily																	
Sanitation Compliance Rating of Raw Milk for Pasteurization																	
Sanitation Compliance Rating of Milk Plant, Receiving Station or Transfer Station																	
Enforcement Rating																	

Recommendations of the Rating Officer

2. FORM NCIMS 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2)

MILK SANITATION RATING REPORT

SHIPPER _____

DATE OF RATING _____

SECTION B. REPORT OF ENFORCEMENT METHODS

ENFORCEMENT RATING _____

DAIRY FARMS PART I						MILK PLANT PART II						INDIVIDUAL SHIPPER RATING PART III											
Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	3	All dairy farmers hold a valid permit				5.5		1	3	All milk plant, receiving station and transfer station operators hold a valid permit				5		1		Enter TOTAL CREDIT from PART I under Percent Complying			0.0	47	
2	5	All dairy farms inspected once every six (6) months or as required in Appendix "P"				15.5		2	5	Milk plant and receiving station(s) inspected once every three (3) months, aseptic and retort milk plant and transfer station(s) once every six (6) months				15		2		Enter TOTAL CREDIT from PART II under Percent Complying			0.0	47 / 94	
3	5	Inspection sheet posted or available				5.5		3	5	Inspection sheet posted or available				5		3	4	All milk and milk products properly labeled				6	
4	7	Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections				10.5		4	7	Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections				10		TOTAL CREDIT, PART III ▶ 0.0							
5	8	TB & Brucellosis Certification on file as required				10.5		5	7 App I	Pasteurization equipment tested at required frequency (Not required for aseptic and retort milk plants.)				15		INDIVIDUAL SHIPPER ENFORCEMENT RATINGS INDIVIDUAL SHIPPER OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING: • Without Milk Plant, Receiving Station or Transfer Station: – Evaluate all Items PART I. and record. • With Receiving Station(s) or Transfer Station(s): – Evaluate all Items PART I. – Evaluate all Items PART II., except Numbers 5 and 7. Divide by 75. – Evaluate all Items PART III.							
6	7	Water samples tested and reports on file as required				5.5		6	7	Individual and cooling water samples tested and reports on file as required				5		INDIVIDUAL SHIPPER OF PASTEURIZED MILK AND MILK PRODUCTS: • Aseptic and Retort Milk Plants: – Evaluate all Items PART II., except Number 5. Divide by 85. • With Attached Raw Supply: – Evaluate all Items PART I. – Evaluate all Items PART II., use 47 Weight. – Evaluate all Items PART III.							
7	6	At least four (4) samples collected from each dairy farm's supply every six (6) months and all necessary laboratory examinations made				10.5		7	6	Samples of each milk plant's milk and milk products collected at required frequency and all necessary laboratory examinations made				10		• With Unattached Raw Supply: – Evaluate all Items PART II., use 94 Weight. – Evaluate all Items PART III., except Number 1.							
8	6 App B	Sampling procedures approved by PHS/FDA evaluation methods				10.5		8	6 App B	Sampling procedures approved by PHS/FDA evaluation methods				10									
9	3, 5, 6, 16	Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required				15.5		9	3, 5, 6, 16	Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required				15									
10		Records systematically maintained and current				10.5		10		Records systematically maintained and current				10									
TOTAL CREDIT, PART I ▶ 0.0								TOTAL CREDIT, PART II ▶ 0.0															
REMARKS								REMARKS								REMARKS							

3. FORM NCIMS 2359j-MILK SANITATION RATING REPORT-SECTION C. EVALUATION
OF SAMPLING PROCEDURES (PAGE 3)

MILK SANITATION RATING REPORT

SECTION C. EVALUATION OF SAMPLING PROCEDURES

SHIPPER
LOCATION
BTU / PLANT NUMBER
INSPECTING AGENCY
DATE(S) TO

The calculations below address Items from Section B. REPORT OF ENFORCEMENT METHODS on Page 2 of this Form.														
For the Calculation of DAIRY FARM SAMPLING PROCEDURES (Refer to PART I, ITEM 8 on Page 2 of this Form)						For the Calculation of MILK PLANT SAMPLING PROCEDURES (Refer to PART II, ITEM 8 on Page 2 of this Form)								
Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	
1	Sampling surveillance officers properly certified				5		1	Sampling surveillance officers properly certified				5		
2	Adequate training program provided				5		2	Adequate training program provided				5		
3	Sampling surveillance authority properly delegated				10		3	Sampling surveillance authority properly delegated				10		
4	All samplers hold a valid permit				10		4	All samplers hold a valid permit	N/A	N/A	N/A		N/A	
5	Samplers evaluated every two (2) years and reports properly filed				30		5	Samplers evaluated every two (2) years and reports properly filed				30		
6	Sampling procedures in substantial compliance				15		6	Sampling procedures in substantial compliance				15		
7	Permit suspension, etc., taken as required				15		7	Permit suspension, etc., taken as required	N/A	N/A	N/A		N/A	
8	Records systematically maintained and current				10		8	Records systematically maintained and current				10		
						100							75	
TOTAL CREDIT ▶						0.0	TOTAL CREDIT ▶						0.0	
REMARKS						NOTE: Items 4 and 7 above are not applicable when calculating Milk Plant Sampling Procedures (Part II, Item 8 from Section B, "Report of Enforcement Methods" on Page 2 of this Form). Calculation of the Score: Divide the TOTAL CREDIT by seventy-five (75)* for milk plants, receiving stations (RS) and transfer stations (TR). * Then multiply by 100 to create a percentage. FINAL TOTAL CREDIT (Milk Plant, RS or TR) ▶								
REMARKS						REMARKS								

4. FORM NCIMS 2359j-MILK SANITATION RATING REPORT-SECTION D. DAIRY FARM
ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 4)

MILK SANITATION RATING REPORT

SECTION D. DAIRY FARM ENFORCEMENT ACTION
AND RECORDS EVALUATIONS

SHIPPER
LOCATION
BTU NUMBER
INSPECTING AGENCY
DATE(S) TO

The calculations below address Items from Section B. REPORT OF ENFORCEMENT METHODS on Page 2 of this Form.														
For the Calculation of DAIRY FARM ENFORCEMENT PROCEDURES (Refer to PART I, ITEM 9 on Page 2 of this Form)							For the Calculation of DAIRY FARM RECORDS (Refer to PART 1, ITEM 10 on Page 2 of this Form)							
Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	
1	Category I - Permit Issuance				20		1	Category I - Permit Records				25		
2	Category II - Permit Suspension				20		2	Category II - Inspection Records				25		
3	Category III - Permit Revocation				20		3	Category III - Laboratory Records				25		
4	Category IV - Permit Reinstatement				20		4	Category IV - Plan Review Files (Within Rating Period)				25		
5	Category V - Hearing/Court Action				20							100		
						100							TOTAL CREDIT	0.0
						TOTAL CREDIT	0.0	TOTAL CREDIT to be entered into PART I, Item 10 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.						
TOTAL CREDIT to be entered into PART I, Item 9 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.												TOTAL CREDIT to be entered into PART I, Item 10 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.		
REMARKS							REMARKS							

5. FORM NCIMS 2359j-MILK SANITATION RATING REPORT-SECTION E. MILK PLANT
ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 5)

MILK SANITATION RATING REPORT

**SECTION E. MILK PLANT ENFORCEMENT ACTION
AND RECORDS EVALUATIONS**

SHIPPER
LOCATION
PLANT NUMBER
INSPECTING AGENCY
DATE(S) TO

The calculations below address Items from Section B. REPORT OF ENFORCEMENT METHODS on Page 2 of this Form.															
For the Calculation of MILK PLANT ENFORCEMENT PROCEDURES (Refer to PART II, ITEM 9 on Page 2 of this Form)						For the Calculation of MILK PLANT RECORDS (Refer to PART II, ITEM 10 on Page 2 of this Form)									
Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit		
1	Category I - Permit Issuance				20		1	Category I - Permit Records				25			
2	Category II - Permit Suspension				20		2	Category II - Inspection/Equipment Records				25			
3	Category III - Permit Revocation				20		3	Category III - Laboratory Records (Also Containers/Vitamin Volume Control)				25			
4	Category IV - Permit Reinstatement				20		4	Category IV - Plan Review Files (Within Rating Period)				25			
5	Category V - Hearing/Court Action				20							100			
						100						TOTAL CREDIT	0.0		
						TOTAL CREDIT	0.0							TOTAL CREDIT	0.0
TOTAL CREDIT to be entered into PART II, Item 9 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.						TOTAL CREDIT to be entered into PART II, Item 10 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.									
REMARKS						REMARKS									

6. FORM NCIMS 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING, RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING

Shipper		Date of Rating		NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS		STATUS OF RAW MILK FOR PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING		Sanitation Compliance Rating ¹																													
NAME OF DAIRY FARM	Pounds Sold Daily (100# Units) ³	ITEMS OF SANITATION																				REMARKS															
		Abnormal Milk		Milking Barn Construction					Milkhouse Construction and Facilities					Utensils and Equipment		Milking	Drug and Chemical Control	Personnel	Insects and Rodents																		
		Somatic Cell Count ⁴	Floors	Walls and Ceilings	Separate Stalls	Lighting	Ventilation	Cleanliness	Cowyard	Floors	Walls and Ceilings	Lighting and Ventilation	Miscellaneous Requirements	Cleaning Facilities	Cleanliness	Toilet	Water Supply	Construction	Cleaning	Sanitization	Storage		Flanks, Udders and Teats	Protection from Contamination	Cleaners/Sanitizers, Drug Equipment and Drugs Labeled, Handled and Stored	Labelled for Use, Stored to Preclude the Contamination of Milk or Product-Contact Surfaces	Handwashing Facilities	Personal Cleanliness	Cooling, Recirculated Cooling Water Safe/Protected	Temperature Monitoring Devices when Required	Fly Breeding Minimized	Manure Pools Maintained	Milkhouse Openings Screened, Doors Tight, Milkhouse Free of Insects/Rodents	Approved Pesticides Used, Equipment and Utensils not Exposed to Contamination	Surroundings Neat and Clean, Free of Harborage and Breeding Areas	Bacterial Count or Drug Residue Analysis ⁵	
		1	2	A	B	C	D	E	3	4	A	B	C	D	E	6	7	8	9	10	11		12	13	14	15	A-C	DE	16	17	18	AB	C	19	AB	CD	EF
WEIGHT	5	5*	1	1	1	1	1	3	3	1	1	2	2	2	4	4	2 or 4	4	5	5	2	5	3	2 - (7) - 5	2	1	5 - (5) - 1	3	2	2	2	2	10*				
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16.																																					
17.																																					
Total or Subtotal																																					
% of Dairy Farms Violating																																					

CONTINUATION OF THE "STATUS OF RAW MILK FOR PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING" FOR		AS OF																																	
ITEM	1	2					3	4	5					6	7	8	9	10	11	12	13	14	15	16	17	18	19				BACTI	Total Debits ²	Pounds Sold Daily (100# Units) ³ X	Total Debits ²	REMARKS
WEIGHT	5	5*	1	1	1	1	1	3	3	1	1	2	2	2	4	4	2 or 6	4	5	5	2	5	3	2 - (7) - 5	2	1	5 - (5) - 1	3	2	2	2	10*			
Subtotal from Page 1																																			
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Total or Subtotal																																			
% of Dairy Farms Violating																																			

Footnotes: ¹ Sanitation Compliance Rating = 100 - $\frac{\text{Total Pounds Sold Daily (100\# Units)}^3 \times \text{Total Debits}^2}{\text{Total Pounds Sold Daily (100\# Units)}^3}$

² Total Debits for each dairy farm is the sum of the weights of the items violated. (NOTE: Any item violated indicate by placing the debit value (weight) of that item or an "X" under that item.)

³ Total Pounds Sold Daily are calculated in 100# Units.

* Used only when not in compliance.

COMMENTS

Milk Products Plant _____

Date of Rating _____

National Conference on
Interstate Milk Shipments

STATUS OF MILK PLANTS

(INCLUDING DRYING AND CONDENSING MILK PRODUCTS PLANTS,
RECEIVING STATIONS AND TRANSFER STATIONS)

Sanitation Compliance Rating ¹ _____

Footnotes:

¹Sanitation Compliance Rating = 100 – $\frac{\text{Total Pounds Processed Daily (100\# Units)}^3 \times \text{Total Debits}^2}{\text{Total Pounds Processed Daily (100\# Units)}^3}$

*Used only when not in compliance. Pro-rated by product.

8. FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION				INTERSTATE MILK SHIPPER's REPORT				3-A. COUNTRY 				
1. NAME OF SHIPPER					2. CITY			3. STATE				
4. STREET					5. PLANT or BTU #			6. PRODUCT CODE #s				
7. SURVEY DATA												
PRODUCT	DAIRY FARMS		RECEIVING OR TRANSFER STATION	MILK PLANT ¹			ENFORCEMENT					
	TYPE OF RATING ☐ AREA ☐ INDIVIDUAL											
RATING (%)												
DATE OF RATING												
TOTAL NUMBER												
NUMBER INSPECTED												
VOLUME RECEIVED DAILY (Cwt)												
APPENDIX N IS THE SHIPPER IN COMPLIANCE WITH THE PROVISIONS OF APPENDIX N? ☐ YES ☐ NO						FSP/PCs WHEN APPLICABLE, IS THE SHIPPER IN COMPLIANCE WITH THE PROVISIONS OF APPENDIX T? ☐ YES ☐ NO						
RATING AGENCY ☐ SHD ☐ SDL ☐ SDA ☐ TPC ☐ OTHER _____		CERTIFIED RATING OFFICER 			OFFICER'S CERTIFICATION EXPIRATION DATE 			EARLIEST RATING DATE				
								MONTH DAY YEAR 				
AGENCY PROVIDING CONTINUOUS SUPERVISION OF SUPPLY 							EXPIRATION RATING DATE ²					
							MONTH DAY YEAR 					
8. LABORATORY CONTROL												
APPROVED LABORATORY NUMBER A. _____ B. _____		EXPIRATION DATE A. _____ B. _____		PROCESSED MILK TESTS APPROVED					RAW MILK TESTS APPROVED			
				SPC	COLI	PHOS	RBC	DRUG RESIDUE TESTS	VIABLE COUNTS	SOMATIC CELL COUNTS	DRUG RESIDUE TESTS	
				A. _____	A. _____	A. _____	A. _____	A. _____	A. _____	A. _____	A. _____	
				B. _____	B. _____	B. _____	B. _____	B. _____	B. _____	B. _____	B. _____	
DATE OF LAST TWO (2) SPLIT SAMPLES A. _____ A. _____ B. _____ B. _____				APPROVED WATER LABORATORY AND DATE 				WATER TESTS APPROVED 				
9. PUBLICATION <i>(Written permission from a shipper shall be on file at the Regulatory/Rating Office prior to the publication of rating/listing.)</i>												
WRITTEN PERMISSION FROM SHIPPER DATED _____ ON FILE? ☐ YES ☐ NO												
10. SUBMISSION OF REPORT BY RATING AGENCY												
DATE OF REPORT		SUBMITTED BY (Signature)						Title				

¹ Submit separate Form for each milk plant.

² The expiration rating date is two (2) years after the earliest rating date, plus the remaining days of the month, i.e., earliest rating date is 10/1/2023 with a corresponding expiration rating date of 10/31/2025, except if the Enforcement Rating is <90, then the expiration rating date is six (6) months after the earliest rating date, i.e., earliest rating date is 10/1/2021 with a corresponding expiration rating date of 4/30/2022.

Written permission from shipper dated _____ on file and publication of rating/listing recommended.

SIGNATURE (FDA Milk Specialist)

THEORY

[illegible]

Item 6: Product Code #'s – Enter Product Code #'s starting in the first (left-hand) space. Product Code #'s are listed below:

1. Raw Milk for Pasteurization (May Include Lowfat, Skim or Cream)
2. Pasteurized Milk, Reduced Fat, Lowfat, or Skim
3. Heat-Treated (May Include Reduced Fat, Lowfat, Skim or Cream)
4. Pasteurized Half & Half, Coffee Cream, Creams
5. Ultra-Pasteurized (UP) Milk and Milk Products
6. Aseptic or Retort Milk and Milk Products (Including Flavored)
7. Cottage Cheese (Including Lowfat, Nonfat or Dry Curd)
8. Cultured or Acidified Milk and Milk Products
9. Yogurt (Including Lowfat or Skim)
10. Sour Cream Products (Acidified or Cultured)
11. Whey (Liquid)
12. Whey (Condensed)
13. Whey (Dry)
14. Modified Whey Products (Condensed or Dry)
15. Condensed Milk and Milk Products
16. Nonfat Dry Milk
17. Buttermilk (Condensed or Dry)
18. Eggnog
19. Lactose Reduced Milk and Milk Products
20. Low-Sodium Milk and Milk Products
21. Milk and Milk Products with Added Safe and Suitable Microbial Organisms
(Such as *Lactobacillus acidophilus*)
22. Dry Milk and Milk Products
23. Anhydrous Milk Fat
24. Cholesterol Modified Anhydrous Milk Fat

25. Cholesterol Modified Fluid Milk Products
26. Cream (Condensed or Dry)
27. Blended Dry Products
28. Whey Cream
29. Whey Cream and Cream Blends
30. Grade "A" Lactose
31. Raw Goat Milk for Pasteurization
32. Pasteurized Goat Milk and Milk Products
33. Cultured Goat Milk and Milk Products
34. Condensed or Dry Goat Milk and Milk Products
35. Ultra-Pasteurized (UP) Goat Milk and Milk Products
36. Aseptic Goat Milk and Milk Products
37. Raw Sheep Milk for Pasteurization
38. Pasteurized Sheep Milk and Milk Products
39. Cultured Sheep Milk and Milk Products
40. Concentrated Raw Milk Products for Pasteurization
41. Concentrated Pasteurized Milk Products
42. Ultrafiltered Permeate from Milk
43. Ultrafiltered Permeate from Whey
44. Raw Water Buffalo Milk for Pasteurization
45. Pasteurized Water Buffalo Milk and Milk Products
46. Cultured Water Buffalo Milk and Milk Products
47. Raw Camel Milk for Pasteurization
48. Pasteurized Camel Milk and Milk Products
49. Cultured Camel Milk and Milk Products

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

National Conference on Interstate Milk Shipments		MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT	
DATE	TYPE OF AUDIT ☐ REGULATORY* ☐ REGULATORY FOLLOW-UP ☐ LISTING ☐ FDA AUDIT OF LISTING		
FIRM NAME	LICENSE/PERMIT NO.	IMS PLANT NO.	
ADDRESS (Line 1)			
ADDRESS (Line 2)	CITY	STATE/COUNTRY	ZIP CODE
IMS LISTED PRODUCT(S) MANUFACTURED AND REVIEWED		Prerequisite Program(s) Issue Date(s)	
Hazard Analysis Issue Date(s) _____	HACCP Plan Issue Date(s) _____		
ITEMS MARKED DID NOT MEET THE NCIMS HACCP PROGRAM CRITERIA DESCRIBED BELOW Starred ★★ Items are Critical Listing Elements			
*NOTE: This regulatory NCIMS System Audit Report of your milk plant, receiving station, or transfer station serves as a notification of the intent to suspend your permit if Items marked on this audit report are not in compliance at the time of the next regulatory audit or within established timelines. (Refer to PMO Sections 3 and 6, and Appendix K. for details.)			
Section 1 HAZARD ANALYSIS ☐ A. Flow Diagram and Hazard Analysis conducted and written for each kind or group of milk or milk product processed.** ☐ B. Written Hazard Analysis identifies all potential milk or milk product safety hazards and determines those that are reasonably likely to occur (including hazards within and outside the processing plant environment). ☐ C. Written Hazard Analysis reassessed after changes in raw materials, formulations, processing methods/systems, distribution, intended use or consumers. ☐ D. Written Hazard Analysis signed and dated as required.		Section 6 HACCP PLAN CORRECTIVE ACTION ☐ A. Corrective actions when defined in the HACCP Plan were followed when deviations occurred. ☐ B. Predetermined corrective actions defined in the HACCP Plan ensure the cause of the deviation is corrected. ☐ C. Corrective action taken for products produced during a deviation from CL(s) defined in the HACCP Plan.** ☐ D. Affected milk or milk product produced during the deviation segregated and held, AND a review to determine product acceptability performed, AND corrective action taken to ensure that no adulterated milk and/or milk product that is injurious to health enters commerce. ☐ E. Cause of deviation was corrected. ☐ F. Reassessment of HACCP Plan performed and modified accordingly. ☐ G. Corrective actions documented.	
Section 2 HACCP PLAN ☐ A. Written HACCP Plan prepared for each kind or group of milk or milk product processed.** ☐ B. Written HACCP Plan implemented. ☐ C. Written HACCP Plan identifies all milk or milk product safety hazards that are reasonably likely to occur. ☐ D. Written HACCP Plan signed and dated as required.		Section 7 HACCP PLAN VERIFICATION & VALIDATION ☐ A. HACCP plan defines verification procedures, including frequency. ☐ B. Verification activities are conducted and comply with HACCP Plan. ☐ C. Reassessment of HACCP Plan conducted annually, OR ☐ 1. After changes that could affect the hazard analysis, OR ☐ 2. After significant changes in the operation including raw materials and/or source, product formulation, processing methods/systems, distribution intended use or intended consumer. ☐ D. Calibration of CCP process monitoring instruments performed as required and at the frequency defined in the HACCP Plan.** ☐ E. CCP monitoring records document that values are within CL(s) and reviewed as required within seven (7) working days of the records being created. ☐ F. Corrective action records reviewed as required within seven (7) working days of the records being created ☐ G. Calibration records and end product or in-process testing results defined in HACCP Plan reviewed as required. ☐ H. Records reviewed as required, including date and signature.	
Section 3 HACCP PLAN CRITICAL CONTROL POINTS (CCP) ☐ A. HACCP Plan lists CCP(s) for each milk or milk product safety hazard identified as reasonably likely to occur. ☐ B. CCP(s) identified are adequate control measures for the milk or milk product safety hazard(s) identified. ☐ C. Control measures associated with CCP(s) listed are appropriate at the processing step identified.		Section 4 HACCP PLAN CRITICAL LIMITS (CL) ☐ A. HACCP Plan lists critical limits for each CCP. ☐ B. CL(s) are adequate to control the hazard identified.** ☐ C. CL(s) are achievable with existing monitoring instruments or procedures. ☐ D. CL(s) are met.	
Section 5 HACCP PLAN MONITORING ☐ A. HACCP Plan defines monitoring procedures for each CCP. (what, how, frequency, whom, etc.) ☐ B. Monitoring procedures as defined in the HACCP Plan followed. ☐ C. Monitoring procedures as defined in the HACCP Plan adequately measure CL(s) at each CCP. ☐ D. Monitoring record data consistent with the actual value(s) observed during the audit. ☐ E. Monitoring records reviewed as required within seven (7) working days of the records being created.			

NCIMS HACCP SYSTEM AUDIT REPORT DISCUSSION SHEET

FIRM NAME

DATE OF AUDIT

**EXPLANATION OF DEVIATIONS/DEFICIENCIES/NON-CONFORMITIES THAT DID NOT MEET
THE NCIMS HACCP PROGRAM CRITERIA**

(Use additional sheets as necessary if entry field is non-expandable.)

NOTE: When Regulatory Audits are conducted, timelines for corrections of all identified deviations, deficiencies and non-conformities shall be established.

10. FORM NCIMS 2359n-NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT

National Conference on Interstate Milk Shipments		NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT (To be included with all NCIMS HACCP Listings and FDA Audits)	
REGULATORY AGENCY		DATE OF EVALUATION	
FIRM NAME	LICENSE/PERMIT NO.	IMS PLANT NO.	
ADDRESS			
EXPLANATION OF CONCERNS NOTED REGARDING REGULATORY AGENCY OBLIGATIONS UNDER THE NCIMS HACCP SYSTEM (Use additional sheets if necessary.)			
A narrative description shall be provided as a part of all NCIMS HACCP Listings and FDA Audits, including aseptic and/or retort milk plants with NCIMS HACCP Listings. This report shall include an evaluation of the following requirements:			
1. Milk plant, receiving station or transfer station holds a valid permit.			
2. Milk plant, receiving station or transfer station audited by a HACCP trained Regulatory Agency auditor at the minimum required frequency and follow-ups conducted as required.			
3. Requirements interpreted in accordance with the Grade "A" PMO as indicated by past audits.			
4. Pasteurization equipment tested at required frequency. (Not applicable to receiving stations, transfer stations, aseptic milk plants and retort milk plants.)			
5. Individual and cooling water samples tested and reports on file as required.			
6. Samples of milk plant's milk and/or milk products collected at the required frequency and all necessary laboratory examinations made. (Not applicable to receiving and transfer stations.)			
7. Sampling procedures approved by PHS/FDA evaluation methods.			
8. Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required.			
9. Records systematically maintained and current.			

FORM NCIMS 2359n (10/23)

11. FORM NCIMS 2359o-PERMISSION FOR PUBLICATION- INTERSTATE MILK SHIPPER'S LISTING

PERMISSION FOR PUBLICATION Interstate Milk Shipper's Listing							
SHIPPER'S NAME							
ADDRESS							
You are hereby advised that on (date[s]) _____ a Rating or HACCP Listing Audit was conducted with the following results: Producer Supply (BTU) _____ Transfer Station _____ Receiving Station _____ Milk Plant _____ Enforcement Rating (For all Ratings and for attached farm supplies of HACCP listings) _____ The results will be transmitted to the U.S. Food and Drug Administration. They will publish the information in the <i>"IMS List-Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers"</i>. The official Rating or HACCP Listing is valid for a period not to exceed two (2) years from the earliest rating/listing date, except if the Enforcement Rating is less than 90 percent (< 90%), then the official Rating/Listing is valid for a period not to exceed six (6) months from the earliest rating date, subject to the rules of the National Conference on Interstate Milk Shipments. Publication Permission Section Permission is hereby granted to release and publish the above-stated Rating or HACCP Listing for use by Regulatory Agencies and prospective purchasers. <i>It is understood and agreed</i> by the undersigned that the official Rating or HACCP Listing Agency may review this supply at any time during the two (2)-year or six (6) month period, respectively, referred to above. <i>It is further understood</i> that we will notify the Rating or HACCP Listing Agency if any significant change should occur, which affects our raw milk supply, milk plant, receiving station or transfer station status, including products listed. <i>It is understood and agreed</i> that the failure to maintain the Rating or HACCP System at a level, which is acceptable for listing, shall result in immediate withdrawal of this listing. <i>It is further agreed</i> that milk plants, receiving stations or transfer stations, which receive milk or milk products for processing into milk or milk products for which that milk plant, receiving station or transfer station is listed, are from a non-listed source or a source having a Milk Sanitation Compliance Rating of less than ninety percent (90%) shall be immediately withdrawn from the Interstate Milk Shipper's List. SIGN AND RETURN TO _____ WITHIN FIVE (5) DAYS OF RECEIPT. (Name of Agency) <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <tr> <td colspan="2" style="padding: 5px;">NAME OF SHIPPER</td> </tr> <tr> <td colspan="2" style="padding: 5px;">SIGNATURE OF REPRESENTATIVE</td> </tr> <tr> <td style="width: 60%; padding: 5px;">TITLE</td> <td style="width: 40%; padding: 5px;">DATE</td> </tr> </table>		NAME OF SHIPPER		SIGNATURE OF REPRESENTATIVE		TITLE	DATE
NAME OF SHIPPER							
SIGNATURE OF REPRESENTATIVE							
TITLE	DATE						

FORM NCIMS 2359o (10/23)

12. 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)

National Conference on Interstate Milk Shipments	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)	
<i>(To be included with all NCIMS Aseptic Processing and Packaging Program and Retort Processed after Packaging Program Ratings/HACCP Listings and FDA Check Ratings/HACCP Audits.)</i>		
MILK PLANT	DATE OF RATING	
ADDRESS	LICENSE/PERMIT NO.	
RATING AGENCY		
EXPLANATION OF CONCERNS NOTED REGARDING CRITICAL LISTING ELEMENTS UNDER THE NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND RETORT PROCESSED AFTER PACKAGING PROGRAM <i>(Use additional sheets as necessary.)</i>		
A narrative description shall be provided as a part of all NCIMS Aseptic Processing and Packaging Program and Retort Processed after Packaging Program Ratings/HACCP Listings and FDA Check Ratings/HACCP Audits. This report shall include an evaluation of the following requirements:		
1. Is the milk plant registered with FDA LACF and are all of the milk plant's low-acid aseptic and/or retort processed after packaging Grade "A" milk and/or milk products covered by a filing with the FDA LACF using Form FDA 2541c, or Form FDA 2341a, respectively, or equivalent electronic filing?		
2. Are the milk plant's filed scheduled processes for all of its low-acid aseptic and/or retort processed after packaging Grade "A" milk and/or milk products developed by a recognized Process Authority qualified as having expert knowledge of thermal processing requirements?		
3. Are the operators of the milk plant's aseptic processing and packaging systems and/or retort processed after packaging systems under the supervision of a person who has attended a school approved by the FDA (such as Better Process Control School or recognized equivalent)?		
4. Is the milk plant currently under an "Order of Determination of Need" for an Emergency Permit or a suspension of FDA food facility registration?		

13. 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

National Conference on Interstate Milk Shipments	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
<i>(To be included with NCIMS State Ratings/HACCP Listings and FDA Check Ratings/Audits.)</i>	
MILK PLANT	DATE OF INSPECTION/RATING
ADDRESS	LICENSE/PERMIT NO.
RATING AGENCY	
EXPLANATION OF CONCERNS NOTED REGARDING CRITICAL LISTING ELEMENTS UNDER THE NCIMS PROGRAM COMMITTEE <i>(Use additional sheets as necessary.)</i>	
A narrative description shall be provided as a part of all NCIMS Aseptic Program Committee State Ratings/ HACCP Listings and FDA Check Ratings/Audits. This report shall include an evaluation of the following requirements:	
1. Does the milk plant have an FDA Low-Acid Canned Foods (LACF) Food Canning Establishment (FCE) Number?	
2. Are the milk plant's Grade "A" fermented high-acid (FHA), shelf-stable milk and/or milk product(s) produced using an Aseptic-Qualified filler and Product Sterilizer System (AQFPSS) which is under a current FDA LACF 2541g (Food Process Filing for Low-Acid Aseptic Systems)?	
3. Are the milk plant's process recommendations for its Grade "A" fermented high-acid, shelf-stable milk and/or milk product(s) developed by a recognized process authority qualified as having expert knowledge of aseptic processes?	
4. Have the milk plant's process recommendations for its Grade "A" fermented high-acid, shelf-stable milk and/or milk product(s) been reviewed [with no objections] by the Regulatory Agency prior to production of these products?	
5. Are the milk plant's process recommendations that have been reviewed and confirmed by the Regulatory Agency for its Grade "A" fermented high-acid, shelf-stable milk and/or milk product(s) being implemented by the milk plant?	
6. Are the operators of the milk plant's aseptic-qualified filler and product sterilizer under the supervision of a person who has attended a school approved by the FDA (such as Better Process Control School or recognized equivalent)?	
7. Is the milk plant currently under an "Order of Determination of Need" for an emergency Permit for its LACF filing, or a suspension of food facility registration?	

FORM NCIMS 2359q (10/23)

14. FORM NCIMS 2359e-STATUS OF MANUFACTURING PLANTS (Single-Service Containers and/or Closures for Milk and/or Milk Products)

National Conference on Interstate Milk Shipments
STATUS OF MANUFACTURING PLANTS
(SINGLE-SERVICE CONTAINERS AND/OR CLOSURES FOR MILK AND/OR MILK PRODUCTS)

Plant _____

Date of Certification _____

Sanitation Compliance Rating¹ _____

NAME OF PLANT		ITEMS OF SANITATION																				REMARKS							
		Floors	Walls and Ceilings	Doors and Windows	Lighting and Ventilation	Separate Rooms	Toilet/Facilities / Sewage Disposal	Water Supply	Handwashing Facilities	Plant Cleanliness	Lockers and Lunchrooms	Disposal of Wastes	Personnel / Practices	Protection From Contamination	Storage of Materials and Finished Product	Fabrication Equipment	Materials for Construction of Containers and/or Closures	Waxes, Adhesives, Sealants, Coating and Inks	Handling of Containers, Closures and Equipment	Wrapping and Shipping	Identification and Records		Surroundings	Bacterial Count*	Coliform Count*	Total Debits ²			
	ITEM	1	2	3	4	5	6	7	8	9	10	11	12	13 a,b,c, f,g,i,k	13 d,e, h, j	14	15	16 a	16 b,c	17 a,b d,e	17 c	18	19	20 a,b,f	20 c,d,e	21			
	WEIGHT	1	1	2	2	3	3	4	2	3	2	2	3	3	11	3	5	11	3	3	11	2	4	3	11	2	5	10	
TOTALS	0																												

Footnotes: ¹ Sanitation Compliance Rating = 100 – Total Debits ² Total Debits for each manufacturing plant are the sum of the weights of the Items violated. (**NOTE:** Any Item or sub-item violated, indicate by placing the debit value (weight) of that Item or an "X" under that Item.) * Use only when not in compliance.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		REPORT OF CERTIFICATION <i>(Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products)</i>		FOR FDA USE ONLY				
				1	2	3	4	5

IDENTIFICATION																																															
1. NAME OF SINGLE-SERVICE FABRICATING PLANT										2. CITY					3. STATE/COUNTRY																																
4. STREET															5. MFG. CODE NO.					6. CODE																											
7. AGENCY OR SSC, AS APPLICABLE, PROVIDING ROUTINE INSPECTION															56		57		58		59		60		61		62																				
															PRODUCT CODE (60)										MATERIAL CODE (62)																						
7.a. RATING/CERTIFICATION PERSONNEL ☐ SHD ☐ Other ☐ SDA ☐ TPC ☐ SDL ☐ SSC															7.b. DATE OF PLANT CERTIFICATION 7.c. SANITATION COMPLIANCE RATING										7.d. EXPIRATION DATE * <table style="width:100%; text-align: center;"> <tr> <th colspan="2">MONTH</th> <th colspan="2">DAY</th> <th colspan="2">YEAR</th> </tr> <tr> <td>67</td><td>68</td> <td>69</td><td>70</td> <td>71</td><td>72</td> </tr> <tr> <td></td><td></td> <td></td><td></td> <td></td><td>20</td> </tr> </table>					MONTH		DAY		YEAR		67	68	69	70	71	72						20
																									MONTH		DAY		YEAR																		
67	68	69	70	71	72																																										
					20																																										
*EXPIRATION DATE Certification of single-service manufacturing plants may be valid for a period not to exceed one (1) or two (2) years from the earliest certification date, plus the remaining days of the month. The expiration date is one (1) or two (2) years from the earliest certification date. NOTE: Certifications conducted by SSCs shall only be valid for a period not to exceed one (1) year, plus the remaining days of the month from the earliest certification date.															8. SRO OR SSC																																
															9. CERTIFICATION RECOMMENDED ☐ YES ☐ NO										9.a. LISTING TYPE ☐ FULL ☐ PARTIAL																						

LABORATORY CONTROL																								
10. NAME AND ADDRESS (OR CODE) OF APPROVED LABORATORY																								

11. INSPECTION RESULTS <i>(Place an "X" under items debited)</i>																											
	1	2	3	4	5	6	7	8	9	10	11	12	13 a,b,c, f,g,i,k	13 d,e, h,j	14	15	16 a	16 b,c	17 a,b d,e	17 c	18	19	20 a,b,f	20 c,d,e	21	BACT	COU

12. PERMISSION TO PUBLISH																								
Permission is hereby granted to release and publish the above stated certification for use by Regulatory/Rating Agencies and prospective purchasers. It is understood and agreed by the undersigned that the official Rating Agency or SSC, as applicable, may review and appraise the single-service fabricating plant at any time during the period of time the above certification is in effect. It is further understood that failure to maintain the above certification will subject this plant to withdrawal from the IMS Listing. We will notify the Rating Agency or SSC, as applicable, of any significant changes made in the operation of this plant.																								

12.a. NAME OF PLANT																								
12.b. OFFICER AUTHORIZING RELEASE															12.c. TITLE									
13. SUBMISSION OF REPORT BY MILK SANITATION RATING AGENCY OR SSC, AS APPLICABLE																								
13.a. DATE OF REPORT					13.b. RECOMMENDED CLASSIFICATION ACCEPTED ☐ YES ☐ NO										13.c. SUBMITTED BY <i>(Signature and Title)</i>									

FOR FDA USE ONLY																								
14. DATE RECEIVED					15. PUBLICATION OF RATING RECOMMENDED ☐ YES ☐ NO <i>(If "NO", indicate why.)</i>																			
16. DATE TRANSMITTED					17. SIGNATURE <i>(FDA Milk Specialist)</i>																			

K. EXAMPLES OF HOW TO PROPERLY COMPLETE RATING, NCIMS IMS HACCP LISTING, ASEPTIC PROCESSING AND PACKAGING PROGRAM, RETORT PROCESSED AFTER PACKAGING PROGRAM, AND FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING PROGRAM LISTING FORMS AND SINGLE-SERVICE CONTAINERS AND/OR CLOSURES FOR MILK AND/OR MILK PRODUCTS MANUFACTURERS CERTIFICATION IMS LISTING FORMS

The following pages provide examples of FORMS that have been completed to demonstrate how observations should be recorded and how the FORMS should be completed. These include:

1. FORM NCIMS 2359j-MILK SANITATION RATING REPORT-SECTION A. REPORT OF THE MILK SANITATION RATING (PAGE 1) 65
2. FORM NCIMS 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2) (*EXAMPLE: MILK PLANT ONLY*)..... 66
3. FORM NCIMS 2359j- MILK SANITATION RATING REPORT-SECTION C. EVALUATION OF SAMPLING PROCEDURES (PAGE 3) (*EXAMPLE: MILK PLANT ONLY*) (Used to Complete FORM NCIMS 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), PART II, ITEM 8). 67
4. FORM NCIMS 2359j-MILK SANITATION RATING REPORT-SECTION E. MILK PLANT ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 5) (*EXAMPLE: MILK PLANT ONLY*) (Used to Complete FORM NCIMS 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), PART II, ITEMS 9 and 10).....68
5. FORM NCIMS 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2) (*EXAMPLE: MULTIPLE FARM BTU AND RECEIVING STATION*).....69
6. FORM NCIMS 2359j- MILK SANITATION RATING REPORT-SECTION C. EVALUATION OF SAMPLING PROCEDURES (PAGE 3) (*EXAMPLE: MULTIPLE FARM BTU AND RECEIVING STATION*) (Used to Complete FORM NCIMS 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), PART I, ITEM 8 and PART II, ITEM 8)..... 70
7. FORM NCIMS 2359j-MILK SANITATION RATING REPORT-SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 4) (*EXAMPLE: MULTIPLE FARM BTU*) (Used to Complete FORM NCIMS 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), PART I, ITEMS 9 and 10) 71
8. FORM NCIMS 2359j- MILK SANITATION RATING REPORT-SECTION E. MILK PLANT ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 5) (*EXAMPLE: RECEIVING STATION*) (Used to Complete FORM NCIMS 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), PART II, ITEMS 9 and 10) 72
9. FORM NCIMS 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2) (*EXAMPLE: SINGLE FARM BTU*).....73

10. FORM NCIMS 2359j-MILK SANITATION RATING REPORT-SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 4) (<i>EXAMPLE: SINGLE FARM BTU</i>) (Used to Complete FORM NCIMS 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), PART I, ITEMS 9 and 10)	74
11. FORM NCIMS 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2) (<i>EXAMPLE: MULTIPLE FARM BTU</i>)	75
12. FORM NCIMS 2359j-MILK SANITATION RATING REPORT-SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 4) (<i>EXAMPLE: MULTIPLE FARM BTU</i>) (Used to Complete FORM NCIMS 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), PART I, ITEMS 9 and 10)	76
13. FORM NCIMS 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING, RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING (<i>EXAMPLE</i>).....	77
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16. FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT	81
17. FORM NCIMS 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT.....	83
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20. FORM NCIMS 2359o-PERMISSION FOR PUBLICATION - INTERSTATE MILK SHIPPER's LISTING (<i>EXAMPLE: MILK PLANT HACCP LISTING</i>).....	89
21. FORM NCIMS 2359o-PERMISSION FOR PUBLICATION - INTERSTATE MILK SHIPPER's LISTING (<i>EXAMPLE: BTU AND MILK PLANT RATING LISTING</i>).....	90
22. FORM NCIMS 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND/OR RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS (<i>EXAMPLE: Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products</i>).....	91
23. 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.....	92
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25. FORM NCIMS 2359e-STATUS OF MANUFACTURING PLANTS (SINGLE-SERVICE CONTAINERS AND/OR CLOSURES FOR MILK AND/OR MILK PRODUCTS).....	95

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1. FORM NCIMS 2359j-MILK SANITATION RATING REPORT-SECTION A. REPORT OF THE
MILK SANITATION RATING (PAGE 1)

National Conference on Interstate Milk Shipments	MILK SANITATION RATING REPORT	SECTION A. REPORT OF THE MILK SANITATION RATING	
Of <u>A Brown Dairy</u> (Shipper's Name and Address)		As of <u>June 14, 2023</u> (Date)	
REGULATORY AGENCY State Department of Health	MILK SANITARIAN M.I. Good	ORDINANCE IN EFFECT Edition <u>2023</u> Date Adopted <u>April 1, 2022</u>	
RATED BY NAME <u>M. Milkramer</u> TITLE <u>SRO</u> AGENCY <u>State Dept. of Health</u>	DATE CERTIFIED BY PHS/FDA <u>June 17, 2023</u>	RATING BASED ON <u>2023</u> Edition of the Pasteurized Milk Ordinance	APPROVED LABORATORY (Name or #) <u>#63540</u> DATE <u>July 20, 2022</u>

SUMMARY OF RATING RESULTS

Number of Dairy Farms	314	Sanitation Compliance Rating of Raw Milk for Pasteurization	91
Number of Dairy Farms Inspected	40	Sanitation Compliance Rating of Milk Plant, Receiving Station or Transfer Station	94
Number of Milk Plants, Receiving Stations or Transfer Stations	1	Enforcement Rating	84
Number of Milk Plants, Receiving Stations or Transfer Stations Inspected	1		
Total Pounds of Pasteurized Milk Produced Daily	1,628,000		

Recommendations of the Rating Officer

The Sanitation Compliance Rating of the raw milk for pasteurization and the milk plant and the Enforcement Score are approximately the same as reported for the previous rating. Although these scores meet the minimum requirements for participation in the IMS program, the observations made during this rating indicate the need to improve some areas of the milk sanitation program. These include:

1. Attention should be directed to the items of sanitation, which were found in violations at twenty-five percent (25%) or more of the dairy farms (Items #'s 3,6,12 and 16).
2. In the milk plant, particular attention should be directed to the HTST pasteurization deficiencies (Item 16p(B)2.)
3. The Regulatory Agency should adhere more closely to the minimum required frequency for inspecting milk tank trucks.
4. Written notices of intent to suspend the permit should be issued when there are repeat violations.

NOTE: Two (2) new farm bulk milk storage tanks, manufactured after January 1, 2000, that were recently installed were not equipped with acceptable recording devices.

2. FORM NCIMS 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2) (EXAMPLE: MILK PLANT ONLY)

MILK SANITATION RATING REPORT

SHIPPER Clear Milk Dairy

DATE OF RATING 6/12/23

(Example: Milk Plant Only)

SECTION B. REPORT OF ENFORCEMENT METHODS

ENFORCEMENT RATING 84

DAIRY FARMS PART I						MILK PLANT PART II						INDIVIDUAL SHIPPER RATING PART III											
Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	3	All dairy farmers hold a valid permit				55		1	3	All milk plant, receiving station and transfer station operators hold a valid permit				5	5	1		Enter TOTAL CREDIT from PART I under Percent Complying			100	47	NA
2	5	All dairy farms inspected once every six (6) months or as required in Appendix "P"				155		2	5	Milk plant and receiving station(s) inspected once every three (3) months; aseptic and retort milk plant and transfer station(s) once every six (6) months	8	8	100	15	15	2		Enter TOTAL CREDIT from PART II under Percent Complying			84.50	47 / 94	79.43
3	5	Inspection sheet posted or available				55		3	5	Inspection sheet posted or available				5	5	3	4	All milk and milk products properly labeled	5	4	80.0	6	4.8
4	7	Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections				105		4	7	Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections	1	.8	80	10	8	TOTAL CREDIT, PART III 84.23							
5	8	TB & Brucellosis Certification on file as required				105		5	7 App I	Pasteurization equipment tested at required frequency (Not required for aseptic and retort milk plants.)	8	6	75	5	11.25	INDIVIDUAL SHIPPER ENFORCEMENT RATINGS INDIVIDUAL SHIPPER OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING: • Without Milk Plant, Receiving Station or Transfer Station: – Evaluate all Items PART I. and record. • With Receiving Station(s) or Transfer Station(s): – Evaluate all Items PART I. – Evaluate all Items PART II., except Numbers 5 and 7. Divide by 75. – Evaluate all Items PART III. INDIVIDUAL SHIPPER OF PASTEURIZED MILK AND MILK PRODUCTS: • Aseptic and Retort Milk Plants: – Evaluate all Items PART II., except Number 5. Divide by 85. • With Unattached Raw Supply: – Evaluate all Items PART II., use 94 Weight. – Evaluate all Items PART III., except Number 1. • With Attached Raw Supply: – Evaluate all Items PART I. – Evaluate all Items PART II., use 47 Weight. – Evaluate all Items PART III.							
6	7	Water samples tested and reports on file as required				55		6	7	Individual and cooling water samples tested and reports on file as required	8	6	75	5	3.75								
7	6	At least four (4) samples collected from each dairy farm's supply every six (6) months and all necessary laboratory examinations made				105		7	6	Samples of each milk plant's milk and milk products collected at required frequency and all necessary laboratory examinations made	5	4	80	10	8								
8	6 App B	Sampling procedures approved by PHS/FDA evaluation methods				105		8	6 App B	Sampling procedures approved by PHS/FDA evaluation methods	1	.9	90	10	9								
9	3, 5, 6, 16	Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required				155		9	3, 5, 6, 16	Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required	1	.8	80	15	12								
10		Records systematically maintained and current				105		10		Records systematically maintained and current	1	.75	75	10	7.5								
TOTAL CREDIT, PART I 84.50						TOTAL CREDIT, PART II 84.50																	
REMARKS						REMARKS						REMARKS											
4. Violation of Item 16b(2)(d) (15pts) existed but was not marked on the last inspection. On a previous inspection, Item 15a(a) was marked, but under remarks it described a packaging violation. This should have been correctly marked under Item 18(b) (5 pts). 5. Two of 8 tests (6/21/22 and 3/2/23) were not completed properly.						6. Two (2) water samples were missing (1/22 and 7/22). 7. No annual vitamin assay for fat free milk for CY 2022. 8. Refer to Section C. Evaluation of Sampling Procedures Page 67. 9. Refer to Section E. Milk Plant Enforcement Action and Records Evaluations on Page 68. 10. Refer to Section E. Milk Plant Enforcement Action and Records Evaluations on Page 68.						Part III Remarks 3. "Grade A" only in yogurt ingredients statement.											

3. FORM NCIMS 2359j-MILK SANITATION RATING REPORT-SECTION C. EVALUATION OF SAMPLING PROCEDURES (PAGE 3) (EXAMPLE: MILK PLANT ONLY-PART II, ITEM 8)

MILK SANITATION RATING REPORT

(Example: Milk Plant Only)

SECTION C. EVALUATION OF SAMPLING PROCEDURES

SHIPPER Clear Milk Dairy
LOCATION One Milk Road Cowtown, ST 00000
BTU / PLANT NUMBER 72-125
INSPECTING AGENCY State Dept. of Health
DATE(S) June 12-13, 2023

The calculations below address Items from Section B. REPORT OF ENFORCEMENT METHODS on Page 2 of this Form.														
For the Calculation of DAIRY FARM SAMPLING PROCEDURES (Refer to PART I, ITEM 8 on Page 2 of this Form)						For the Calculation of MILK PLANT SAMPLING PROCEDURES (Refer to PART II, ITEM 8 on Page 2 of this Form)								
Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	
1	Sampling surveillance officers properly certified				5		1	Sampling surveillance officers properly certified	2	2	100	5	5	
2	Adequate training program provided				5		2	Adequate training program provided	1	1	100	5	5	
3	Sampling surveillance authority properly delegated				10		3	Sampling surveillance authority properly delegated	2	2	100	10	10	
4	All samplers hold a valid permit				10		4	All samplers hold a valid permit	N/A	N/A	N/A		N/A	
5	Samplers evaluated every two (2) years and reports properly filed				30		5	Samplers evaluated every two (2) years and reports properly filed	8	6	75	30	22.5	
6	Sampling procedures in substantial compliance				15		6	Sampling procedures in substantial compliance	6	6	100	15	15	
7	Permit suspension, etc., taken as required				15		7	Permit suspension, etc., taken as required	N/A	N/A	N/A		N/A	
8	Records systematically maintained and current				10		8	Records systematically maintained and current	10	10	100	10	10	
						100							75	
TOTAL CREDIT							TOTAL CREDIT						67.50	
REMARKS														
Calculation of the Score for the Milk Plant: $67.50/75 \times 100 = 90.00 = 90$														
NOTE: Items 4 and 7 above are not applicable when calculating Milk Plant Sampling Procedures (Part II, Item 8 from Section B, "Report of Enforcement Methods" on Page 2 of this Form). Calculation of the Score: Divide the TOTAL CREDIT by seventy-five (75)* for milk plants, receiving stations (RS) and transfer stations (TR). * Then multiply by 100 to create a percentage. FINAL TOTAL CREDIT (Milk Plant, RS or TR) 90														
REMARKS														
5 - One (1) of two (2) State Regulatory Officials, who collects samples at this plant, and one (1) of six (6) milk plant receiving personnel, who samples incoming tankers, have not been evaluated in the last two (2) years. 8 - Add the Number Inspected under #'s 3 and 5 to arrive at total for the Number Inspected to enter in #8 (10).														

4. FORM NCIMS 2359j-MILK SANITATION RATING REPORT-SECTION E. MILK PLANT
ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 5) (EXAMPLE: MILK PLANT
ONLY-PART II, ITEMS 9 AND 10)

MILK SANITATION RATING REPORT

(Example: Milk Plant Only)

**SECTION E. MILK PLANT ENFORCEMENT ACTION
AND RECORDS EVALUATIONS**

SHIPPER Clear Milk Dairy
LOCATION One Milk Road Cowtown, ST 00000
PLANT NUMBER 72-125
INSPECTING AGENCY State Dept. of Health
DATE(S) June 12-13, 2023

The calculations below address Items from Section B. REPORT OF ENFORCEMENT METHODS on Page 2 of this Form.															
For the Calculation of MILK PLANT ENFORCEMENT PROCEDURES (Refer to PART II, ITEM 9 on Page 2 of this Form)							For the Calculation of MILK PLANT RECORDS (Refer to PART II, ITEM 10 on Page 2 of this Form)								
Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit		
1	Category I - Permit Issuance	1	1	100	20	20	1	Category I - Permit Records	1	1	100	25	25		
2	Category II - Permit Suspension	1	0	0	20	0	2	Category II - Inspection/Equipment Records	1	0	0	25	0		
3	Category III - Permit Revocation	1	1	100	20	20	3	Category III - Laboratory Records (Also Containers/Vitamin Volume Control)	1	1	100	25	25		
4	Category IV - Permit Reinstatement	1	1	100	20	20	4	Category IV - Plan Review Files (Within Rating Period)	1	1	100	25	25		
5	Category V - Hearing/Court Action	1	1	100	20	20							100		
						100							TOTAL CREDIT	75	
						TOTAL CREDIT	80							TOTAL CREDIT to be entered into PART II, Item 10 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.	
REMARKS							REMARKS								
2. Permit was not suspended on 3 of 5 samples (3/15/22). (Category II - Permit Suspension)							2. Last Inspection report (5/13/23) was missing from the regulatory files; however, it was available and reviewed at the milk plant. (Category II - Inspection Records).								

5. FORM NCIMS 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2) (EXAMPLE: MULTIPLE FARM BTU AND RECEIVING STATION)

MILK SANITATION RATING REPORT

SHIPPER Clear Milk Coop (BTU)-RS

DATE OF RATING June 14-16, 2023

(Example: Multiple Farm BTU and Receiving Station)

SECTION B. REPORT OF ENFORCEMENT METHODS

ENFORCEMENT RATING 91

DAIRY FARMS PART I						MILK PLANT PART II						INDIVIDUAL SHIPPER RATING PART III															
Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit				
1	3	All dairy farmers hold a valid permit	35	35	100	5.5	5.5	1	3	All milk plant, receiving station and transfer station operators hold a valid permit				5	5	1		Enter TOTAL CREDIT from PART I under Percent Complying			90.97	47	42.29				
2	5	All dairy farms inspected once every six (6) months or as required in Appendix "P"	35	30	86	15.5	12.4	2	5	Milk plant and receiving station(s) inspected once every three (3) months; aseptic and retort milk plant and transfer station(s) once every six (6) months	0	0	0	15	11.25	2		Enter TOTAL CREDIT from PART II under Percent Complying			90.97	47 / 94	42.81				
3	5	Inspection sheet posted or available	35	35	100	5.5	5.5	3	5	Inspection sheet posted or available				5	5	3	4	All milk and milk products properly labeled	1	1	100	5	5				
4	7	Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections	35	30	86	10.5	8.4	4	7	Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections	1	0	0	10	0	TOTAL CREDIT, PART III						90.9					
5	8	TB & Brucellosis Certification on file as required				10.5	10.5	5	7	Pasteurization equipment tested at required frequency (Not required for aseptic and retort milk plants.)	NA	NA	NA	15	NA	INDIVIDUAL SHIPPER ENFORCEMENT RATINGS INDIVIDUAL SHIPPER OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING: • Without Milk Plant, Receiving Station or Transfer Station: – Evaluate all items PART I and record. • With Receiving Station(s) or Transfer Station(s): – Evaluate all items PART I. – Evaluate all items PART II, except Numbers 5 and 7. Divide by 75. – Evaluate all items PART III. INDIVIDUAL SHIPPER OF PASTEURIZED MILK AND MILK PRODUCTS: • Aseptic and Retort Milk Plants: – Evaluate all items PART II, except Number 5. Divide by 85. • With Unattached Raw Supply: – Evaluate all items PART II, use 94 Weight. – Evaluate all items PART III, except Number 1. • With Attached Raw Supply: – Evaluate all items PART I. – Evaluate all items PART II, use 47 Weight. – Evaluate all items PART III.											
6	7	Water samples tested and reports on file as required	35	35	100	5.5	5.5	6	7	Individual and cooling water samples tested and reports on file as required	0	0	0	5	3.75												
7	6	At least four (4) samples collected from each dairy farm's supply every six (6) months and all necessary laboratory examinations made	35	30	86	10.5	8.4	7	6	Samples of each milk plant's milk and milk products collected at required frequency and all necessary laboratory examinations made	NA	NA	NA	10	NA												
8	6 App B	Sampling procedures approved by PHS/FDA evaluation methods	1	0	0	10.5	0.31	8	6 App B	Sampling procedures approved by PHS/FDA evaluation methods	1	0	0	10	0												
9	3, 5 6, 10	Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required	1	0	0	15.5	15.19	9	3, 5 6, 10	Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required	1	1	100	15	15												
10		Records systematically maintained and current	1	0	0	10.5	10.29	10		Records systematically maintained and current	1	1	100	10	10												
TOTAL CREDIT, PART I								88.076 x 100=90.87								TOTAL CREDIT, PART II								68			
REMARKS								REMARKS								REMARKS											
2. Minimum inspection interval was not met on five (5) dairy farms. (Dairy Farms #3, 7, 9, 11 and 18) 4. Significant violations existing during the last inspection that were not marked at five (5) dairy farms on their previous inspection sheet. (Dairy Farms #1-Item 8a; #6-Items 2a & 2b; #10-Item 9d; #14 - Item 7a; and #20-Item 16a).								8. Insufficient number of samples collected from five (5) dairy farms. (Dairy Farms #2, 8, 12, 15 and 19) 9. Refer to Section C. Evaluation of Sampling Procedures on Page 70. 10. Refer to Section D. Dairy Farm Enforcement Action and Records Evaluations on Page 71. 11. Refer to Section D. Dairy Farm Enforcement Action and Records Evaluations on Page 71.								Part II Remarks 2. Two inspection frequencies missing (9/2021 and 2/2022). 4. Violations of 15b(c) (5pts) and 17d (5pts) existed but were not marked on the last inspection. 5. Recirculated cooling water sampling frequency was missing twice (5/2022 and 1/2023). 8. Refer to Section C. Evaluation of Sampling Procedures on Page 70. 9 and 10. Refer to Section E. Milk Plant Enforcement and Records Evaluations on Page 72.											

6. FORM NCIMS 2359j-MILK SANITATION RATING REPORT-SECTION C. EVALUATION OF SAMPLING PROCEDURES (PAGE 3) (EXAMPLE: MULTIPLE FARM BTU AND RECEIVING STATION-Part I, Item 9 and Part II, Item 8)

MILK SANITATION RATING REPORT

SECTION C. EVALUATION OF SAMPLING PROCEDURES

(Example: Multiple Farm BTU and Receiving Station)

SHIPPER Clear Milk Coop (BTU)-RS		The calculations below address Items from Section B. REPORT OF ENFORCEMENT METHODS on Page 2 of this Form.														
LOCATION Two Milk Road Cowtown, ST 00001		For the Calculation of DAIRY FARM SAMPLING PROCEDURES (Refer to PART I, ITEM 8 on Page 2 of this Form)						For the Calculation of MILK PLANT SAMPLING PROCEDURES (Refer to PART II, ITEM 8 on Page 2 of this Form)								
		Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	
BTU / PLANT NUMBER 72-122 / 72-152		1	Sampling surveillance officers properly certified	2	2	100	5	5.0	1	Sampling surveillance officers properly certified	2	2	100	5	5	
INSPECTING AGENCY State Dept. of Health		2	Adequate training program provided	1	1	100	5	5.0	2	Adequate training program provided	1	1	100	5	5	
DATE(S) June 14-16, 2023		3	Sampling surveillance authority properly delegated	2	2	100	10	10	3	Sampling surveillance authority properly delegated	2	2	100	10	10	
		4	All samplers hold a valid permit	12	8	66.7	10	6.7	4	All samplers hold a valid permit	N/A	N/A	N/A		N/A	
		5	Samplers evaluated every two (2) years and reports properly filed	12	6	50	30	15	5	Samplers evaluated every two (2) years and reports properly filed	4	3	75.0	30	22.5	
		6	Sampling procedures in substantial compliance	6	5	83.3	15	12.5	6	Sampling procedures in substantial compliance	3	3	100	15	15	
		7	Permit suspension, etc., taken as required	12	12	100	15	15	7	Permit suspension, etc., taken as required	N/A	N/A	N/A		N/A	
		8	Records systematically maintained and current	14	14	100	10	10	8	Records systematically maintained and current	6	6	100	10	10	
		100							75							
		TOTAL CREDIT ▶ 79.17							TOTAL CREDIT ▶ 67.50							
		REMARKS 4. Eleven (11) bulk milk hauler/samplers were identified from weight tickets found at the dairy farms from the previous thirty (30) days plus one (1) field person who takes somatic cell count reinstatement samples. Three (3) "weekend" haulers and the field person were not permitted. 5. In addition to the four (4) individuals identified in #4, two (2) permitted bulk milk hauler/samplers were not evaluated in the last two (2) years. 6. One (1) of the samplers that had been evaluated was observed committing the following violations: Failing to sanitize the thermometer that was used to check the temperature of the milk, sampling the milk before the required agitation time had elapsed, filling the sample container over the open tank, and not taking a temperature control at the first stop. 8. Add the Number of Inspected under #'s 3 and 5 to arrive at the total for the Number Inspected to enter into #8 (14).														
		NOTE: Items 4 and 7 above are not applicable when calculating Milk Plant Sampling Procedures (Part II, Item 8 from Section B, "Report of Enforcement Methods" on Page 2 of this Form). Calculation of the Score: Divide the TOTAL CREDIT by seventy-five (75)* for milk plants, receiving stations (RS) and transfer stations (TR). * Then multiply by 100 to create a percentage. FINAL TOTAL CREDIT (Milk Plant, RS or TR) ▶ 90														
		REMARKS 5. One (1) evening/weekend receiver had not been evaluated in the last two (2) years. 8. Add the Number Inspected under #'s 3 and 5 to arrive at a total for the Number Inspected to enter in #8 (6).														

7. FORM NCIMS 2359j-MILK SANITATION RATING REPORT-SECTION D. DAIRY FARM
ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 4) (EXAMPLE: MULTIPLE
FARM BTU-Part I, Items 9 and 10)

MILK SANITATION RATING REPORT

(Example: Multiple Farm BTU and Receiving Station)

**SECTION D. DAIRY FARM ENFORCEMENT ACTION
AND RECORDS EVALUATIONS**

SHIPPER Clear Milk Coop (BTU)-RS
LOCATION Two Milk Road Cowtown, ST 00001
BTU NUMBER 72-122 / 72-152
INSPECTING AGENCY State Dept. of Health
DATE(S) June 14-16, 2023

The calculations below address Items from Section B. REPORT OF ENFORCEMENT METHODS on Page 2 of this Form.													
For the Calculation of DAIRY FARM ENFORCEMENT PROCEDURES (Refer to PART I, ITEM 9 on Page 2 of this Form)							For the Calculation of DAIRY FARM RECORDS (Refer to PART 1, ITEM 10 on Page 2 of this Form)						
Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	Category I - Permit Issuance	25	25	100	20	20	1	Category I - Permit Records	25	25	100	25	25
2	Category II - Permit Suspension	25	22	88	20	17.6	2	Category II - Inspection Records	25	23	92	25	23
3	Category III - Permit Revocation	25	25	100	20	20	3	Category III - Laboratory Records	25	25	100	25	25
4	Category IV - Permit Reinstatement	25	25	100	20	20	4	Category IV - Plan Review Files (Within Rating Period)	25	25	100	25	25
5	Category V - Hearing/Court Action	25	25	100	20	20						100	98
						100	97.6	TOTAL CREDIT					98
TOTAL CREDIT						98	TOTAL CREDIT to be entered into PART I, Item 10 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.						
REMARKS							REMARKS						
2. Regulatory action not properly taken on three (3) dairy farms. (Dairy Farms #4-Item 6-3X; #15-Item 2a-4X; and #17-Item 8a-3X). (Category II - Permit Suspension).							2. Inspection results were not up to date for two (2) dairy farms on their individual ledgers. (Dairy Farm #5 and #16) (Category II - Inspection Records)						

8. FORM NCIMS 2359j-MILK SANITATION RATING REPORT-SECTION E. MILK PLANT
ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 5) (EXAMPLE: RECEIVING
STATION-Part II, Items 9 and 10)

MILK SANITATION RATING REPORT

(Example: Multiple Farm BTU and Receiving Station)

**SECTION E. MILK PLANT ENFORCEMENT ACTION
AND RECORDS EVALUATIONS**

SHIPPER Clear Milk Coop (BTU)-RS
LOCATION Two Milk Road Cowntown, ST 00001
PLANT NUMBER 72-122
INSPECTING AGENCY State Dept. of Health
DATE(S) June 14-16, 2023

The calculations below address Items from Section B. REPORT OF ENFORCEMENT METHODS on Page 2 of this Form.														
For the Calculation of MILK PLANT ENFORCEMENT PROCEDURES (Refer to PART II, ITEM 9 on Page 2 of this Form)							For the Calculation of MILK PLANT RECORDS (Refer to PART II, ITEM 10 on Page 2 of this Form)							
Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	
1	Category I - Permit Issuance	1	1	100	20	20	1	Category I - Permit Records	1	1	100	25	25	
2	Category II - Permit Suspension	1	1	100	20	20	2	Category II - Inspection/Equipment Records	1	1	100	25	25	
3	Category III - Permit Revocation	1	1	100	20	20	3	Category III - Laboratory Records (Also Containers/Vitamin Volume Control)	1	1	100	25	25	
4	Category IV - Permit Reinstatement	1	1	100	20	20	4	Category IV - Plan Review Files (Within Rating Period)	1	1	100	25	25	
5	Category V - Hearing/Court Action	1	1	100	20	20							100	
						100							100	
						TOTAL CREDIT							TOTAL CREDIT	100
TOTAL CREDIT to be entered into PART II, Item 9 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.							TOTAL CREDIT to be entered into PART II, Item 10 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.							
REMARKS							REMARKS							
No Debits Observed							No Debits Observed							

9. FORM NCIMS 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2) (EXAMPLE: SINGLE FARMS BTU)

MILK SANITATION RATING REPORT

SHIPPER United Dairy (BTU)

DATE OF RATING June 16, 2023

(Example: Single Farm BTU)

SECTION B. REPORT OF ENFORCEMENT METHODS

ENFORCEMENT RATING 75

DAIRY FARMS PART I						MILK PLANT PART II						INDIVIDUAL SHIPPER RATING PART III											
Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	3	All dairy farmers hold a valid permit	1	1	100	55	5.5	1	3	All milk plant, receiving station and transfer station operators hold a valid permit				5		1		Enter TOTAL CREDIT from PART I under Percent Complying				47	
2	5	All dairy farms inspected once every six (6) months or as required in Appendix "P"	4	3	75	155	11.63	2	5	Milk plant and receiving station(s) inspected once every three (3) months, aseptic and retort milk plant and transfer station(s) once every six (6) months				15		2		Enter TOTAL CREDIT from PART II under Percent Complying				47 / 94	
3	5	Inspection sheet posted or available	1	1	100	55	5.5	3	5	Inspection sheet posted or available				5		3	4	All milk and milk products properly labeled				6	
4	7	Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections	1	.91	91	105	9.56	4	7	Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections				10		TOTAL CREDIT, PART III ▶							
5	8	TB & Brucellosis Certification on file as required				105	10.5	5	7	Pasteurization equipment tested at required frequency (Not required for aseptic and retort milk plants.)				15		INDIVIDUAL SHIPPER ENFORCEMENT RATINGS INDIVIDUAL SHIPPER OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING: • Without Milk Plant, Receiving Station or Transfer Station: – Evaluate all Items PART I. and record. • With Receiving Station(s) or Transfer Station(s): – Evaluate all Items PART I. – Evaluate all Items PART II., except Numbers 5 and 7. Divide by 75. – Evaluate all Items PART III. INDIVIDUAL SHIPPER OF PASTEURIZED MILK AND MILK PRODUCTS: • Aseptic and Retort Milk Plants: – Evaluate all Items PART II., except Number 5. Divide by 85. – Evaluate all Items PART III., except Number 1. • With Unattached Raw Supply: – Evaluate all Items PART II., use 94 Weight. • With Attached Raw Supply: – Evaluate all Items PART I. – Evaluate all Items PART II., use 47 Weight. – Evaluate all Items PART III.							
6	7	Water samples tested and reports on file as required	5	4	80	55	4.4	6	7	Individual and cooling water samples tested and reports on file as required				5									
7	6	At least four (4) samples collected from each dairy farm's supply every six (6) months and all necessary laboratory examinations made	1	0	0	105	0	7	6	Samples of each milk plant's milk and milk products collected at required frequency and all necessary laboratory examinations made				10									
8	6 App B	Sampling procedures approved by PHS/FDA evaluation methods	1	1	100	105	10.5	8	6 App B	Sampling procedures approved by PHS/FDA evaluation methods				10									
9	3, 5, 6, 16	Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required	1	.6	60	155	9.3	9	3, 5, 6, 16	Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required				15									
10		Records systematically maintained and current	1	.75	75	105	7.88	10		Records systematically maintained and current				10									
TOTAL CREDIT, PART I ▶								TOTAL CREDIT, PART II ▶															
REMARKS								REMARKS								REMARKS							
2. One inspection frequency missed. (4/2023) 4. Violations: 2a (1 pt), 14 (3 pts) and 8c (5 pts) existing but were not marked on the last inspection.								6. Recirculated cooling water sampling frequency was missed once in the two-year period. (6/2022) {Farm - 1 recirculated cooling (RC) water system and 1 well water (WW) system (4RC + 1 WW = 5 Total Samples.) 7. Insufficient number of samples were collected and analyzed. (July-December 2022)								9. Refer to Section C. Evaluation of Sampling Procedures. 10. Refer to Section D. Dairy Farm Enforcement Action and Records Evaluations on Page 74. 11. Refer to Section D. Dairy Farm Enforcement Action and Records Evaluations on Page 74.							

10. FORM NCIMS 2359j-MILK SANITATION RATING REPORT-SECTION D. DAIRY FARM
ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 4) (EXAMPLE: SINGLE
FARM BTU-Part I, Items 9 and 10)

MILK SANITATION RATING REPORT

(Example: Single Farm BTU)

**SECTION D. DAIRY FARM ENFORCEMENT ACTION
AND RECORDS EVALUATIONS**

SHIPPER United Dairy (BTU)
LOCATION 100 Dairy Lane Bossy, ST 00009
BTU NUMBER 90-100
INSPECTING AGENCY State Depart. of Health
DATE(S) June 16, 2023

The calculations below address Items from Section B. REPORT OF ENFORCEMENT METHODS on Page 2 of this Form.															
For the Calculation of DAIRY FARM ENFORCEMENT PROCEDURES (Refer to PART I, ITEM 9 on Page 2 of this Form)							For the Calculation of DAIRY FARM RECORDS (Refer to PART 1, ITEM 10 on Page 2 of this Form)								
Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit		
1	Category I - Permit Issuance	1	0	0	20	0	1	Category I - Permit Records	1	1	100	25	25		
2	Category II - Permit Suspension	1	0	0	20	0	2	Category II - Inspection Records	1	1	100	25	25		
3	Category III - Permit Revocation	1	1	100	20	20	3	Category III - Laboratory Records	1	0	0	25	0		
4	Category IV - Permit Reinstatement	1	1	100	20	20	4	Category IV - Plan Review Files (Within Rating Period)	1	1	100	25	25		
5	Category V - Hearing/Court Action	1	1	100	20	20							100	75	
						100	60							TOTAL CREDIT	75
						TOTAL CREDIT	60							TOTAL CREDIT to be entered into PART I, Item 10 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.	
TOTAL CREDIT to be entered into PART I, Item 9 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.							TOTAL CREDIT to be entered into PART I, Item 10 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.								
REMARKS							REMARKS								
1. Dairy farm was not inspected prior to issuing a permit. (Category I – Permit Issuance) 2. A warning letter was not issued on 2 of 4 samples exceeding the standard for SPC (10/31/2022). (Category II – Permit Suspension)							3. Laboratory records for SSC and SPC were not maintained on ledgers. However, the samples were collected/analyzed and verified from the lab reports. (Category III - Laboratory Records)								

11. FORM NCIMS 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2) (EXAMPLE: MULTIPLE FARM BTU)

MILK SANITATION RATING REPORT

SHIPPER Great Cows BTU

DATE OF RATING August 10-12, 2023

(Example: Multiple Farm BTU)

SECTION B. REPORT OF ENFORCEMENT METHODS

ENFORCEMENT RATING 90

DAIRY FARMS PART I							MILK PLANT PART II							INDIVIDUAL SHIPPER RATING PART III									
Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	3	All dairy farmers hold a valid permit	25	25	100	5.5	5.5	1	3	All milk plant, receiving station and transfer station operators hold a valid permit				5		1		Enter TOTAL CREDIT from PART I under Percent Complying				47	
2	5	All dairy farms inspected once every six (6) months or as required in Appendix "P"	25	20	80	15.5	12.4	2	5	Milk plant and receiving station(s) inspected once every three (3) months; aseptic and retort milk plant and transfer station(s) once every six (6) months				15		2		Enter TOTAL CREDIT from PART II under Percent Complying				47 / 94	
3	5	Inspection sheet posted or available	25	25	100	5.5	5.5	3	5	Inspection sheet posted or available				5		3	4	All milk and milk products properly labeled				6	
4	7	Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections	25	19	76	10.5	7.98	4	7	Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections				10		TOTAL CREDIT, PART III							
5	8	TB & Brucellosis Certification on file as required				10.5	10.5	5	7	Pasteurization equipment tested at required frequency (Not required for aseptic and retort milk plants.)				15		INDIVIDUAL SHIPPER ENFORCEMENT RATINGS INDIVIDUAL SHIPPER OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING: • Without Milk Plant, Receiving Station or Transfer Station: – Evaluate all Items PART I. and record. • With Receiving Station(s) or Transfer Station(s): – Evaluate all Items PART I. – Evaluate all Items PART II., except Numbers 5 and 7. Divide by 75. – Evaluate all Items PART III. INDIVIDUAL SHIPPER OF PASTEURIZED MILK AND MILK PRODUCTS: • Aseptic and Retort Milk Plants: – Evaluate all Items PART II., except Number 5. Divide by 85. • With Attached Raw Supply: – Evaluate all Items PART I. – Evaluate all Items PART II., use 47 Weight. – Evaluate all Items PART III. • With Unattached Raw Supply: – Evaluate all Items PART II., use 94 Weight. – Evaluate all Items PART III., except Number 1.							
6	7	Water samples tested and reports on file as required	25	21	84	5.5	4.62	6	7	Individual and cooling water samples tested and reports on file as required				5									
7	6	At least four (4) samples collected from each dairy farm's supply every six (6) months and all necessary laboratory examinations made	25	23	92	10.5	9.66	7	6	Samples of each milk plant's milk and milk products collected at required frequency and all necessary laboratory examinations made				10									
8	6 App B	Sampling procedures approved by PHS/FDA evaluation methods	1	791	79.1	10.5	8.31	8	6 App B	Sampling procedures approved by PHS/FDA evaluation methods				10									
9	3, 5, 6, 16	Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required	1	98	98	15.5	15.19	9	3, 5, 6, 16	Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required				15									
10		Records systematically maintained and current	1	98	98	10.5	10.29	10		Records systematically maintained and current				10									
TOTAL CREDIT, PART I							89.95	TOTAL CREDIT, PART II															
REMARKS							REMARKS							REMARKS									
2. Minimum inspection interval not met on five (5) dairy farms. (Dairy Farms #6, 9, 12, 17 and 19).							6. Outdated water samples at four (4) dairy farms. (Dairy Farms #2, 5, 13 and 17)							9. Refer to Section C. Evaluation of Sampling Procedures on Page 70.									
4. Violations existing on six (6) dairy farms during the last inspection and were not marked on the last inspection sheets. (Dairy Farms #1-Item 5 floors; #4-Item 7; #10-Item 19c; #11-Item 8c; #15-Item 9b; and #18-Item 18c)							7. Insufficient samples from two (2) dairy farms. (Dairy Farms #3 and 20).							10. Refer to Section D. Dairy Farm Enforcement Action and Records Evaluations on Page 76.									
														11. Refer to Section D. Dairy Farm Enforcement Action and Records Evaluations on Page 76.									

12. FORM NCIMS 2359j-MILK SANITATION RATING REPORT-SECTION D. DAIRY FARM
ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 4) (EXAMPLE: MULTIPLE
FARM BTU-Part I, Items 9 and 10)

MILK SANITATION RATING REPORT

(Example: Multiple Farm BTU)

**SECTION D. DAIRY FARM ENFORCEMENT ACTION
AND RECORDS EVALUATIONS**

SHIPPER United Dairy (BTU)
LOCATION 100 Dairy Lane Bossy, ST 00009
BTU NUMBER 90-100
INSPECTING AGENCY State Dept of Health
DATE(S) June 16, 2023

The calculations below address Items from Section B. REPORT OF ENFORCEMENT METHODS on Page 2 of this Form.													
For the Calculation of DAIRY FARM ENFORCEMENT PROCEDURES (Refer to PART I, ITEM 9 on Page 2 of this Form)							For the Calculation of DAIRY FARM RECORDS (Refer to PART 1, ITEM 10 on Page 2 of this Form)						
Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	Category I - Permit Issuance	25	25	100	20	20.0	1	Category I - Permit Records	25	25	100	25	25
2	Category II - Permit Suspension	25	22	88	20	17.6	2	Category II - Inspection Records	25	25	100	25	25
3	Category III - Permit Revocation	25	25	100	20	20.0	3	Category III - Laboratory Records	25	23	92	25	23
4	Category IV - Permit Reinstatement	25	25	100	20	20.0	4	Category IV - Plan Review Files (Within Rating Period)	25	25	100	25	25
5	Category V - Hearing/Court Action	25	25	100	20	20.0						100	98
						100	97.6	TOTAL CREDIT ▶					98
TOTAL CREDIT ▶						98	TOTAL CREDIT to be entered into PART I, Item 10 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.						
TOTAL CREDIT to be entered into PART I, Item 9 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.													
REMARKS							REMARKS						
2. Regulatory action not properly taken on three (3) dairy farms. (Dairy Farms #7-Item 3a-4X; #14-Item 16a-3X; and #16-Item 14b-3X) (Category II - Permit Suspension)							3. Drug residue tests not recorded on ledgers for two (2) dairy farms. (Dairy Farms #10 and 22) (Category III - Laboratory Records)						

Shipper Great Cows BTU Date of Rating August 10-12, 2022	NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS	STATUS OF RAW MILK FOR PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF- STABLE PROCESSING AND PACKAGING
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NATIONAL CONFERENCE
ON INTERSTATE MILK
SHIPMENTS

STATUS OF RAW MILK FOR PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING

Sanitation Compliance Rating ¹ **91**FORM NCIMS 2355K (1/26) PAGE-1

CONTINUATION OF THE "STATUS OF RAW MILK FOR PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING " FOR <u>Great Cows BTU</u>																														AS OF <u>August 10-12, 2022</u>									
	ITEM	1		2					3	4	5					6	7	8	9	10	11	12	13	14	15		16	17	18			19				EACT	Total Debits ²	Violative Solds Daily (100 # Units) ³ X Total Debits ⁴	REMARKS
	WEIGHT	5	5*	1	1	1	1	1	3	3	1	1	2	2	2	4	4	2 or 5	4	5	5	2	5	3	2 = (7) - 5		2	1	5 - (5) - 1			3	2	2	2	10*			
Subtotal from Page 1	268	2	2	1	3	1	1	1	7	3	-	2	1	2	-	4	-	6	2	-	-	2	5	1	4	2	1	1	1	-	-	-	1	1	1	108	2510		
18. Henry Ronan	13																			5	5	2													12	150			
19. Smith & Jones	4			1	1	1	1	1	3										4			2	5												16	72			
20. H. Adams	42			1																		2			2										5	210	No vet name on prescription cattle dose.		
21. Joe Lamb	9			1	1																	2												10	14	126	2 of 4 SPC, Last 1 violative		
22. B. Forest	12			1										2																					5	60			
23. Anna Bowers	11				1				3													5													9	99			
24. L.R. Hayser	4																			5		2													7	28			
25. Pete Carson	15				1													5																	6	90	Major water violation		
26.																																							
27.																																							
28.																																							
29.																																							
30.																																							
31.																																							
32.																																							
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36.																																							
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38.																																							
39.																																							
40.																																							
Total or Subtotal	378	2	2	5	7	2	2	1	9	3	-	2	1	3	-	4	-	7	3	2	2	7	6	1	5	2	1	1	1	-	-	1	1	1	2	252	3361		
% of Dairy Farms Violating		8	8	20	28	8	8	4	36	12	0	8	4	12	0	16	0	28	12	8	8	28	24	4	20	8	4	4	4	0	0	4	4	4	8				

Footnotes: ¹Sanitation Compliance Rating = $100 - \frac{\text{Total Pounds Sold Daily (100\# Units)}^3 \times \text{Total Debits}^2}{\text{Total Pounds Sold Daily (100\# Units)}^3}$

²Total Debits for each dairy farm is the sum of the weights of the items violated. (NOTE: Any item violated indicate by placing the debit value (weight) of that item or an "X" under that item.)

³Total Pounds Sold Daily are calculated in 100# Units.

⁴Used only when not in compliance.

COMMENTS

100-3351/378 = 100-8.8 = 91.1 = 91

14. FORM NCIMS 2359L-STATUS OF MILK PLANTS (INCLUDING DRYING AND
CONDENSING MILK PRODUCTS PLANTS, RECEIVING STATIONS AND TRANSFER
STATIONS) (*EXAMPLE: Milk Plant*)

National Conference on
Interstate Milk Shipments

Milk Products Plant I.M.A. DAIRYDate of Rating **September 20-21, 2022**

STATUS OF MILK PLANTS

(INCLUDING DRYING AND CONDENSING MILK PRODUCTS PLANTS,
RECEIVING STATIONS and TRANSFER STATIONS)

Sanitation Compliance Rating ¹

90

NAME OF PLANT (MILK PRODUCT/ PASTEURIZATION/ FILLING AND CAPPING)	Pounds Processed Daily (100# Units) ³	ITEMS OF SANITATION																										Pounds Processed Daily (100# Units) ¹ X Total Debits ²	REMARKS							
		Floors	Walls and Ceilings	Doors and Windows	Lighting	Ventilation	Separate Rooms	Toilet/Sewage Disposal Facilities	Water Supply	Handwashing Facilities	Milk Plant Cleanliness	Sanitary Piping	Containers and Equipment			Storage of Single- Service Articles	Protection From Contamination	Cross Connections	Animal Food - Holding and Distribution	Pasteurization				Bottling Capping		Personnel Cleanliness, Protective Clothing	Vehicles			Surroundings	Bacterial Count*	Coliform Count*	Total Debits ²			
													Construction and Repair	Cleaning	Sanitization					Storage of Clean Equipment	Indicating and Recording Thermometers	Time and Temperature Controls	Adulteration Controls	Regenerative Heating	Temperature Recording Charts									Cooling	Container Filling, Capping and Sealing	
	ITEM	1	2	3	4a	4b	5	6	7	8	9	10	11	12ab	12c-e	13	14	15a	15b	15c	16ab (1)	16b (2)	16c	16d	17	18	19	20	21	22						
	WEIGHT	1	1	2	1	1	3	3	4	2	3	3	3	5	5	3	2	3	5	1	4	15	3	10	4	5		5		1	1	1	5*	10		
I.M.A. Dairy	5,000						3											3														6	30,000			
Buttermilk Vat #1 (15)																						15										15	225	Inlet valve not removed during HT		
C. Cheese Starter Vat (3)																								4								4	12	Air space reading not made at BOTH beginning and end of Holding period		
By-Products HTST (360)																					15		10									25	9,000	Plant operating computer can start the booster pump in divert mode.		
1% Milk (500)																								5								5	10	20	10,000	Insuff # of samples taken in last 6 months
Tub Container (70)																									5								5	350	Hand capping of 5 lb. containers	
Sour Cream (5)																																10	10	50	2 of last 4 coli counts high (last 1 positive)(last 1 violative)	
TOTALS	5,000																																85	49,637	100-49,637/5,000=100-9.9=90.1=90	

Footnotes:

$$^1 \text{Sanitation Compliance Rating} = 100 - \frac{\text{Total Pounds Processed Daily (100\# Units)}^3 \times \text{Total Debits}^2}{\text{Total Pounds Processed Daily (100\# Units)}^3}$$

² Total Debits for each milk plant, receiving station or transfer station are the sum of the weights of the Items violated. (NOTE: Any Item or subitem violated, indicate by placing the debit value (weight) of that Item or an "X" under that Item.)

³ Total Pounds Processed Daily are calculated in 100# Units.

*Used only when not in compliance. Pro-rated by product.

15. FORM NCIMS 2359L-STATUS OF MILK PLANTS (INCLUDING DRYING AND CONDENSING MILK PRODUCTS PLANTS, RECEIVING STATIONS AND TRANSFER STATIONS) (EXAMPLE: MILK PLANT WITH A ATTACHED RECEIVING AND TRANSFER STATION)

National Conference on
Interstate Milk Shipments

Milk Products Plant Metro Dairy Company
Date of Rating October 30-31, 2022

STATUS OF MILK PLANTS
(INCLUDING DRYING AND CONDENSING MILK PRODUCTS PLANTS,
RECEIVING STATIONS AND TRANSFER STATIONS)

Sanitation Compliance Rating ¹ 91

NAME OF PLANT (MILK PRODUCT/ PASTEURIZATION/ FILLING AND CAPPING)	Pounds Processed Daily (100# Units) ³	ITEMS OF SANITATION																										REMARKS							
		Floors	Walls and Ceilings	Doors and Windows	Lighting	Ventilation	Separate Rooms Toilet/Sewage Disposal Facilities	Water Supply	Handwashing Facilities	Milk Plant Cleanliness	Sanitary Piping	Containers and Equipment			Storage of Single- Service Articles	Protection From Contamination	Cross Connections	Animal Food - Holding and Distribution	Pasteurization					Cooling	Bottling Capping	Personnel Cleanliness, Protective Clothing	Vehicles		Surroundings	Bacterial Count*	Coliform Count*	Total Debits ²	Pounds Processed Daily (100# Units) ³ X Total Debits ²		
												Construction and Repair	Cleaning	Sanitization					Storage of Clean Equipment	Indicating and Recording Thermometers Time and Temperature Controls	Adulteration Controls	Regenerative Heating	Temperature Recording Charts											Container Filling, Capping and Sealing	
																																			11
	ITEM	1	2	3	4a	4b	5	6	7	8	9	10	11	12ab	12c-e	13	14	15a	15b	15c	16ab (1)	16b (2)	16c	16d	17	18	19	20	21	22	23	24			
	WEIGHT	1	1	2	1	1	3	3	4	2	3	3	3	5	5	3	2	3	5	1	4	15	3	10	4	5	5	1	1	1	5*	10*			
Metro Dairy Co	1,000												3						5													8	8,000	100-8=92	
Metro RS (680)		1	2								3							3														9		Above 90 (would not be included in Plant Score)	
White Milk TS (220)											3													5					1	2		11		100-11=89 (Below 90)	
																																		(Subtract TS Score from Plant Score)	
																															3	680	92-89=3 x 220 = 680		
TOTALS	1,000																																8,660	100-8,660/1,000=100-8.7=91.3=91	

Footnotes:

¹Sanitation Compliance Rating = 100 - $\frac{\text{Total Pounds Processed Daily (100# Units)} \times \text{Total Debits}^2}{\text{Total Pounds Processed Daily (100# Units)}^3}$

²Total Debits for each milk plant, receiving station or transfer station are the sum of the weights of the Items violated. (NOTE: Any Item or subitem violated, indicate by placing the debit value (weight) of that Item or an "X" under that Item.)

³Total Pounds Processed Daily are calculated in 100# Units.

*Used only when not in compliance. Pro-rated by product.

16. FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		INTERSTATE MILK SHIPPER's REPORT				3-A. COUNTRY USA																									
1. NAME OF SHIPPER Clean Milk Dairy			2. CITY Moosville		3. STATE State 00007																										
4. STREET 2525 Milky Way			5. PLANT or BTU # 0 0 2 5 0		6. PRODUCT CODE #s 1 2 4 5 7 9 - 1 8																										
7. SURVEY DATA																															
PRODUCT	DAIRY FARMS TYPE OF RATING ☐ AREA ☒ INDIVIDUAL	RECEIVING OR TRANSFER STATION	MILK PLANT ¹		ENFORCEMENT																										
RATING (%)	92	NA	91		90																										
DATE OF RATING	8/5-7/2022	NA	8/3-4/2022		8/2/2022																										
TOTAL NUMBER	120	NA	1																												
NUMBER INSPECTED	34	NA	1																												
VOLUME RECEIVED DAILY (Cwt)		NA	9,800																												
APPENDIX N IS THE SHIPPER IN COMPLIANCE WITH THE PROVISIONS OF APPENDIX N? ☒ YES ☐ NO			FSP/PCs WHEN APPLICABLE, IS THE SHIPPER IN COMPLIANCE WITH THE PROVISIONS OF APPENDIX T? ☐ YES ☐ NO																												
RATING AGENCY ☒ SHD ☐ SDL ☐ SDA ☐ TPC ☐ OTHER _____		CERTIFIED RATING OFFICER Mary Milkraater		OFFICER'S CERTIFICATION EXPIRATION DATE Sept. 19, 2023		EARLIEST RATING DATE <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <th colspan="2">MONTH</th> <th colspan="2">DAY</th> <th colspan="2">YEAR</th> </tr> <tr> <td style="text-align: center;">0</td><td style="text-align: center;">8</td> <td style="text-align: center;">0</td><td style="text-align: center;">3</td> <td style="text-align: center;">2</td><td style="text-align: center;">2</td> </tr> </table>		MONTH		DAY		YEAR		0	8	0	3	2	2												
MONTH		DAY		YEAR																											
0	8	0	3	2	2																										
AGENCY PROVIDING CONTINUOUS SUPERVISION OF SUPPLY State Department of Health					EXPIRATION RATING DATE ² <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <th colspan="2">MONTH</th> <th colspan="2">DAY</th> <th colspan="2">YEAR</th> </tr> <tr> <td style="text-align: center;">0</td><td style="text-align: center;">8</td> <td style="text-align: center;">3</td><td style="text-align: center;">1</td> <td style="text-align: center;">2</td><td style="text-align: center;">4</td> </tr> </table>			MONTH		DAY		YEAR		0	8	3	1	2	4												
MONTH		DAY		YEAR																											
0	8	3	1	2	4																										
8. LABORATORY CONTROL																															
APPROVED LABORATORY NUMBER A. 00001 B. 00302		EXPIRATION DATE A. 02/2023 B. 09/2023		PROCESSED MILK TESTS APPROVED <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <th>SPC</th><th>COLI</th><th>PHOS</th><th>RBC</th><th>DRUG RESIDUE TESTS</th></tr> <tr> <td>A. 2a</td><td>A. 21a</td><td>A. 28a</td><td>A. 22</td><td>A. 9C2, 9D3</td></tr> <tr> <td>B. _____</td><td>B. _____</td><td>B. _____</td><td>B. _____</td><td>B. _____</td></tr> </table>		SPC	COLI	PHOS	RBC	DRUG RESIDUE TESTS	A. 2a	A. 21a	A. 28a	A. 22	A. 9C2, 9D3	B. _____	B. _____	B. _____	B. _____	B. _____	RAW MILK TESTS APPROVED <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <th>VIABLE COUNTS</th><th>SOMATIC CELL COUNTS</th><th>DRUG RESIDUE TESTS</th></tr> <tr> <td>A. 2</td><td>A. 12</td><td>A. 9C2, 9D3</td></tr> <tr> <td>B. 3</td><td>B. 16</td><td>B. _____</td></tr> </table>		VIABLE COUNTS	SOMATIC CELL COUNTS	DRUG RESIDUE TESTS	A. 2	A. 12	A. 9C2, 9D3	B. 3	B. 16	B. _____
SPC	COLI	PHOS	RBC	DRUG RESIDUE TESTS																											
A. 2a	A. 21a	A. 28a	A. 22	A. 9C2, 9D3																											
B. _____	B. _____	B. _____	B. _____	B. _____																											
VIABLE COUNTS	SOMATIC CELL COUNTS	DRUG RESIDUE TESTS																													
A. 2	A. 12	A. 9C2, 9D3																													
B. 3	B. 16	B. _____																													
DATE OF LAST TWO (2) SPLIT SAMPLES A. 09/2021 A. 04/2022 B. 04/2020 B. 09/2021				APPROVED WATER LABORATORY AND DATE State Health Dept. Lab (State EPA) 10/2020		WATER TESTS APPROVED 24-MPN																									
9. PUBLICATION (Written permission from a shipper shall be on file at the Regulatory/Rating Office prior to the publication of rating/listing.)																															
WRITTEN PERMISSION FROM SHIPPER DATED 8/10/2022 ON FILE? ☒ YES ☐ NO																															
10. SUBMISSION OF REPORT BY RATING AGENCY																															
DATE OF REPORT 8/10/2022		SUBMITTED BY (Signature) 				Title Milk Sanitation Rating Officer																									
¹ Submit separate Form for each milk plant. ² The expiration rating date is two (2) years after the earliest rating date, plus the remaining days of the month, i.e., earliest rating date is 10/1/2023 with a corresponding expiration rating date of 10/31/2025, except if the Enforcement Rating is <90, then the expiration rating date is six (6) months after the earliest rating date, i.e., earliest rating date is 10/1/2021 with a corresponding expiration rating date of 4/30/2022.																															

FOR FDA OFFICE USE ONLY

Written permission from shipper dated 8/10/22 on file and publication of rating/listing recommended.

DATE _____

8/10/22

SIGNATURE (FDA Milk Specialist)

11. **MILK PLANTS:** List below the Name and Address of all shippers of raw milk and milk products received during the thirty (30) days preceding the earliest rating date of the Rating; Sanitation Compliance Rating; and Expiration Rating Date. Plants receiving milk from an unlisted source(s), or source(s) with a Sanitation Compliance Rating below ninety (90), are not eligible for listing in the electronic publication, *IMS LIST – SANITATION COMPLIANCE AND ENFORCEMENT RATINGS OF INTERSTATE MILK SHIPPERS*.

[illegible]

INSTRUCTIONS:

Completed Forms shall be received by the Milk Safety Team (HFS-316) to be included in the IMS List. Additional explanation is offered for the following Items:

Item 1: Name of Shipper – Limit shipper's name to not more than thirty-four (34) characters and spaces. If a receiving or transfer station is to be listed, please include "Receiving Station" or "Transfer Station" or "(RS)" or "(TS)" with the name of the shipper. Suggested abbreviations are published in the IMS List.

Item 5: Plant or BTU # – When the IMS Number is less than five (5) digits, leave the left-hand square(s) blank.

Item 6: Product Code #'s – Enter Product Code #'s starting in the first (left-hand) space. Product Code #'s are listed below:

PRODUCT CODES:

1. Raw Milk for Pasteurization (May Include Lowfat, Skim or Cream)
2. Pasteurized Milk, Reduced Fat, Lowfat, or Skim
3. Heat-Treated (May Include Reduced Fat, Lowfat, Skim or Cream)
4. Pasteurized Half & Half, Coffee Cream, Creams
5. Ultra-Pasteurized (UP) Milk and Milk Products
6. Aseptic or Retort Milk and Milk Products (Including Flavored)
7. Cottage Cheese (Including Lowfat, Nonfat or Dry Curd)
8. Cultured or Acidified Milk and Milk Products
9. Yogurt (Including Lowfat or Skim)
10. Sour Cream Products (Acidified or Cultured)
11. Whey (Liquid)
12. Whey (Condensed)
13. Whey (Dry)
14. Modified Whey Products (Condensed or Dry)
15. Condensed Milk and Milk Products
16. Nonfat Dry Milk
17. Buttermilk (Condensed or Dry)
18. Eggnog
19. Lactose Reduced Milk and Milk Products
20. Low-Sodium Milk and Milk Products
21. Milk and Milk Products with Added Safe and Suitable Microbial Organisms
(Such as *Lactobacillus acidophilus*)
22. Dry Milk and Milk Products
23. Anhydrous Milk Fat
24. Cholesterol Modified Anhydrous Milk Fat
25. Cholesterol Modified Fluid Milk Products
26. Cream (Condensed or Dry)
27. Blended Dry Products
28. Whey Cream
29. Whey Cream and Cream Blends
30. Grade "A" Lactose
31. Raw Goat Milk for Pasteurization
32. Pasteurized Goat Milk and Milk Products
33. Cultured Goat Milk and Milk Products
34. Condensed or Dry Goat Milk and Milk Products
35. Ultra-Pasteurized (UP) Goat Milk and Milk Products
36. Aseptic Goat Milk and Milk Products
37. Raw Sheep Milk for Pasteurization
38. Pasteurized Sheep Milk and Milk Products
39. Cultured Sheep Milk and Milk Products
40. Concentrated Raw Milk Products for Pasteurization
41. Concentrated Pasteurized Milk Products
42. Ultrafiltered Permeate from Milk
43. Ultrafiltered Permeate from Whey
44. Raw Water Buffalo Milk for Pasteurization
45. Pasteurized Water Buffalo Milk and Milk Products
46. Cultured Water Buffalo Milk and Milk Products
47. Raw Camel Milk for Pasteurization
48. Pasteurized Camel Milk and Milk Products
49. Cultured Camel Milk and Milk Products

FORM FDA 2359j (1/26)

FORM NCIMS 2359m (10/23)

Page 1

Milk Plant, Receiving Station or Transfer Station – NCIMS HACCP SYSTEM AUDIT REPORT

ITEMS MARKED DID NOT MEET THE NCIMS HACCP PROGRAM CRITERIA DESCRIBED BELOW
Starred ★★ Items are Critical Listing Elements

Section 8 HACCP SYSTEM RECORDS

- ☐ A. Required information included in the record, e.g., name/location of processor and/or date/time of activity and/or signature/initials of person performing operation and/or identity of product/product code.
- ☐ B. Processing/other information entered on record at time observed.
- ☐ C. Records retained for 2 years.
- ☐ D. Records relating to adequacy of equipment or processes retained for 2 years.
- ☐ E. HACCP records correct, complete and available for official review.
- ☐ F. Information on HACCP records not falsified.**
- ☐ G. Requirements in 21 CFR 117 Subpart F are addressed.

Section 9 HACCP SYSTEM PREREQUISITE PROGRAMS (PPs)

- ☐ A. Required PP written, implemented, and in substantial compliance by firm.
 - ☐ 1. Safety of the water that comes into contact with milk or milk contact surfaces (including steam and ice);
 - ☒ 2. Condition and cleanliness of equipment milk contact surfaces;
 - ☐ 3. Prevention of cross contamination from unsanitary objects and/or practices to milk and milk products, packaging material and other milk contact surfaces, including utensils, gloves, outer garments, etc., and from raw product to processed product;
 - ☐ 4. Maintenance of hand washing, hand sanitizing, and toilet facilities;
 - ☐ 5. Protection of milk and milk product, milk packaging material, and milk contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate and other chemical, physical and biological contaminants;
 - ☐ 6. Proper labeling, storage, and use of toxic compounds;
 - ☐ 7. Control of employee health conditions that could result in the microbiological contamination of milk and milk products, milk packaging materials, and milk contact surfaces; and
 - ☐ 8. Pest exclusion from the milk plant, receiving station, or transfer station.
 - ☐ 9. Requirements in 21 CFR 117 Subparts A and B are addressed.
- ☐ B. Additional PP's required or justified by the hazard analysis are written and implemented by firm.
- ☒ C. PP conditions and practices monitored as required.
- ☐ D. PP monitoring performed at a frequency to ensure conformance.
- ☐ E. Corrections performed in a timely manner when PP monitoring records reflect deficiencies or non-conformities.
- ☒ F. PP audited by firm.
- ☐ G. PP monitoring records adequately reflect conditions observed.
- ☐ H. PP signed and dated as required.

Section 10 OTHER NCIMS REQUIREMENTS

- ☐ A. Incoming milk supply from NCIMS listed source(s) with sanitation scores of 90 or better or acceptable HACCP Listing.**
- ☐ B. Drug residue control program implemented.**
- ☐ C. Drug residue control program records complete.
- ☐ D. Labeling compliance as required.
- ☐ E. Prevention of adulteration of milk products.
- ☐ F. Regulatory samples comply with standards.
- ☐ G. Pasteurization Equipment design and construction.
- ☐ H. Approved Laboratory Utilized - (if not, Rating not conducted).
- ☐ I. Substantially compliant on the following items as outlined in Appendix T.
 - ☐ 1. Written Recall Plan;
 - ☐ 2. Written Risk Based Supply-Chain Program
 - ☐ 3. Written Environmental Monitoring Program; and
 - ☐ 4. All other applicable requirements
- ☐ J. Holding and Distribution of Human Food By-Products for use as Animal Food.
- ☐ K. Other items as noted.

Section 11 HACCP SYSTEM TRAINING (Individuals trained according to Appendix K or alternatively have equivalent job experience.)

- ☐ A. PPs developed by trained personnel.
- ☐ B. Hazard Analysis developed by trained personnel.
- ☐ C. HACCP Plan developed by trained personnel.
- ☒ D. HACCP Plan validation, modification or reassessment performed by trained personnel.
- ☐ E. HACCP Plan records review performed by trained individual.
- ☐ F. Employees trained in monitoring operations.
- ☐ G. Employees trained in PP operations and food hygiene.
- ☐ H. Records that document training shall be established, maintained and retained at the milk plant for at least two(2) years after the date they are prepared.

Section 12 HACCP SYSTEM AUDIT FOLLOW-UP ACTION

- ☐ A. Previous audit findings corrected.
- ☐ B. Previous audit findings remain corrected at time of this audit.
- ☐ C. STATE MILK PLANT, RECEIVING STATION OR TRANSFER STATION HACCP SYSTEM AUDIT REPORT issued and follow-up conducted as required (HACCP Listing Audits and FDA Audits only).
- ☐ D. A series of observations that lead to a finding of a potential HACCP System failure that is likely to result in a compromised to milk or milk product safety**

Refer to attached Audit Discussion sheet(s) for details.

NCIMS HACCP SYSTEM AUDIT REPORT DISCUSSION SHEET

FIRM NAME

My HACCP Dairy Plant

DATE OF AUDIT

January 23-25, 2023

EXPLANATION OF DEVIATIONS/DEFICIENCIES/NON-CONFORMITIES THAT DID NOT MEET THE NCIMS HACCP PROGRAM CRITERIA

(Use additional sheets as necessary if entry field is non-expandable.)

NOTE: When Regulatory Audits are conducted, timelines for corrections of all identified deviations, deficiencies and non-conformities shall be established.

Section 1.C - The firm has failed to reassess the hazard analysis after changes in raw materials, formulations, processing methods/systems, distribution, and intended use or consumer as evidenced by the lack of the hazard analysis being reviewed and re-dated after the 6/2022 addition of a new ingredient, chocolate slurry, and again after the case washing area was relocated 7/21/2022. The current hazard analysis documented and signed is dated 3/15/2021.

Section 9.A.2. - The plant has failed to write and implement required prerequisite programs that are in substantial compliance with the HACCP requirements. Specifically, the plant has failed to monitor and comply with the HACCP requirement for the Condition and Cleanliness of Milk Contact Surfaces of Equipment as evidenced by the following: Product residues were observed in raw silos #1, #2, and #3, blending vat B and tank R7 following CIP; stabilizer residues were observed on the bottom of raw storage tank R16 after it had been cleaned; and there is no brief written description or checklist of monitoring the cleaning effectiveness after cleaning has occurred.

Based upon the equipment cleaning history at this plant, cleaning effectiveness checks shall be addressed in the written prerequisite program.

Section 9.C. & F. - The plant has failed to monitor or audit prerequisite program conditions, as required to ensure conformance. Specifically, the written procedures for CIP of raw silos #1, #2, and #3, blending vat B and tank R7 stipulated an alkali wash at 147°F for 20 minutes. An examination of the CIP charts for those circuits indicated that the temperature of the alkali wash ranged from 118°F to 128°F. There was no evidence that any of the CIP charts were monitored and signed by the operator or verified by the sanitation shift supervisor as required by the prerequisite program. The operator shall monitor, and the sanitation shift supervisor shall verify CIP charts as required by the written prerequisite program.

Section 11.D. - The plant failed to adequately train employees in their responsibilities related to the HACCP System. Specifically the employees operating the CIP systems and their supervisors evaluating the CIP recording charts. (Refer to Section 9.C. & F. comments.)

I.M.A. Milkraiter

18. FORM NCIMS 2359n-NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT

National Conference on Interstate Milk Shipments		NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT (To be included with all NCIMS HACCP Listings and FDA Audits)	
REGULATORY AGENCY State Department of Health		DATE OF EVALUATION January 22-25, 2022	
FIRM NAME My HACCP Dairy Plant	LICENSE/PERMIT NO. 123	IMS PLANT NO. 00-123	
ADDRESS 234 Milk Road, My City, MY 11111			
EXPLANATION OF CONCERNS NOTED REGARDING REGULATORY AGENCY OBLIGATIONS UNDER THE NCIMS HACCP SYSTEM (Use additional sheets if necessary.)			
A narrative description shall be provided as a part of all NCIMS HACCP Listings and FDA Audits, including aseptic and/or retort milk plants with NCIMS HACCP Listings. This report shall include an evaluation of the following requirements:			
1. Milk plant, receiving station or transfer station holds a valid permit. My HACCP Dairy Plant permit #123 is valid. It was issued January 1, 2023 and expires December 31, 2023.			
2. Milk plant, receiving station or transfer station audited by a HACCP trained Regulatory Agency auditor at the minimum required frequency and follow-ups conducted as required. The routine milk plant regulatory audits were conducted at the required frequencies. Follow up audits to verify correction on non-conformities from previous audits are not being conducted until the next routine audit. The last sweet water sample (1/5/23) was violative; therefore, the previous minimum frequency of once each six (6) months has been changed to once each four (4) months. (Note: The follow up sample taken 1/11/23 was satisfactory.)			
3. Requirements interpreted in accordance with the Grade "A" PMO as indicated by past audits. The Regulatory audit made 8/3-5/2020 did not note the need to re-evaluate the hazard analysis after the new chocolate slurry system was installed or after the case washer was moved. The 10/26-28/2020 regulatory audit did not question the equipment plant cleaning prerequisite program even though ongoing problems with equipment cleaning were observed in the plant records and by observation of the regulatory inspector. In the case of such repeated problems, in addition to assuring that the equipment is cleaned before being used again, the Regulatory Agency should be requiring the milk plant to investigate the cause of the problem and modify their HACCP system, if needed, to prevent re-occurrence.			
4. Pasteurization equipment tested at required frequency. (Not applicable to receiving stations, transfer stations, aseptic milk plants and retort milk plants.) All equipment tests were conducted at the required frequencies for HTST #1 and HTST #2.			
5. Individual and cooling water samples tested and reports on file as required. Sweet water and glycol samples were taken at the required frequency and, with the exception of the 1/5/2021 sample, all results were satisfactory.			
6. Samples of milk plant's milk and/or milk products collected at the required frequency and all necessary laboratory examinations made. (Not applicable to receiving and transfer stations.) Only three (3) samples of fat free chocolate milk were taken between March 2022 and September 2022.			
7. Sampling procedures approved by PHS/FDA evaluation methods. One (1) evening/weekend Industry Plant Sampler had not been evaluated in the last two (2) years.			
8. Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required. Two (2) of four (4) high coliform counts for whole milk chocolate were observed (4/6/2021 [Coliform 40] and 6/21/2022 [Coliform 26]), however a warning letter was not sent.			
9. Records systematically maintained and current. Overall, the records are generally up to date and accurate.			

19. FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT (EXAMPLE: NCIMS HACCP LISTING)

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		INTERSTATE MILK SHIPPER's REPORT		3-A. COUNTRY																																	
				USA																																	
1. NAME OF SHIPPER My HACCP Milk Plant			2. CITY My City		3. STATE My 11111																																
4. STREET 234 Milk Road		5. PLANT or BTU # 0 0 1 2 3		6. PRODUCT CODE #s 2 4 7 5 8 9 - 1 8																																	
7. SURVEY DATA																																					
PRODUCT	DAIRY FARMS	RECEIVING OR TRANSFER STATION	MILK PLANT ¹	ENFORCEMENT																																	
	TYPE OF RATING ☒ AREA ☐ INDIVIDUAL																																				
RATING (%)	90	NA	HACCP Listing Acceptable	Acceptable																																	
DATE OF RATING		NA	1/23-25/2022																																		
TOTAL NUMBER		NA	1																																		
NUMBER INSPECTED		NA	1																																		
VOLUME RECEIVED DAILY (Cwt)		NA	9,800																																		
APPENDIX N IS THE SHIPPER IN COMPLIANCE WITH THE PROVISIONS OF APPENDIX N? ☒ YES ☐ NO			FSP/PCs WHEN APPLICABLE, IS THE SHIPPER IN COMPLIANCE WITH THE PROVISIONS OF APPENDIX T? ☐ YES ☐ NO																																		
RATING AGENCY ☒ SHD ☐ SDL ☐ SDA ☐ TPC ☐ OTHER _____		CERTIFIED RATING OFFICER I.M.A. Milkraiter	OFFICER'S CERTIFICATION EXPIRATION DATE October 12, 2023	EARLIEST RATING DATE MONTH DAY YEAR 0 1 2 3 2 2																																	
AGENCY PROVIDING CONTINUOUS SUPERVISION OF SUPPLY State Department of Health			EXPIRATION RATING DATE ² MONTH DAY YEAR 0 1 3 1 2 4																																		
8. LABORATORY CONTROL																																					
APPROVED LABORATORY NUMBER A. 00001 B. 00302		EXPIRATION DATE A. 02/2023 B. 09/2023		<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <th colspan="5">PROCESSED MILK TESTS APPROVED</th> <th colspan="3">RAW MILK TESTS APPROVED</th> </tr> <tr> <td>SPC</td> <td>COLI</td> <td>PHOS</td> <td>RBC</td> <td>DRUG RESIDUE TESTS</td> <td>VIABLE COUNTS</td> <td>SOMATIC CELL COUNTS</td> <td>DRUG RESIDUE TESTS</td> </tr> <tr> <td>A. 2a</td> <td>A. 21a</td> <td>A. 28a</td> <td>A. 22</td> <td>A. 9C2, 9D3</td> <td>A. 2</td> <td>A. 12</td> <td>A. 9C2, 9D3</td> </tr> <tr> <td>B. _____</td> <td>B. _____</td> <td>B. _____</td> <td>B. _____</td> <td>B. _____</td> <td>B. 3</td> <td>B. 16</td> <td>B. _____</td> </tr> </table>		PROCESSED MILK TESTS APPROVED					RAW MILK TESTS APPROVED			SPC	COLI	PHOS	RBC	DRUG RESIDUE TESTS	VIABLE COUNTS	SOMATIC CELL COUNTS	DRUG RESIDUE TESTS	A. 2a	A. 21a	A. 28a	A. 22	A. 9C2, 9D3	A. 2	A. 12	A. 9C2, 9D3	B. _____	B. _____	B. _____	B. _____	B. _____	B. 3	B. 16	B. _____
PROCESSED MILK TESTS APPROVED					RAW MILK TESTS APPROVED																																
SPC	COLI	PHOS	RBC	DRUG RESIDUE TESTS	VIABLE COUNTS	SOMATIC CELL COUNTS	DRUG RESIDUE TESTS																														
A. 2a	A. 21a	A. 28a	A. 22	A. 9C2, 9D3	A. 2	A. 12	A. 9C2, 9D3																														
B. _____	B. _____	B. _____	B. _____	B. _____	B. 3	B. 16	B. _____																														
DATE OF LAST TWO (2) SPLIT SAMPLES A. 09/2021 A. 04/2022 B. 04/2020 B. 09/2023		APPROVED WATER LABORATORY AND DATE State Health Dept. Lab (State EPA) 10/2022		WATER TESTS APPROVED 24-MPN																																	
9. PUBLICATION (Written permission from a shipper shall be on file at the Regulatory/Rating Office prior to the publication of rating/listing.)																																					
WRITTEN PERMISSION FROM SHIPPER DATED 8/10/2022		ON FILE? ☒ YES ☐ NO																																			
10. SUBMISSION OF REPORT BY RATING AGENCY																																					
DATE OF REPORT 8/10/2022	SUBMITTED BY (Signature) <i>John Q. Inspector</i>			Title Milk Sanitation Rating Officer																																	
¹ Submit separate Form for each milk plant. ² The expiration rating date is two (2) years after the earliest rating date, plus the remaining days of the month, i.e., earliest rating date is 10/1/2023 with a corresponding expiration rating date of 10/31/2025, except if the Enforcement Rating is <90, then the expiration rating date is six (6) months after the earliest rating date, i.e., earliest rating date is 10/1/2021 with a corresponding expiration rating date of 4/30/2022.																																					

FOR FDA OFFICE USE ONLY

Written permission from shipper dated 8/10/22 on file and publication of rating/listing recommended.

DATE 8/10/22	SIGNATURE (FDA Milk Specialist)
---------------------	---------------------------------

11. MILK PLANTS: List below the Name and Address of all shippers of raw milk and milk products received during the thirty (30) days preceding the earliest rating date of the Rating; Sanitation Compliance Rating; and Expiration Rating Date. Plants receiving milk from an unlisted source(s), or source(s) with a Sanitation Compliance Rating below ninety (90), are not eligible for listing in the electronic publication, *IMS LIST – SANITATION COMPLIANCE AND ENFORCEMENT RATINGS OF INTERSTATE MILK SHIPPERS*.

NAME OF SHIPPER (Include BTU or Plant #)	CITY AND STATE/COUNTRY	SANITATION COMPLIANCE RATING	EXPIRATION RATING DATE
ABC BTU	Bulls Role, State/County	91	12/31/23
Udderly Delightful BTU	Tootle Town, State/County	92	6/30/24
GMI Good Dairy	Paradise, State/County	90	4/30/24

INSTRUCTIONS:

Completed Forms shall be received by the Milk Safety Team (HFS-316) to be included in the IMS List. Additional explanation is offered for the following items:

Item 1: Name of Shipper – Limit shipper's name to not more than thirty-four (34) characters and spaces. If a receiving or transfer station is to be listed, please include "Receiving Station" or "Transfer Station" or "(RS)" or "(TS)" with the name of the shipper. Suggested abbreviations are published in the IMS List.

Item 5: Plant or BTU # – When the IMS Number is less than five (5) digits, leave the left-hand square(s) blank.

Item 6: Product Code #s – Enter Product Code #s starting in the first (left-hand) space. Product Code #s are listed below:

PRODUCT CODES:

- | | |
|--|--|
| 1. Raw Milk for Pasteurization (May Include Lowfat, Skim or Cream) | 25. Cholesterol Modified Fluid Milk Products |
| 2. Pasteurized Milk, Reduced Fat, Lowfat, or Skim | 26. Cream (Condensed or Dry) |
| 3. Heat-Treated (May Include Reduced Fat, Lowfat, Skim or Cream) | 27. Blended Dry Products |
| 4. Pasteurized Half & Half, Coffee Cream, Creams | 28. Whey Cream |
| 5. Ultra-Pasteurized (UP) Milk and Milk Products | 29. Whey Cream and Cream Blends |
| 6. Aseptic or Retort Milk and Milk Products (Including Flavored) | 30. Grade "A" Lactose |
| 7. Cottage Cheese (Including Lowfat, Nonfat or Dry Curd) | 31. Raw Goat Milk for Pasteurization |
| 8. Cultured or Acidified Milk and Milk Products | 32. Pasteurized Goat Milk and Milk Products |
| 9. Yogurt (Including Lowfat or Skim) | 33. Cultured Goat Milk and Milk Products |
| 10. Sour Cream Products (Acidified or Cultured) | 34. Condensed or Dry Goat Milk and Milk Products |
| 11. Whey (Liquid) | 35. Ultra-Pasteurized (UP) Goat Milk and Milk Products |
| 12. Whey (Condensed) | 36. Aseptic Goat Milk and Milk Products |
| 13. Whey (Dry) | 37. Raw Sheep Milk for Pasteurization |
| 14. Modified Whey Products (Condensed or Dry) | 38. Pasteurized Sheep Milk and Milk Products |
| 15. Condensed Milk and Milk Products | 39. Cultured Sheep Milk and Milk Products |
| 16. Nonfat Dry Milk | 40. Concentrated Raw Milk Products for Pasteurization |
| 17. Buttermilk (Condensed or Dry) | 41. Concentrated Pasteurized Milk Products |
| 18. Eggnog | 42. Ultrafiltered Permeate from Milk |
| 19. Lactose Reduced Milk and Milk Products | 43. Ultrafiltered Permeate from Whey |
| 20. Low-Sodium Milk and Milk Products | 44. Raw Water Buffalo Milk for Pasteurization |
| 21. Milk and Milk Products with Added Safe and Suitable Microbial Organisms
(Such as Lactobacillus acidophilus) | 45. Pasteurized Water Buffalo Milk and Milk Products |
| 22. Dry Milk and Milk Products | 46. Cultured Water Buffalo Milk and Milk Products |
| 23. Anhydrous Milk Fat | 47. Raw Camel Milk for Pasteurization |
| 24. Cholesterol Modified Anhydrous Milk Fat | 48. Pasteurized Camel Milk and Milk Products |
| | 49. Cultured Camel Milk and Milk Products |

20. FORM NCIMS 2359o-PERMISSION FOR PUBLICATION-INTERSTATE MILK SHIPPER'S
LISTING
(EXAMPLE: MILK PLANT HACCP LISTING)

PERMISSION FOR PUBLICATION Interstate Milk Shipper's Listing	
SHIPPER'S NAME My HACCP Plant	
ADDRESS 234 Milk Road, My City, MY 11111	
You are hereby advised that on (date[s]) <u>January 23-25, 2022</u> a Rating or HACCP Listing Audit was conducted with the following results: Producer Supply (BTU) <u>90*</u> Transfer Station <u>NA</u> Receiving Station <u>NA</u> Milk Plant <u>Acceptable HACCP Listing</u> Enforcement Rating (For all Ratings and for attached farm supplies of HACCP listings) <u>Acceptable</u> The results will be transmitted to the U.S. Food and Drug Administration. They will publish the information in the "IMS List-Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers". The official Rating or HACCP Listing is valid for a period not to exceed two (2) years from the earliest rating/listing date, except if the Enforcement Rating is less than 90 percent (< 90%), then the official Rating/Listing is valid for a period not to exceed six (6) months from the earliest rating date, subject to the rules of the National Conference on Interstate Milk Shipments.	
Publication Permission Section Permission is hereby granted to release and publish the above-stated Rating or HACCP Listing for use by Regulatory Agencies and prospective purchasers. <i>It is understood and agreed by the undersigned that the official Rating or HACCP Listing Agency may review this supply at any time during the two (2)-year or six (6) month period, respectively, referred to above. It is further understood that we will notify the Rating or HACCP Listing Agency if any significant change should occur, which affects our raw milk supply, milk plant, receiving station or transfer station status, including products listed.</i> <i>It is understood and agreed that the failure to maintain the Rating or HACCP System at a level, which is acceptable for listing, shall result in immediate withdrawal of this listing.</i> <i>It is further agreed that milk plants, receiving stations or transfer stations, which receive milk or milk products for processing into milk or milk products for which that milk plant, receiving station or transfer station is listed, are from a non-listed source or a source having a Milk Sanitation Compliance Rating of less than ninety percent (90%) shall be immediately withdrawn from the Interstate Milk Shipper's List.</i> SIGN AND RETURN TO <u>MY State Department of Health</u> WITHIN FIVE (5) DAYS OF RECEIPT. (Name of Agency)	
NAME OF SHIPPER My HACCP Dairy Plant	
SIGNATURE OF REPRESENTATIVE 	
TITLE Chief Operating Officer	DATE January 29, 2022

21. FORM NCIMS 2359o-PERMISSION FOR PUBLICATION-INTERSTATE MILK SHIPPER'S LISTING
(EXAMPLE: BTU AND MILK PLANT RATING LISTING)

PERMISSION FOR PUBLICATION Interstate Milk Shipper's Listing							
SHIPPER'S NAME Clean Milk Dairy							
ADDRESS 2525 Milky Way, Moosville, State 00007							
You are hereby advised that on (date[s]) <u>August 3-7, 2022</u> a Rating or HACCP Listing Audit was conducted with the following results: <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">Producer Supply (BTU) <u>92%</u></td> <td style="width: 50%;">Transfer Station <u>NA</u></td> </tr> <tr> <td>Receiving Station <u>NA</u></td> <td>Milk Plant <u>91%</u></td> </tr> <tr> <td colspan="2">Enforcement Rating (For all Ratings and for attached farm supplies of HACCP listings) <u>90%</u></td> </tr> </table> The results will be transmitted to the U.S. Food and Drug Administration. They will publish the information in the "IMS List-Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers". The official Rating or HACCP Listing is valid for a period not to exceed two (2) years from the earliest rating/listing date, except if the Enforcement Rating is less than 90 percent (< 90%), then the official Rating/Listing is valid for a period not to exceed six (6) months from the earliest rating date, subject to the rules of the National Conference on Interstate Milk Shipments.		Producer Supply (BTU) <u>92%</u>	Transfer Station <u>NA</u>	Receiving Station <u>NA</u>	Milk Plant <u>91%</u>	Enforcement Rating (For all Ratings and for attached farm supplies of HACCP listings) <u>90%</u>	
Producer Supply (BTU) <u>92%</u>	Transfer Station <u>NA</u>						
Receiving Station <u>NA</u>	Milk Plant <u>91%</u>						
Enforcement Rating (For all Ratings and for attached farm supplies of HACCP listings) <u>90%</u>							
Publication Permission Section Permission is hereby granted to release and publish the above-stated Rating or HACCP Listing for use by Regulatory Agencies and prospective purchasers. <i>It is understood and agreed by the undersigned that the official Rating or HACCP Listing Agency may review this supply at any time during the two (2)-year or six (6) month period, respectively, referred to above. It is further understood that we will notify the Rating or HACCP Listing Agency if any significant change should occur, which affects our raw milk supply, milk plant, receiving station or transfer station status, including products listed.</i> <i>It is understood and agreed that the failure to maintain the Rating or HACCP System at a level, which is acceptable for listing, shall result in immediate withdrawal of this listing.</i> <i>It is further agreed that milk plants, receiving stations or transfer stations, which receive milk or milk products for processing into milk or milk products for which that milk plant, receiving station or transfer station is listed, are from a non-listed source or a source having a Milk Sanitation Compliance Rating of less than ninety percent (90%) shall be immediately withdrawn from the Interstate Milk Shipper's List.</i> SIGN AND RETURN TO <u>State Department of Health</u> WITHIN FIVE (5) DAYS OF RECEIPT. (Name of Agency)							
NAME OF SHIPPER Clean Milk Dairy							
SIGNATURE OF REPRESENTATIVE 							
TITLE Chief Operating Officer	DATE August 12, 2022						

**22. FORM NCIMS 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM
AND/OR RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING
ELEMENTS**

(EXAMPLE: Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products)

National Conference on Interstate Milk Shipments	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)
<i>(To be included with all NCIMS Aseptic Processing and Packaging Program and Retort Processed after Packaging Program Ratings/HACCP Listings and FDA Check Ratings/HACCP Audits.)</i>	
MILK PLANT Aseptic Dairy	DATE OF RATING October 8-9, 2022
ADDRESS 100 Plant Drive Mootopia, USA 00000	LICENSE/PERMIT NO. 80-001
RATING AGENCY USA Milk Control Agency	
EXPLANATION OF CONCERNS NOTED REGARDING CRITICAL LISTING ELEMENTS UNDER THE NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND RETORT PROCESSED AFTER PACKAGING PROGRAM <i>(Use additional sheets as necessary.)</i>	
A narrative description shall be provided as a part of all NCIMS Aseptic Processing and Packaging Program and Retort Processed after Packaging Program Ratings/HACCP Listings and FDA Check Ratings/HACCP Audits. This report shall include an evaluation of the following requirements:	
1. Is the milk plant registered with FDA LACF and are all of the milk plant's low-acid aseptic and/or retort processed after packaging Grade "A" milk and/or milk products covered by a filing with the FDA LACF using Form FDA 2541c, or Form FDA 2341a, respectively, or equivalent electronic filing? Yes - FCE number 000000; Grade "A" Products: White Milk (Whole, 2%, 1%, and Skim), Flavored Milk including chocolate (Whole, 2%, and Skim). SID 2005-01-12/001 indirect UHT processor. SUP SID 2005-01-12/2003 Tetra Pak A3/Flex. (or refer to attached list of additional SIDs and SUP SIDs.)	
2. Are the milk plant's filed scheduled processes for all of its low-acid aseptic and/or retort processed after packaging Grade "A" milk and/or milk products developed by a recognized Process Authority qualified as having expert knowledge of thermal processing requirements? Yes - Sterilization Processing System #1 and 2: Processing Authorities, Inc., 400 SE 1st, Aseptic, State 00000 (George reviewer); Aseptic Fillers #3 and 4: Good Packaging, LLC, 1111 Filler Lane, Bottle, State 00000 (Johnny B. Sterile).	
3. Are the operators of the milk plant's aseptic processing and packaging systems and/or retort processed after packaging systems under the supervision of a person who has attended a school approved by the FDA (such as Better Process Control School or recognized equivalent)? Yes - Supervisors on site are: Jeff Plant - Better Processing Control School - Purdue University (10/2018); Robert Fixer - Better Processing Control School - WA State University (6/2015); and Jamie Boss - Better Processing Control School - University of Arkansas (8/2017).	
4. Is the milk plant currently under an "Order of Determination of Need" for an Emergency Permit or a suspension of FDA food facility registration? No.	

23. 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

(EXAMPLE: ASEPTIC AND/OR RETORT MILK PLANT AND/OR FERMENTED HIGH-ACID, SHELF-STABLE MILK PLANT)

National Conference on Interstate Milk Shipments	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	
<i>(To be included with NCIMS State Ratings/HACCP Listings and FDA Check Ratings/Audits.)</i>		
MILK PLANT FHA Yogurt	DATE OF INSPECTION/RATING October 25, 2023	
ADDRESS 300 6th St, Washington, DC 20001	LICENSE/PERMIT NO. 11-1234	
RATING AGENCY Washington DC Department of Agriculture		
EXPLANATION OF CONCERNS NOTED REGARDING CRITICAL LISTING ELEMENTS UNDER THE NCIMS PROGRAM COMMITTEE <i>(Use additional sheets as necessary.)</i>		
A narrative description shall be provided as a part of all NCIMS Aseptic Program Committee State Ratings/ HACCP Listings and FDA Check Ratings/Audits. This report shall include an evaluation of the following requirements:		
1. Does the milk plant have an FDA Low-Acid Canned Foods (LACF) Food Canning Establishment (FCE) Number? Yes, this plant is registered as Food Canning Establishment 012345 with FDA-CFSAN. 2. Are the milk plant's Grade "A" fermented high-acid (FHA), shelf-stable milk and/or milk product(s) produced using an Aseptic-Qualified filler and Product Sterilizer System (AQFPSS) which is under a current FDA LACF 2541g (Food Process Filing for Low-Acid Aseptic Systems)? Processing equipment: TerraTherm tubular thermal processor. Packaging equipment: SaniPak aseptic filler. Yes, both of these components of the AQFPSS have a 2541g Food Process Filing for Low-Acid Aseptic Systems, I.D. 20171015001, filed on 10/15/22, for the aseptic processing and packaging of a low-acid protein drink product. 3. Are the milk plant's process recommendations for its Grade "A" fermented high-acid, shelf-stable milk and/or milk product(s) developed by a recognized process authority qualified as having expert knowledge of aseptic processes? Yes, the plant's process authority for the fermented high-acid low fat yogurt product is Smith Consulting LLC of Washington, D who also developed the process recommendations for the 2451g filing of the aseptic low-acid protein drink product listed above. 4. Have the milk plant's process recommendations for its Grade "A" fermented high-acid, shelf-stable milk and/or milk product(s) been reviewed [with no objections] by the Regulatory Agency prior to production of these products? Yes, the plant has a letter dated 1/25/23 from the USA Milk Control Agency indicating that the process recommendations for the fermented high-acid low fat yogurt product developed by Smith Consulting LLC dated 11/3/22 has been reviewed with no objections.		

5. Are the milk plant's process recommendations that have been reviewed and confirmed by the Regulatory Agency for its Grade "A" fermented high-acid, shelf-stable milk and/or milk product(s) being implemented by the milk plant?

Yes, random production records were reviewed for the processing of the shelf-stable low fat yogurt product on 10/24/23, 10/23/23, 9/17/23, and 7/5/23. Review of these production records revealed that processing recommendations for the shelf-stable low fat yogurt are being met by the plant. Critical limits in the process recommendations include: Pre-sterilization of the TerraTherm and SaniPak using hot water at a minimum of 198F for at least 25 minutes, Maximum pH of 4.55 per vat of yogurt prior to transfer to the TerraTherm as recorded on the yogurt production log sheet, maximum flow rate of 15.0 gallons per minute as recorded by the TerraTherm flow recorder, minimum temperature of 164.5F at the end of the hold tube as recorded by the TerraTherm temperature recorder.

6. Are the operators of the milk plant's aseptic-qualified filler and product sterilizer under the supervision of a person who has attended a school approved by the FDA (such as Better Process Control School or recognized equivalent)?

Yes, line operators and supervisors overseeing operations of the AQFPSS include: Sally Smith-Better Process Control School, Pennsylvania State University-University Park 2020, John Williams-Better Process Control School- University of California-Davis 2020, Mary Jones-Better Process Control School-Corvallis 2017, Brian Miller - Better Process Control School - Purdue University- West Lafayette 2022.

7. Is the milk plant currently under an "Order of Determination of Need" for an emergency Permit for its LACF filing, or a suspension of food facility registration?

No.

24. FORM NCIMS 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2) (EXAMPLE: ASEPTIC, RETORT MILK PLANT AND/OR FERMENTED HIGH-ACID, SHELF-STABLE MILK PLANT)

MILK SANITATION RATING REPORT

SHIPPER ASEPTIC OR RETORT DAIRY

DATE OF RATING 10/8-10/2023

(Example: Aseptic, Retort, or Fermented High-Acid, Shelf-Stable Milk Plants)

ENFORCEMENT RATING 91

SECTION B. REPORT OF ENFORCEMENT METHODS

DAIRY FARMS PART I						MILK PLANT PART II						INDIVIDUAL SHIPPER RATING PART III												
Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	
1	3	All dairy farmers hold a valid permit				5.5		1	3	All milk plant, receiving station and transfer station operators hold a valid permit				5	5	1		Enter TOTAL CREDIT from PART I under Percent Complying				NA	47	NA
2	5	All dairy farms inspected once every six (6) months or as required in Appendix "P"				15.5		2	5	Milk plant and receiving station(s) inspected once every three (3) months; aseptic and retort milk plant and transfer station(s) once every six (6) months	4	3	75	15	11.25	2		Enter TOTAL CREDIT from PART II under Percent Complying			92.06	47	86.54	
3	5	Inspection sheet posted or available				5.5		3	5	Inspection sheet posted or available				5	5	3	4	All milk and milk products properly labeled	5	4	80.0	6	4.80	
4	7	Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections				10.5		4	7	Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections	1	9	80	10	9	TOTAL CREDIT, PART III ▶ 91.34								
5	8	TB & Brucellosis Certification on file as required				10.5		5	7	Pasteurization equipment tested at required frequency (Not required for aseptic and retort milk plants.)	NA	NA	NA	15	NA	INDIVIDUAL SHIPPER ENFORCEMENT RATINGS								
6	7	Water samples tested and reports on file as required				5.5		6	7	Individual and cooling water samples tested and reports on file as required	6	6	100	5	5	INDIVIDUAL SHIPPER OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING:								
7	6	At least four (4) samples collected from each dairy farm's supply every six (6) months and all necessary laboratory examinations made				10.5		7	6	Samples of each milk plant's milk and milk products collected at required frequency and all necessary laboratory examinations made	5	4	80	10	8	• Without Milk Plant, Receiving Station or Transfer Station: – Evaluate all Items PART I. and record. • With Receiving Station(s) or Transfer Station(s): – Evaluate all Items PART I. – Evaluate all Items PART II., except Numbers 5 and 7. Divide by 75. – Evaluate all Items PART III.								
8	6	Sampling procedures approved by PHS/FDA evaluation methods				10.5		8	6	Sampling procedures approved by PHS/FDA evaluation methods	1	1	100	10	10	INDIVIDUAL SHIPPER OF PASTEURIZED MILK AND MILK PRODUCTS:								
9	3, 5, 6, 16	Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required				15.5		9	3, 5, 6, 16	Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required	1	1	100	15	15	• Aseptic and Retort Milk Plants: – Evaluate all Items PART II., except Number 5. Divide by 85. • With Attached Raw Supply: – Evaluate all Items PART I. – Evaluate all Items PART II., use 47 Weight. – Evaluate all Items PART III. • With Unattached Raw Supply: – Evaluate all Items PART II., use 94 Weight. – Evaluate all Items PART III., except Number 1.								
10		Records systematically maintained and current				10.5		10		Records systematically maintained and current	1	1	100	10	10									
TOTAL CREDIT, PART I ▶								TOTAL CREDIT, PART II ▶ 92.06																
REMARKS								REMARKS								REMARKS								
#2. One (1) of the required six (6) month inspections was missed (12/22) #4. Violation of Item 7(b) (4 pts) - Submerged water inlet in the CIP make-up tank. Item 15b(c) (5 pts) - Cross connection between the raw milk storage silo #2 and the CIP system in the receiving area. Item 1 (a) (1 pt) - The flooring in the APPS (or RPPS)								room was in very poor condition. All existed but were not debited on the last inspection. #7. Aseptic (or Retort) 2% chocolate milk, vitamins A & D fortified, did not have a vitamin assay conducted during CY 2017. 78.25/85 = 92.06								#3. Aseptic (or Retort) nonfat milk was not labeled as Grade "A" and "Keep Refrigerated After Opening."								

25. FORM NCIMS 2359e-STATUS OF MANUFACTURING PLANTS (Single-Service Containers and/or Closures for Milk and/or Milk Products)

National Conference on Interstate Milk Shipments

STATUS OF MANUFACTURING PLANTS

(SINGLE-SERVICE CONTAINERS AND/OR CLOSURES FOR MILK AND/OR MILK PRODUCTS)

Plant Blow Mold Plastics

Date of Certification June 21, 2023

Sanitation Compliance Rating¹ 85

NAME OF PLANT	ITEM	ITEMS OF SANITATION																		REMARKS									
		Floors	Walls and Ceilings	Doors and Windows	Lighting and Ventilation	Separate Rooms	Toilet/Facilities / Sewage Disposal	Water Supply	Handwashing Facilities	Plant Cleanliness	Lockers and Lunchrooms	Disposal of Wastes	Personnel / Practices	Protection From Contamination	Storage of Materials and Finished Product	Fabrication Equipment	Materials for Construction of Containers and/or Closures	Waxes, Adhesives, Sealants, Coating and Inks	Handling of Containers, Closures and Equipment		Wrapping and Shipping	Identification and Records	Surroundings	Bacterial Count*	Coliform Count*	Total Debits ²			
		1	2	3	4	5	6	7	8	9	10	11	12	13 a,b,c, f,g,i,k	13 d,e, h, j	14	15	16 a	16 b,c	17 a,b d,e	17 c	18	19	20 a,b,f	20 c,d,e	21			
	WEIGHT	1	1	2	2	3	3	4	2	3	2	2	3	3	11	3	5	11	3	3	11	2	4	3	11	2	5	10	
Blow Mold Plastics		1														3								e11				15	SCR=100-15=85
TOTALS		1														1								1				15	

Footnotes: ¹ Sanitation Compliance Rating = 100 – Total Debits ² Total Debits for each manufacturing plant are the sum of the weights of the Items violated. (**NOTE:** Any Item or sub-item violated, indicate by placing the debit value (weight) of that Item or an "X" under that Item.) * Use only when not in compliance.

26. FORM FDA 2359d-REPORT OF CERTIFICATION (*Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products*)

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		REPORT OF CERTIFICATION <i>(Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products)</i>		FOR FDA USE ONLY																								
				1	2	3	4	5																				
IDENTIFICATION																												
1. NAME OF SINGLE-SERVICE FABRICATING PLANT Blow Mold Plastics				2. CITY Container		3. STATE/COUNTRY Country																						
4. STREET 4200 Injection Point St.				5. MFG. CODE NO.		6. CODE																						
7. AGENCY OR SSC, AS APPLICABLE, PROVIDING ROUTINE INSPECTION Resin Single-Service Consultants 2100 Injection Point St. Nozzle, State, 00000				56 XX 57 XX 58 0 59 1 60 1 61 - 62 3		PRODUCT MATERIAL 1. Containers 1. Metal 2. Closures 2. Paper (Includes laminates) 3. Other products 3. Plastic 4. Containers and closures 4. Metal and paper 5. Containers and other products 5. Metal and plastic 6. Closures and other products 6. Paper and plastic 7. Containers, closures and other products 7. Metal, paper and plastic 8. Glass 9. Rubber 10. Paper, metal, plastic and glass 11. Ceramic																						
7.a. RATING/CERTIFICATION PERSONNEL ☐ SHD ☐ Other ☐ SDA ☐ TPC ☐ SDL ☒ SSC		7.b. DATE OF PLANT CERTIFICATION 6/21/23		7.d. EXPIRATION DATE *																								
		7.c. SANITATION COMPLIANCE RATING 85		MONTH DAY YEAR 67 68 69 70 71 72 0 6 3 0 20 24																								
*EXPIRATION DATE Certification of single-service manufacturing plants may be valid for a period not to exceed one (1) or two (2) years from the earliest certification date, plus the remaining days of the month. The expiration date is one (1) or two (2) years from the earliest certification date. NOTE: Certifications conducted by SSCs shall only be valid for a period not to exceed one (1) year, plus the remaining days of the month from the earliest certification date.				8. SRO OR SSC Hammer Down, SSC																								
9. CERTIFICATION RECOMMENDED ☒ YES ☐ NO				9.a. LISTING TYPE ☒ FULL ☐ PARTIAL																								
LABORATORY CONTROL																												
10. NAME AND ADDRESS (OR CODE) OF APPROVED LABORATORY XX-XX-100																												
11. INSPECTION RESULTS (<i>Place an "X" under items debited</i>)																												
	1	2	3	4	5	6	7	8	9	10	11	12	13 a,b,c, f,g,i,k	13 d,e, h,j	14	15	16 a	16 b,c	17 a,b d,e	17 c	18	19	20 a,b,f	20 c,d,e	21	BACTI	COLI	
	X														X									X				
12. PERMISSION TO PUBLISH																												
Permission is hereby granted to release and publish the above stated certification for use by Regulatory/Rating Agencies and prospective purchasers. It is understood and agreed by the undersigned that the official Rating Agency or SSC, as applicable, may review and appraise the single-service fabricating plant at any time during the period of time the above certification is in effect. It is further understood that failure to maintain the above certification will subject this plant to withdrawal from the IMS Listing. We will notify the Rating Agency or SSC, as applicable, of any significant changes made in the operation of this plant.																												
12.a. NAME OF PLANT Blow Mold Plastics																												
12.b. OFFICER AUTHORIZING RELEASE Jane Doe					12.c. TITLE Owner																							
13. SUBMISSION OF REPORT BY MILK SANITATION RATING AGENCY OR SSC, AS APPLICABLE																												
13.a. DATE OF REPORT 6/22/23			13.b. RECOMMENDED CLASSIFICATION ACCEPTED ☒ YES ☐ NO			13.c. SUBMITTED BY (<i>Signature and Title</i>) Hammer Down, SSC																						
FOR FDA USE ONLY																												
14. DATE RECEIVED			15. PUBLICATION OF RATING RECOMMENDED ☐ YES ☐ NO (<i>if "NO", indicate why.</i>)																									
16. DATE TRANSMITTED			17. SIGNATURE (<i>FDA Milk Specialist</i>)																									

TABLE FOR COMPUTING PERCENT VIOLATION

Number of Dairy Farms or Milk Plants in Sample																																																		Number of Dairy Farms or Milk Plants Violating an Item
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	50						
100	50	33	25	20	17	14	13	11	10	9	8	8	7	7	6	6	6	5	5	5	5	4	4	4	4	4	4	3	3	3	3	3	3	3	3	3	3	3	3	3	2	2	2	2	2	1				
100	67	50	40	33	29	25	22	20	18	17	15	14	13	13	12	11	11	10	10	9	9	8	8	8	8	7	7	7	7	6	6	6	6	6	6	5	5	5	5	5	5	5	5	4	4	2				
100	75	60	50	43	38	33	30	27	25	23	21	20	19	18	17	16	15	14	14	13	13	12	12	11	11	10	10	10	10	9	9	9	9	9	8	8	8	8	8	7	7	7	7	6	3					
100	80	67	57	50	44	40	36	33	31	29	27	25	24	22	21	20	19	18	17	16	15	14	14	13	13	12	12	11	11	11	11	11	11	11	11	10	10	10	10	9	9	8	4							
100	83	71	63	56	50	45	42	38	36	33	31	29	28	26	25	24	23	22	21	20	19	19	19	17	17	16	16	15	15	14	14	14	13	13	13	12	12	12	12	11	10	5								
100	86	75	67	60	55	50	46	43	40	38	35	33	32	30	29	27	26	25	24	23	22	21	21	20	19	19	18	18	17	17	16	16	15	15	15	15	14	14	14	12	6									
100	88	78	70	64	58	54	50	47	44	41	39	37	35	33	32	30	29	28	27	26	25	24	23	22	21	21	20	19	19	18	18	18	17	17	16	16	14	7												
100	89	80	73	67	62	57	53	50	47	44	42	40	38	36	35	33	32	31	30	29	28	27	26	25	24	23	22	21	21	20	19	19	18	18	18	17	17	16	16	8										
100	90	82	75	69	64	60	56	53	50	47	45	43	41	39	38	36	35	33	32	31	30	29	28	27	26	26	25	24	24	23	23	22	21	21	20	18	9													
100	91	83	77	71	67	63	59	56	53	50	48	45	43	42	40	38	37	36	34	33	32	31	30	29	29	28	27	26	26	25	24	24	23	23	20	10														
100	92	85	79	73	69	65	61	58	55	52	50	48	46	44	42	41	39	38	37	35	34	33	32	31	31	30	29	28	28	27	26	26	25	22	11															
100	92	86	80	75	71	67	63	60	57	55	52	50	48	46	44	43	41	40	39	38	36	35	34	33	32	31	30	29	29	28	27	24	12																	
100	93	87	81	78	72	68	65	62	59	57	54	52	50	48	46	45	43	42	41	39	38	37	36	35	34	33	32	31	30	30	26	13																		
100	93	88	82	78	74	70	67	64	61	58	56	54	52	50	48	47	45	44	42	41	40	39	38	37	36	35	34	33	33	32	28	14																		
100	94	88	83	79	75	71	68	65	63	60	58	56	54	52	50	48	47	45	44	43	42	41	39	38	38	37	36	35	34	30	15																			
100	94	89	84	80	76	73	70	67	64	62	59	57	55	53	52	50	48	47	46	44	43	42	41	40	39	38	37	36	32	16																				
100	94	89	85	81	77	74	71	68	65	63	61	59	57	55	53	52	50	49	47	46	45	44	43	42	40	39	34	17																						
100	95	90	86	82	78	75	72	69	67	64	62	60	58	56	55	53	51	50	49	47	46	45	44	43	42	41	36	18																						
100	95	90	86	83	79	76	73	70	68	66	63	61	59	58	56	54	53	51	50	49	48	46	45	44	43	38	19																							
100	95	91	87	83	80	77	74	71	69	66	65	63	61	59	57	56	54	53	51	50	49	48	47	45	40	20																								
100	96	91	88	84	81	78	75	72	70	68	66	64	62	60	58	57	55	54	53	51	50	49	48	42	21																									
100	95	92	88	85	81	79	76	73	71	69	67	65	63	61	59	58	56	55	54	52	51	50	44	22																										
100	96	92	88	85	82	79	77	74	72	70	68	66	64	62	61	59	58	56	55	53	52	46	23																											
100	96	92	89	86	83	80	77	75	73	71	69	67	65	63	62	61	59	57	56	55	48	24																												
100	96	93	89	86	83	81	78	76	74	71	69	68	66	64	63	61	60	58	57	50	25																													
100	96	93	90	87	84	81	79	76	74	72	70	68	67	65	63	62	60	59	52	26																														
100	96	93	90	87	84	82	79	77	75	73	71	69	68	66	64	63	61	54	27																															
100	97	93	90	88	85	82	80	78	76	74	72	70	68	67	65	64	56	28																																
100	97	94	91	88	85	83	81	78	76	74	73	71	69	67	66	58	29																																	
100	97	94	91	88	86	83	81	79	77	75	73	71	70	68	60	30																																		
100	97	94	91	89	86	84	82	79	78	76	74	72	70	62	31																																			
100	97	94	92	89	87	84	82	80	78	76	74	73	64	32																																				
100	97	94	92	89	86	85	83	80	79	77	75	66	33																																					
100	97	94	92	90	87	85	83	81	79	77	68	34																																						
100	97	95	92	89	88	85	83	81	80	70	35																																							
100	97	95	92	90	88	86	84	82	72	36																																								
100	97	95	93	90	88	86	84	74	37																																									
100	97	95	93	90	88	86	76	38																																										
100	98	95	93	91	89	78	39																																											
100	98	95	93	91	80	40																																												
100	98	95	93	82	41																																													
100	98	95	84	42																																														
100	98	86	43																																															
100	88	44																																																
100	50																																																	

TABLE FOR COMPUTING PERCENT VIOLATION

(Percentage rounded to nearest whole number)

APPENDIX A.

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

DAIRY FARMS-PART I

ER evaluations are based on NCIMS requirements, not on individual State's and/or Country's laws or regulations.

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

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

- a. Every dairy farm operator holds a valid permit.
- b. Only a person who complies with the requirements of the *Grade "A" PMO* shall be entitled to receive and retain such permit.
- c. Permits not transferable with respect to person and/or location.

2. All dairy farms inspected at least once every six (6) months or as required under Appendix P. (*Grade "A" PMO*, Section 5. Inspection Of Dairy Farms and Appendix P. Performance-Based Dairy Farm Inspection System). Prorate by the number of dairy farms in compliance.

NOTE: A single dairy farm BTU shall be prorated by the number of inspections in compliance with the required frequency.

Every dairy farm inspected at least once every six (6) months or as required by Appendix P.

NOTE: Refer to *MMSR*, Section E., 1., e. and E., 2., e. as a guide: "For rating purposes, to determine if inspections have been conducted at the required frequency, the interval shall include the designated period, plus the remaining days of the month in which the inspection is due."

3. Inspection sheet posted or available (*Grade "A" PMO*, Section 5). Prorate by the number of dairy farms in compliance.

A copy of the most recent inspection report shall be available at the dairy farm.

4. Requirements interpreted in accordance with the *Grade "A" PMO* as indicated by past inspections (*Grade "A" PMO*, Section 7). Prorate by the number of dairy farms in compliance.

NOTE: A single dairy farm BTU shall be prorated by significant interpretation violation(s) not noted on previous inspection reports. For each Item that is identified as being misinterpreted, the

value to be taken off from a possible 100 points corresponds to the weight value identified per Item on FORM NCIMS 2359k.

- a. Sanitarian's criterion is neither too lenient nor too stringent.
- b. Significant violations, including construction, debited by the sanitarian on the most recent inspection.
- c. Sanitarian recognizes violations and debits as appropriate on the previous inspection reports.

5. Tuberculosis (TB) and Brucellosis Certification on file as required (*Grade "A" PMO*, Section 8. ANIMAL HEALTH and Appendix A. Animal Disease Control). All or nothing Item based on record verification.

- a. Located in an area that has a Modified Accredited Advance TB status or higher as determined by USDA; or

An area which fails to maintain such status:

- 1.) Any herd shall have been accredited by USDA; or
- 2.) Shall have passed an annual TB test; or
- 3.) The Area shall have established a TB testing protocol for livestock that assures TB protection and surveillance of the dairy industry within the Area and that is approved by FDA, USDA and/or the Regulatory Agency.

NOTE: Under the Federal USDA Bovine Tuberculosis Eradication Program, only cattle, bison and captive cervids are covered under the USDA State tuberculosis status determination. Therefore, other hooved mammals (goats, sheep, water buffalo, camels, etc.) are not covered within the program and shall comply with Item c. below.

- b. Located in a Certified Brucellosis-Free Area as defined by USDA; or

- 1.) Meet USDA requirements for a Certified Brucellosis-Free Herd; or
- 2.) Participate in a milk ring testing program at least two (2) times per year at approximately one hundred eighty (180) day intervals and all herds with positive milk ring results shall have the entire herd blood tested within thirty (30) days from the date of the laboratory ring tests; or
- 3.) Utilize a USDA approved test on all cattle or bison six (6) months of age or older, except steers and spayed heifers, annually with an allowable maximum grace period not exceeding two (2) months; or
- 4.) Have established a brucellosis testing protocol for livestock that assures brucellosis protection and surveillance of the dairy industry within the Area and that is approved by FDA, USDA and/or the Regulatory Agency.

NOTE: Under the Federal USDA Bovine Brucellosis Eradication Program, only cattle and bison are covered under the USDA State brucellosis status determination. Therefore, cattle are the only dairy animal currently covered by both the Federal USDA brucellosis and

tuberculosis programs. All other hooved mammals (goats, sheep, water buffalo, camels, etc.) are not covered within these programs and shall comply with Item c. below.

- c. Goat, sheep, water buffalo, camel or any other hooved mammal, excluding cattle and bison, shall be from a herd or flock that is determined to be free of brucellosis and/or tuberculosis as provided by the development and implementation of a State administered brucellosis-free and/or tuberculosis-free certification program involving a documented surveillance program and an official written certification from the State Veterinarian documenting their brucellosis-free and/or tuberculosis-free status. The surveillance program shall be documented, and the official written State brucellosis-free and/or tuberculosis-free certification shall be retained on file with the State Regulatory Agency.
- d. Tuberculosis and/or Brucellosis certificates on file as required by the Regulatory Agency.
- e. Notice of status changes readily available to the Regulatory Agency.
- f. Milk from Brucellosis reactor animals withheld as required.

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

6. Individual water supply, reclaimed water and recirculated cooling water samples collected, tested and reports on file as required (*Grade "A" PMO*, Section 7, Appendix D. Standards For Water Sources and Appendix G. Chemical And Bacteriological Tests). Prorate by the number of dairy farms in compliance. A dairy farm missing one (1) water sample during a required time period shall not receive any credit for this Item.

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

- a. Samples of individual water supplies, reclaimed water and recirculated cooling water systems, including sweet water and glycol systems, taken upon initial construction/installation; and within thirty (30) days after extensive repairs or alterations.
- b. Individual water supplies sampled every three (3) years.
- c. Hauled water (cisterns) sampled in at least four (4) months out of six (6), at the point of use.
- d. Reclaimed and recirculated water sampled every six (6) months.
- e. Water supplies with buried well seals sampled every six (6) months.

NOTE: Refer to *Grade "A" PMO*, Section 7., Item 8r, Administrative Procedures, Number 7, as a guide: "To determine if water samples have been taken at the frequency established in this Section, the interval shall include the designated three (3) year or six (6) month period, respectively, plus the remaining days of the month in which the sample is due."

f. Sampling is not required for public, community, or rural water system(s), which are under EPA/applicable Government Water Control Authority and in compliance with their requirements.

- g. Appropriate follow-up investigation and re-sampling of the water supply/system following a positive bacteriological result. (Within thirty (30) days.)
- h. *E. coli* and heterotrophic count performed when required by Appendix G. of the *Grade "A" PMO*.
- i. Samples submitted to a laboratory acceptable to the Regulatory Agency.
- j. Current record of sample results on file at the Regulatory Agency, back to the last rating.

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

For Example: If the applicable Government Water Control Authority's law required more frequent individual water supply samples to be taken, an SRO or PHS/FDA MS conducting a rating or PHS/FDA check rating, respectively, which includes that dairy farm, shall give that dairy farm full credit for water sample frequency, if the *Grade "A" PMO* minimum sampling frequency requirement is met, even though the applicable Government Water Control Authority's frequency is not met.

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

7. At least four (4) samples collected in at least four (4) separate months from each dairy farm's Grade "A" raw milk supply, during any consecutive six (6) months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days, and all necessary laboratory examinations made (*Grade "A" PMO*, Section 6. Prorate by the number of dairy farms in compliance.

- a. Four (4) Grade "A" raw milk samples taken from each dairy farm during any consecutive six (6) month period. However, if the production of Grade "A" raw milk is not on a continuous monthly basis and, therefore, cannot meet the *Grade "A" PMO* sampling frequency as cited, then a sample of the Grade "A" raw milk shall be collected during each month of production for any consecutive six (6) month period. (Refer to Page 12 of this *MMSR* as a guide.)

NOTE: Refer to Section B., 2., e.2.) of this *MMSR* as a guide for frequency determination.

- b. Required bacterial counts, somatic cell counts, drug residue and cooling temperature checks performed on each Grade "A" raw milk sample in an Official or Officially Designated Laboratory (Commercial or Industry Laboratory), if acceptable to the Regulatory Agency.

8. Sampling procedures approved by PHS/FDA evaluation methods (*Grade "A" PMO*, Section 6; *EML*; and *Standard Methods For The Examination Of Dairy Products (SMEDP)*).

NOTE: Use *MMSR*, “GUIDANCE FOR COMPUTING ENFORCEMENT CREDIT FOR PART I, GUIDANCE FOR COMPUTING ENFORCEMENT CREDIT FOR PART I ITEM 8 AND/OR PART II, ITEM 8 OF FORM NCIMS 2359j, SECTION B. Report Of Enforcement Methods (PAGE 2)”.

9. Permit issuance, suspension, revocation, reinstatement, hearings and/or court action taken as required (*Grade “A” PMO*, Section 3., Section 5., Section 6. and Section 16. PENALTY). The BTU shall be prorated by enforcement action(s) in compliance per dairy farm. Five (5) Categories (a-e) shall be utilized for determining compliance with this Item and each shall possess a value of twenty percent (20%) compliance. The Categories are as follows:

- a. Category I: Permit Issuance;
- b. Category II: Permit Suspension;
- c. Category III: Permit Revocation;
- d. Category IV: Permit Reinstatement; and
- e. Category V: Hearing/Court Action.

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

NOTE: Use FORM NCIMS 2359j-SECTION D. Dairy Farm Enforcement Action And Records Evaluations (PAGE 4). (Refer to Section J., Number 4 of this *MMSR* for an example of the FORM.)

SANITATION REQUIREMENTS

Category I: Permit Issuance

- a. Inspected prior to the issuance of a permit.
- b. Permit issuance based on compliance.

Category II: Permit Suspension

- a. Notice issued for intent to suspend permit if an inspection(s) discloses a violation of a *Grade “A” PMO* requirement(s). Reinspection(s) made as required.
- b. Permit suspension upon violation of:
 - 1.) *Grade “A” PMO*, Section 3. for a serious health hazard or interference by the permit holder in the performance of the Regulatory Agency’s duties; or
 - 2.) *Grade “A” PMO*, Section 5. for consecutive violation(s) of the same requirements of Section 7. of the *Grade “A” PMO*.
- c. *Grade “A”* raw milk produced during permit suspension or while a monetary penalty is imposed for repeated inspection violations is not eligible for sale as *Grade “A”*.

NOTE: *Grade “A” PMO*, Section 3. states: “The Regulatory Agency may forego suspension of the permit, provided the milk and/or milk product in violation is not sold or offered for sale

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

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

Category III: Permit Revocation

Action to revoke a permit taken upon multiple permit suspensions.

Category IV: Permit Reinstatement

Reinstatement procedures followed.

NOTE: *Grade “A” PMO*, Section 3. states: "Within one (1) week of the receipt of such notification, the Regulatory Agency shall make an inspection/audit of the applicant’s facility and as many additional inspections/audits thereafter as are deemed necessary to determine that the applicant's facility is complying with the requirements. When the findings justify, the permit is reinstated."

Category V: Hearing/Court Action

Hearings provided for as required.

PRODUCT COMPLIANCE

Category II: Permit Suspension

- a. All Grade “A” raw milk produced during a permit suspension or while a monetary penalty is imposed for bacterial, somatic cell, cooling temperature or drug residue violation is not eligible for sale as Grade “A”.
- b. When two (2) out of the last four (4) Grade “A” raw milk samples exceed the standards, a written notice (Warning Letter) is sent, and an additional Grade “A” raw milk sample is taken within twenty-one (21) days of the date of the written notice (Warning Letter), but not before three (3) days.
- c. Permit suspension; stop sale; or imposition of a monetary penalty upon violation of:
 - 1.) *Grade “A” PMO*, Section 3. for serious health hazard; or
 - 2.) *Grade “A” PMO*, Section 6. for:
 - i. Three (3) out of the last five (5) Grade “A” raw milk samples exceeding the bacterial, somatic cell, or cooling temperature standards; or
 - ii. “Four (4) in six (6) months” positive antibiotic (not of Appendix N. of the *Grade “A” PMO* origin); or

- iii. If pesticide contaminated Grade “A” raw milk was not withheld from sale.

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

Category IV: Permit Reinstatement

- a. Temporary permit issued as required on reinstatement(s) following somatic cell count resampling, which indicates the Grade “A” raw milk supply to be within acceptable limits; or reinspection (bacterial or cooling temperature standards violation) made within one (1) week following proper notification, except after reinstatement for a drug residue or with resampling for somatic cell standard.
- b. “Reinstating accelerated sample(s)” for bacterial, cooling temperature and/or somatic cell counts taken at a rate of not more than two (2) per week, on separate days, within a three (3) week period.
- c. All permits reinstated as required by the *Grade “A” PMO*.

For Example: FORM NCIMS 2359j-PART I, ITEM 9 Calculation (Use FORM NCIMS 2359j - SECTION D. Dairy Farm Enforcement Action And Records Evaluations (PAGE 4). (Refer to Section J., Number 4 of this *MMSR*, for an example of the FORM.)

	Number Inspected	Number Complying	Percent Complying	Weight	Credit
Category I	25	25	100	20	20
Category II	25	22	88	20	17.6
Category III	25	25	100	20	20
Category IV	25	25	100	20	20
Category V	25	25	100	20	20

TOTAL CREDIT ► 97.6 = 98

TOTAL CREDIT to be entered into PART I, ITEM 9 “Percent Complying” column of FORM NCIMS 2359j. (Refer to Section K., Numbers 5, 9 and 11 of this *MMSR*, for examples.)

11. Records systematically maintained and current (*Grade “A” PMO*, Section 3., Section 5., Section 6., and Section 7.). Make use of both general Regulatory Agency official record-keeping deficiencies and specific dairy farm record-keeping deficiencies to determine the value. The BTU shall be prorated by the number of identified Regulatory Agency official record-keeping deficiencies per dairy farm. The four (4) Categories (a-d) listed below shall be utilized for determining compliance with this Item and each shall possess a value of twenty-five percent (25%) compliance. Compliance shall be prorated based on full compliance with each of the four (4) Categories.

NOTE: Use FORM NCIMS 2359j -SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 4). (Refer to Section J., Number 4 of this *MMSR*, for an example of the FORM.)

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

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

b. Category II: Inspection reports on file as directed by the Regulatory Agency and retained at least twenty-four (24) months. The results are entered on a milk ledger form or electronic retrieval system.

c. Category III: All results for bacteria, somatic cells, cooling temperatures, drug residues, pesticides, (if available), and water analysis are promptly recorded on a milk ledger form, a computer program or electronic retrieval system for each individual dairy farm. (Use the arithmetic average calculated by the Regulatory Agency or by personnel approved by the Milk Laboratory Control Agency at an Official or Officially Designated Laboratory, with industry consent where applicable, for bacterial counts, somatic cell counts and cooling temperature determinations when Grade “A” milk samples are collected from the same dairy farm on the same day from multiple storage tanks. This arithmetic average is recorded as the official results for the day on the Regulatory Agency official individual dairy farm record.)

d. Category IV: Within the Rating Period: Plan review file in order and written approval given for construction during the rating period.

For Example: FORM NCIMS 2359j-PART I, ITEM 10 Calculation (Use FORM NCIMS 2359j-SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS Dairy Farm Enforcement Action And Records Evaluations (PAGE 4). (Refer to Section J., Number 4 of this *MMSR*, for an example of the FORM.)

	Number Inspected	Number Complying	Percent Complying	Weight	Credit
Category I	25	25	100	25	25
Category II	25	25	100	25	25
Category III	25	23	92	25	23
Category IV	25	25	100	25	25

TOTAL CREDIT ► 98

TOTAL CREDIT to be entered into PART I, ITEM 10 “Percent Complying” column of FORM NCIMS 2359j. (Refer to Section K., Numbers 5, 9 and 11 of this *MMSR*, for examples.)

MILK PLANT-PART II

ER evaluations are based on NCIMS requirements, not on individual State's and/or Country's laws or regulations.

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

1. All milk plant, receiving station and transfer station operators hold a valid permit (*Grade "A" PMO*, Section 3.). All or nothing Item.
 - a. All milk plants, receiving stations and transfer stations hold a valid permit.
 - b. Permits retained only by those in compliance with the *Grade "A" PMO* requirements.
 - c. Permits not transferable with respect to persons and/or locations.
2. Milk plants and receiving stations inspected at least once every three (3) months (transfer stations, aseptic milk plants and retort milk plants at least once every six (6) months) (*Grade "A" PMO*, Section 5.). Prorate by the number of inspections in compliance with the required frequency.

For Example:

$$= \frac{\text{Number of three (3) or six (6) month periods with an inspection conducted}}{\text{Total number of three (3) or six (6) month periods in rating period, back to the last rating}}$$

- a. Milk plants and receiving stations inspected at least once every three (3) months.
- b. Transfer stations, aseptic milk plants, retort milk plants and fermented high-acid, shelf-stable milk plants inspected at least once every six (6) months.

NOTE: Refer to *MMSR*, Section E., 1., e. as a guide: "...the interval shall include the designated period plus the remaining days of the month in which the inspection is due."

3. Inspection sheet posted or available (*Grade "A" PMO*, Section 5.). All or nothing Item.

A copy of the most recent inspection report shall be available at the milk plant, receiving station or transfer station.

4. Requirements interpreted in accordance with the *Grade "A" PMO* as indicated by past inspections (*Grade "A" PMO*, Section 7.) Prorate by significant interpretation violation(s) not noted on previous inspection reports.

NOTE: For each Item that is identified as being misinterpreted, the value to be taken off from a possible 100 points corresponds to the weight value identified per Item on FORM NCIMS 2359L.

- a. Sanitarian's criterion is neither too lenient nor too stringent.
- b. Significant violations, including construction, debited by the sanitarian on the most recent inspection.

c. Sanitarian recognizes violations and debits as appropriate on the previous inspection reports.

5. Pasteurization equipment tested at required frequency (*Grade “A” PMO*, Section 7. and Appendix I.). Includes all required pasteurization equipment tests, including the test(s) following regulatory seal(s) being broken. This item is prorated by multiplying the number of pasteurization systems (units) by the number of three (3) month periods (quarters), plus the number of regulatory seals(s) being broken in the rating period, and less the number of those notifications or required quarterly pasteurization equipment tests where the testing was not conducted in compliance with the requirements set forth in Appendix I. of the *Grade “A” PMO*.

NOTE: Not required for aseptic, retort and fermented high-acid, shelf-stable milk plants, except when the APPS and/or AQFPSS is utilized to produce aseptically processed and packaged and/or fermented high-acid, shelf-stable Grade “A” milk and/or milk products and pasteurized and/or ultra-pasteurized Grade “A” milk and/or milk products. The APPS and/or AQFPSS shall then be tested by the Regulatory Agency in accordance with the requirements cited in Section 7. and Appendix I. of the *Grade “A” PMO*.

a. Total required pasteurized equipment tests performed, which includes regulatory seal(s) being broken, based on the number of pasteurization system(s) (units) at the milk plant. Within each quarter:

(Pasteurization system(s) (units) equals the number of Vat Pasteurizers, plus the number of HTST Pasteurizers, plus the number of HHST Pasteurizers, plus the number of APPS, if applicable as cited above).

For Example:

*=Number of three (3) month periods (quarters) X number of
pasteurization systems (Units) in which all of the required tests, which
include all milk plant notifications to the Regulatory Agency of a regulatory
seal(s) being broken, have been properly tested within each three (3) month
period (quarter)

divided by

Number of three (3) month periods (quarters) X total number of
pasteurization systems (units)

If a milk plant utilizes two (2) pasteurization systems (units) and was last rated two (2) years ago and one (1) pasteurization system (unit) does not have all of the required tests properly completed during one (1) quarter; plus there were four (4) milk plant notifications to the Regulatory Agency of a regulatory seal(s) being broken, of which one (1) did not have the required test(s) conducted before being re-sealed by the Regulatory Agency, the compliance is calculated as follows:

8 (Quarters) X 2 (Units) = 16 Required Unit Tests, Plus Two (2) Milk Plant Notifications due to broken regulatory seals = 18 Required Unit Tests, Less One (1) Non-Complying Re-seal Test and Less One (1) Non-Complying Quarter Test for a total of Sixteen (16) of Eighteen (18) in Compliance.

$$16/18 = 88.8\% \times 15 \text{ Weight} = 13.33 \text{ Credits}$$

***NOTE:** Credit shall not be given for a pasteurization system(s) (unit(s)) unless all the required tests for an individual pasteurization system (unit), including the test(s) required following regulatory seal(s) being broken, have been properly completed and recorded.

b. Pasteurization equipment tests shall be performed at the required frequency, including quarterly and semi-annual tests conducted by the Regulatory Agency, and tests conducted by the Regulatory Agency following regulatory seal(s) being broken.

NOTE: For the required quarterly and semi-annual pasteurization equipment testing refer to *MMSR*, Section E., 4., a.1.) as a guide: "For rating purposes, to determine if equipment testing have been conducted at the required frequency, the interval shall include the designated period plus the remaining days of the month in which the test(s) is due."

c. All required pasteurization equipment tests shall be properly conducted and the individual test results, including all required calculations, shall be recorded on appropriate forms. The results shall also be entered on appropriate milk ledger forms. A computer or other information retrieval system may be used.

NOTE: In the case of the NCIMS HACCP IMS listed milk plants that utilize industry personnel, acceptable to the Regulatory Agency, for the testing and sealing of pasteurization equipment, credit shall not be given unless all the applicable equipment testing requirements cited in Item 16p.(D)-Pasteurization Records, Equipment Tests And Examinations of the *Grade "A" PMO* and Appendix I. are met.

In the case of a Regulatory Agency authorizing on an emergency basis, an industry testing and temporary sealing program, credit shall not be given unless all the applicable equipment testing requirements cited in Item 16p.(D) of the *Grade "A" PMO* and Appendix I. are met.

6. Individual water supply, reclaimed water and recirculated cooling water samples tested and reports on file as required (*Grade "A" PMO*, Section 7., Appendix D., and Appendix G.). Prorate by the number of water samples tested during the required time period, back to the last rating vs. the total number of water tests due per water system.

a. Total required water tests performed based on each water system requiring testing at the milk plant, receiving station or transfer station.

For Example:

$$= \frac{\text{Number of test(s) performed at the required frequency per water system} \times \text{number of water systems}}{\text{Number of test(s) due at the required frequency per water system} \times \text{number of water systems}}$$

- b. Samples of individual water supplies, reclaimed water and recirculated cooling water, including sweet water and glycol systems, taken upon initial construction/installation; within thirty (30) days after extensive repairs or alterations; and every six (6) months thereafter.
- c. Sampling is not required for public, community, or rural water system(s), which are under EPA/applicable Government Water Control Authority and in compliance with their requirements.
- d. Condensing water for milk evaporators and water reclaimed from milk or milk products complying with Appendix D. of the *Grade "A" PMO*.
- e. Hauled water (cisterns) sampled in at least four (4) months out of six (6) months, at the point of use.
- b. Water supplies with buried well seals sampled every six (6) months.

NOTE: Refer to *Grade "A" PMO*, Section 7., Item 7p, ADMINISTRATIVE PROCEDURES, Number 8 as a guide: "To determine if water samples have been taken at the frequency established in this Item, the interval shall include the designated six (6) month period plus the remaining days of the month in which the sample is due."

- g. Appropriate follow-up investigation and re-sampling of the water supply/system following a positive bacteriological result. (Within thirty (30) days.)
- h. *E. coli* or heterotrophic count performed when required by Appendix G. of the *Grade "A" PMO*.
- i. Samples submitted to a laboratory acceptable to the Regulatory Agency.
- j. Current record of sample results on file at the Regulatory Agency, back to the last rating.

NOTE: Applicable Government Water Control Authority requirements, which are less stringent than the *Grade "A" PMO*, shall be superseded by the *Grade "A" PMO*. Applicable Government Water Control Authority requirements, which are stricter than the *Grade "A" PMO*, shall not be considered in determining the acceptability of water supplies during ratings, check ratings, single-service certification IMS listings and PHS/FDA audits.

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

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

- 7. Samples of each Grade "A" milk plant's milk and/or milk products collected at the required frequency and all necessary laboratory examinations made (*Grade "A" PMO*, Section 6). Prorate by the number of Grade "A" milk and/or milk products in compliance. (Refer to M-a-98, latest

revision, for the FDA validated and NCIMS accepted test methods for the specific Grade “A” milk and/or milk products.)

- a. During any consecutive six (6) months, at least four (4) samples of Grade “A” raw milk, after receipt by the milk plant, including aseptic, retort and fermented high-acid, shelf-stable milk plants, shall be collected, prior to pasteurization, aseptic processing and packaging, retort processed after packaging or fermented high-acid, shelf-stable processing and packaging, in four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days.
- b. During any consecutive six (6) months, at least four (4) samples of each Grade “A” milk and/or milk product processed, as defined in Section 1. of the *Grade “A” PMO* shall be collected in four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days as cited in Section 6. of the *Grade “A” PMO*. However, if the production of any Grade “A” milk or milk product, as defined in the *Grade “A” PMO*, is not on a continuous monthly basis and; therefore, cannot meet the *Grade “A” PMO* sampling frequency requirement as cited, then a sample of the Grade “A” milk or milk product shall be collected during each month of production.
- c. All required examinations performed on each Grade “A” milk and/or milk product sample (bacterial, coliform, drug residue, phosphatase, and cooling temperature, as applicable) in an Official or Officially Designated Laboratory (Commercial, if acceptable to the Regulatory Agency).

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

- d. Assays of Vitamin A, D, and/or A and D Grade “A” fortified milk and/or milk products, including 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 fermented high-acid, shelf-stable milk and/or milk products conducted at least annually in an IMS listed laboratory. Credit for vitamin-fortified milk and/or milk products is not given unless vitamin analysis is annually completed and laboratory results/reports are available in the Regulatory Agency’s official regulatory records. Each vitamin Grade “A” fortified milk and/or milk product is evaluated separately. (Refer to M-a-98, latest revision, for the specific Grade “A” milk and/or milk products that have FDA validated and NCIMS accepted test methods for vitamins.)

8. Sampling procedures approved by PHS/FDA evaluation methods (*Grade “A” PMO*, Section 6.; *EML*; and *SMEDP*).

NOTE: Use *MMSR*, “GUIDANCE FOR COMPUTING ENFORCEMENT CREDIT FOR PART 1, ITEM 8 AND/OR PART II, ITEM 8 OF FORM NCIMS 2359j-SECTION B. Report Of Enforcement Methods (PAGE 2).

ITEMS 4-All samplers hold a valid permit and 7-Permit suspension, revocation and reinstatement

action taken as required on FORM NCIMS 2359j- SECTION C. Evaluation Of Sampling Procedures (PAGE 3) are not applicable for milk plants, receiving and transfer stations when calculating ERs on FORM NCIMS 2359j-SECTION B. Methods Report Of Enforcement Methods (PAGE 2), PART II, ITEM 8.

NOTE: Divide by seventy-five (75) instead of 100 when making the calculations for PART II.

9. Permit issuance, suspension, revocation, reinstatement, hearings and/or court action taken as required (*Grade "A" PMO*, Section 3., Section 5., Section 6. and Section 16. PENALTIES). Prorate by required Regulatory Agency enforcement action(s) in compliance.

Five (5) Categories (a-e) shall be utilized for determining compliance with this Item and each shall possess a value of twenty percent (20%) compliance. The Categories are as follows:

- a. Category I: Permit Issuance;
- b. Category II: Permit Suspension;
- c. Category III: Permit Revocation;
- d. Category IV: Permit Reinstatement; and
- e. Category V: Hearing/Court Action.

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

NOTE: Use FORM NCIMS 2359j-SECTION E. Milk Plant Enforcement Action And Records Evaluations (PAGE 5). (Refer to Section J., Number 5 of this *MMSR*, for an example of the FORM.)

SANITATION REQUIREMENTS

Category I: Permit Issuance

- a. Inspected prior to the issuance of a permit.
- b. Permit issuance based on compliance.

Category II: Permit Suspension

- a. Notice issued for intent to suspend permit if an inspection(s) discloses a violation of a *Grade "A" PMO* requirement(s). Reinspection(s) made as required.
- b. Permit suspension upon violation of:

- 1.) *Grade "A" PMO* Section 3. for a serious health hazard or interference by the permit holder in the performance of the Regulatory Agency's duties; or
- 2.) *Grade "A" PMO* Section 5. for sanitation and/or uncorrected critical processing elements; or
- 3.) *Grade "A" PMO* Section 5. for consecutive violation(s) of the same requirements of Section 7. of the *Grade "A" PMO*.

c. Grade “A” milk and milk products processed during permit suspension or while a monetary penalty is imposed for repeated inspection violations is not eligible for sale as Grade “A”.

NOTE: *Grade “A” PMO*, Section 3. states: “The Regulatory Agency may forego suspension of the permit, provided the milk and/or milk product in violation is not sold or offered for sale as a Grade “A” milk and/or milk product. A Regulatory Agency may allow the imposition of a monetary penalty in lieu of a permit suspension, provided the milk and/or milk product in violation is not sold or offered for sale as a Grade “A” milk and/or milk product.” The option to issue a monetary penalty in lieu of a permit suspension as cited above shall not be applicable to a TPC authorized under the ICP.

Category III: Permit Revocation

Action to revoke a permit taken upon multiple permit suspensions.

Category IV: Permit Reinstatement

Reinstatement procedures followed.

NOTE: *Grade “A” PMO*, Section 3. states: "Whenever the permit suspension has been due to a violation of a requirement other than bacteriological, coliform, somatic cell count, drug residue test or cooling-temperature standards, the notification shall indicate that the violation(s) has been corrected. Within one (1) week of the receipt of such notification the Regulatory Agency shall make an inspection/audit of the applicant’s facility and as many additional inspections/audits thereafter as are deemed necessary, to determine that the applicant's facility is complying with the requirements. When the findings justify, the permit is reinstated."

Category V: Hearing/Court Action

Hearings provided for as required.

PRODUCT COMPLIANCE

Category II: Permit Suspension

a. All Grade “A” milk and/or milk products produced during a permit suspension or while a monetary penalty is imposed for bacterial count, coliform count, cooling temperature or drug residue violations are not eligible for sale as Grade "A".

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

b. When two (2) out of the last four (4) Grade “A” milk and/or milk product samples exceed the standards, a written notice (Warning Letter) is sent, and an additional sample is taken within

twenty-one (21) days of the date of the written notice (Warning Letter), but not before three (3) days.

c. When three (3) out of the last five (5) Grade “A” milk and/or milk product samples exceed the standards; or a positive drug residue or pesticide residue, the permit is immediately suspended.

d. Violation of Vitamin Fortification Levels (Refer to Appendix O. Vitamin Fortification Of Fluid Milk Products of the *Grade “A” PMO*): Determine the cause and re-sample or withhold Grade “A” milk and/or milk product from the market.

e. Positive Phosphatase: Determine the probable cause and if the cause is improper pasteurization, it shall be corrected before further sale of Grade “A” milk and/or milk product is allowed.

f. Positive Drug Residues or Pesticide Test: Investigate, determine the probable cause and correct before further sale of Grade “A” milk and/or milk product is allowed.

g. Permit suspension upon violation of:

1.) *Grade “A” PMO* Section 3. for serious health hazard; or

2.) *Grade “A” PMO* Section 6. for bacterial counts, coliform counts and cooling temperature violations if the product is not otherwise withheld.

h. All permits suspended as required by the *Grade “A” PMO*.

Category IV: Permit Reinstatement

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

b. Temporary permit issued as required on reinstatement(s) and reinspection made within one (1) week following proper notification except after reinstatement for a drug residue.

c. “Reinstating accelerated samples” for bacterial, cooling temperature, or coliform counts taken at a rate of not more than two (2) per week, on separate days, within a three (3) week period.

d. All permits reinstated as required by the *Grade “A” PMO*.

10. Records systematically maintained and current (*Grade “A” PMO*, Section 3., Section 4., Section 5., Section 6., and Section 7.) Make use of both general Regulatory Agency official record-keeping deficiencies and specific milk plant record-keeping deficiencies to determine the value. The four (4) Categories (I-IV) listed below shall be utilized for determining compliance with this Item and each shall possess a value of twenty-five percent (25%) compliance. Compliance shall be prorated based on full compliance with each of the four (4) Categories.

NOTE: Use FORM NCIMS 2359j-SECTION E. Milk Plant Enforcement Action And Records Evaluations (PAGE 5). (Refer to Section J., Number 5 of this *MMSR* for an example of the FORM.)

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

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

- b. Category II: Inspection reports and pasteurization equipment tests filed as directed by the Regulatory Agency and retained for at least twenty-four (24) months. The results are entered on a milk ledger form or other electronic retrieval system.
- c. Category III: All test results for bacterial, coliform, cooling temperature, phosphatase, drug residues, pesticide (if available), vitamin assay, and water analysis promptly recorded on an appropriate ledger form, or other electronic retrieval system for each individual Grade “A” milk and/or milk product. (Use the arithmetic average calculated by the Regulatory Agency or by personnel approved by the Milk Laboratory Control Agency at an Official or Officially Designated Laboratory, with industry consent where applicable, for bacterial counts, coliform counts, and cooling temperature determinations when Grade “A” milk and/or milk samples are collected of the same milk or milk product from the same milk plant on the same day from multiple storage tanks or silos. This arithmetic average is recorded as the official results for the day on the Regulatory official individual milk plant record.)
- d. Category III: Records maintained on bacteriological examination of milk containers, if required.
- e. Category III: Vitamin volume control records complete and on file at the milk plant as required.
- f. Category IV: Within the Rating Period: Plan review file in order and written approval given for construction during the rating period.

INDIVIDUAL SHIPPER RATING-PART III

- 1. Refer to the “TOTAL CREDIT”, PART I value and multiply by "47", if an attached Grade “A” raw milk supply (dairy farms) is included with the milk plant listing. (Refer to the instructions below PART III on FORM NCIMS 2359j-SECTION B. Report Of Enforcement Methods (PAGE 2).) If an attached Grade “A” raw milk supply (dairy farms) is not included with the milk plant listing, leave this Item blank.
- 2. Refer to the “TOTAL CREDIT”, PART II value and multiply by “47”, if an attached Grade “A” raw milk supply (dairy farms) is included with the milk plant listing; or by “94”, if only an unattached Grade “A” raw milk supply(ies) (dairy farm(s)) is utilized. (Refer to the instructions below PART III on FORM NCIMS 2359j-SECTION B. Report Of Enforcement Methods (PAGE 2).)
- 3. All Grade “A” milk and/or milk products properly labeled (*Grade “A” PMO*, Section 4.).
 - a. Prorate by Grade “A” Milk and/or Milk Product: Number of different Grade “A” milk and/or milk products correctly labeled vs. total number of Grade “A” milk and/or milk products, including Grade “A” raw milk.
 - b. Include in Label Review:

- 1.) A representative label(s) for all Grade “A” milk and/or milk products produced, including Grade “A” raw milk. Grade “A” milk and/or milk products are labeled according to the *Grade “A” PMO* definition(s) and requirements and applicable CFRs.
- 2.) Vehicles hauling Grade “A” milk shall be properly identified with the name and address of the milk plant or hauler. (Include under Grade “A” raw milk.)
- 3.) Milk cans from dairy farms properly identified. (Include under Grade “A” raw milk.)
- 4.) Bills-of-lading and dairy farm weight tickets contain all the required information, including BTU #. (Include under Grade “A” raw milk where applicable.)

NOTE: All Regulatory Agency official records shall be summarized on an appropriate milk ledger form. The use of ledgers including other electronic retrieval systems are acceptable. Records include:

- a. Inspections of dairy farms, milk plants, receiving stations and transfer stations, bulk milk hauler/samplers, dairy plant samplers, industry plant samplers, milk tank trucks, etc.;
- b. Laboratory information, i.e., Grade “A” raw milk, finished Grade “A” milk and/or milk products, vitamin assays, water, cooling media, etc.; and
- c. Pasteurization equipment tests.

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

FORM NCIMS 2359j-SECTION C. EVALUATION OF SAMPLING PROCEDURES (PAGE 3) shall be used to determine enforcement credit for PART I, ITEM 8, FORM NCIMS 2359j-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2) (Dairy Farms), and PART II, ITEM 8, FORM NCIMS 2359j-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2) (Milk Plant). ITEMS 4 and 7 on FORM NCIMS 2359j-SECTION C. EVALUATION OF SAMPLING PROCEDURES (PAGE 3) do not apply when calculating ERs for milk plants, receiving stations and transfer stations for FORM NCIMS 2359j-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), PART II, ITEM 8.

Item 1. SSOs Properly Certified

- a. All SSOs are certified by PHS/FDA.
- b. Certification is currently valid (three (3) years and expire at the end of the month from the date identified on the certificate).
- c. SSOs shall be a certified SRO, LEO or in the case of a State or TPC Regulatory Supervisor hold a valid certificate as a dSSO per "*Procedures*" Section V., G.

Item 2. Adequate Training Program Provided

- a. Reference material available to samplers.
- b. Training program conforms to established procedures.
- c. Training program implemented.
- d. Copies of training materials and other related information are on file with the Regulatory Agency for review.

Item 3. Sampling Surveillance Authority Properly Delegated

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

“A” raw milk sample from a milk tank truck at one (1) milk plant, if applicable, with at least eighty percent (80%) agreement on each listed Item.

- e. Proper certification of industry field personnel when applicable.

Item 4. All Samplers Hold a Valid Permit (Applies to PART I- DAIRY FARMS Only)

- a. All bulk milk hauler/samplers have a valid permit.
- b. Inspected prior to the issuance of a permit.
- c. Only bulk milk hauler/samplers who comply with *Ordinance* requirements shall be entitled to receive a permit.
- d. Permits not transferable with respect to persons.

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

- a. Samplers shall have their sampling collection procedures evaluated by a certified SSO or a dSSO every two (2) years. SSOs and/or dSSOs are not required to be evaluated for sampling collection procedures.

NOTE: Refer to *Grade “A” PMO*, Section 5., **Administrative Procedures, Inspection Frequency** as a guide: “For the purposes of determining the inspection frequency for bulk milk hauler/samplers, industry plant samplers and dairy plant samplers, the interval shall include the designated twenty-four (24) month period plus the remaining days of the month in which the inspection is due.”

- b. Proper Agencies are advised of all samplers and of all evaluations annually in accordance with procedures.

Item 6. Sampling Procedures in Substantial Compliance

- a. Appraisal of each sampler’s compliance done by record review.
- b. Appraisal of sampler’s compliance.
- c. Evaluation criteria neither too stringent nor too lenient.

Item 7. Permit Suspension, Revocation, Reinstatement, Hearings and/or Court Actions Taken as Required (Applies to PART I- DAIRY FARMS Only)

- a. Action taken on repeat violations of sampling requirements.
- b. Re-evaluations made as required.

Item 8. Records Systematically Maintained and Current

- a. Regulatory Agency official records of the delegation of sampling evaluation authority to other Regulatory Agency or industry individuals on file and available for review with the Regulatory Agency official dairy farm or milk plant records.
- b. Regulatory Agency official records of each sampler evaluation on file and available for review with the Regulatory Agency official dairy farm or milk plant records.

- c. Regulatory Agency official records for each sampler evaluation entered on individual ledgers. An electronic ledger or other information retrieval system are acceptable.
- d. Regulatory Agency official records of permit issuance, suspension, reinstatement, revocation and hearings on file and available for review.
- e. Regulatory Agency official records of bulk milk hauler/sampler, dairy plant sampler and industry plant sampler inspections on file.

APPENDIX B.

TABLE OF DAIRY FARM WATER SUPPLY VIOLATIONS

The following Table was accepted by the NCIMS Executive Board for use as guidance in evaluating dairy farm water supplies. The Table provides guidance, which may be used to differentiate between two (2) point (minor) and five (5) point (major) violations of Section 7., Item 8r of the *Grade "A" PMO* during ratings and PHS/FDA check ratings.

Primary Violation Areas as Defined by the *Grade "A" PMO*

1. Water supply is safe and complies with Appendix D. of the *Grade "A" PMO*;
2. No cross-connections between safe and unsafe supplies;
3. No submerged inlets;
4. Well location and construction;
5. New individual water supplies disinfected prior to use;
6. All containers/tanks used to transport and protect water are protected from contamination;
7. Periodic sampling; and
8. Water testing records current.

WELLS, SPRINGS AND CISTERNS: CONSTRUCTION AND LOCATION

Major (5 point)	Minor (2 point)
<u>1. Any openings that allow direct contamination of the well water, such as:</u> a. Well cap/cover not in proper position on top of casing to protect against contamination (i.e., missing, lying on ground, hanging off edge of casing, etc.); b. Well cap/cover not impervious; c. Opening in top of casing (i.e., vent hole, opening around electrical wires, etc.); d. Well casing or top cracked/perforated with openings to interior of well; e. Well seal not watertight; and f. Frost-free style water hydrant out of the top of the well casing.	<u>1. Any openings that allow indirect contamination of the well water:</u> a. Well cap/cover not tight or overlapping (i.e., set screws, etc. not tightened) but in proper position to protect against contamination; b. Proper vent (turned down pipe) but unscreened or damaged screen; and c. Loose wires running from the outside of the well into the well casing from the side or underside of the well cap.
<u>2. Large hole/depression, indication of erosion around well casing or standing water around well casing.</u>	<u>2. Slight depression around well with no evidence of standing water.</u>

Major (5 point)	Minor (2 point)
3. <u>Well pit does not meet the following requirements:</u> a. Watertight construction (protected from ground water/rainwater); b. Watertight impervious cover; c. Watertight impervious (concrete) floor sloped to drain; d. Operational sump pump or traceable drain to the surface; e. Dry floor in pit; and f. Well in bottom of pit protected from contamination using cover, seals, etc.	3. <u>Well pit does not meet the following requirements:</u> a. Concrete base for pump/machinery at least 12 inches (30.5 centimeters) above the pit floor; and b. Cover of the overlapping (shoe box) type.
4. <u>Spring box not properly constructed or protected:</u> a. Spring box and cover do not protect spring from direct contamination, (i.e., uncovered, openings in top, cracks in sides, etc.); b. Surface drainage not diverted away from spring; and c. Spring located in open pasture/field with livestock concentrating within 50 feet (15 meters) as evidenced by trampling of ground, accumulation of manure, or a stock tank or cattle feeding area within 50 feet (15 meters) of spring.	4. <u>Spring box not properly constructed or protected:</u> a. Overflow piping not screened; b. Spring box cover not overlapping; and c. Minor construction deficiencies.
5. <u>Water reservoir/cistern/tank construction and use:</u> a. Constructed to allow contamination of the potable water; and b. Transfer/distribution system constructed to allow contamination of the water supply or distribution system.	5. <u>Water reservoir/cistern/tank construction:</u> Minor construction problems.
6. <u>Buried well seal:</u> With a bad water sample not brought into compliance.	6. <u>Inaccessibility:</u> Except for seasonal conditions like snow and insulation wrap during winter months, the following water sources/supplies shall be accessible for routine inspection and rating evaluation: a. Above ground wells and well pits; b. Cisterns, reservoirs and springs; and c. Stock waterers.

Major (5 point)	Minor (2 point)
7. Well within 50 feet (15 meters) of contamination source (i.e., sewer lines, septic tank, drain field, cowyard, cattle housing areas without impervious floors, calf pens, waste disposal lagoons, buried gasoline tanks, herbicide/pesticide storage, etc.).	7. Frost-free style water hydrant located within 10 feet (3 meters) of the well without an approved atmospheric vacuum breaker or with the hose connection threads not cut off.
8. Well casing terminating below or at ground level. (Does not include well pits or buried well seals complying with Item 8r of the <i>Grade "A" PMO</i>.)	8. Any pit not meeting the construction standards of the <i>Grade "A" PMO</i>, which is located within 10 feet (3 meters) of the well.
9. Well located in a known flood plain with well casing terminating less than 2 feet (0.6 meters) above the highest known flood level.	
10. Well located in open pasture/field with livestock concentrating within 50 feet (15 meters) of well as evidenced by trampling of the ground, accumulation of manure, or a stock tank or cattle feeding area within 50 feet (15 meters) of the well*.	
11. Improperly constructed abandoned well(s) located within 10 feet (3 meters) of well(s) used as source of potable water for the dairy.	

* If there is not any evidence of livestock concentration around a well casing that is located in a pasture, then this Item should not be debited.

WATER SAMPLING

Major (5 point)	Minor (2 point)
1. Last water sample unsatisfactory.	1. Last sample on record tested safe, but the next sample was not collected/analyzed within the required time frames: a. New Permit: Then once every three (3) years; b. Buried Well Seal: Every six (6) months; c. Hauled Water: At least four (4) times in separate months during any consecutive six (6) months; and d. After Any Well Repair: Within thirty (30) days.
2. No record of an initial bacteriological sample on file prior to the issuance of a permit for new dairy farms, without any additional sample results on file for the rating period.	
3. Continuous disinfection system, required by the Regulatory Agency, is not operational.	
4. On dairy farms with interconnected wells, if the system is constructed and operated so that a single sample will represent all sources, then a single sample is sufficient. If a single sample does not represent all sources, then each individual well shall be sampled at the required frequency (M-I-86-9).	

CROSS-CONNECTIONS AND SUBMERGED INLETS:

Major (5 point)	Minor (2 point)
1. <u>Submerged inlets:</u> Into non-potable water, (i.e.): a. Submerged line in a stock tank(s)/stock fountain(s); b. 2-compartment wash vat(s) containing water or with the drain plugged; c. Drinking cups; d. Pre-cooler outlet; e. Flush down tanks; f. Water inlet to a CIP/wash vat is submerged in water or solution in the vat; and g. Chill water tank (sweet water, glycol, etc.).	1. <u>Potential submerged inlets:</u> a. Single-cased pipe in a stock tank or fountain; b. Properly working stock tank float located below the overflow rim of the tank; and c. Water inlet (equipped with an automatic shut-off) to a CIP/wash vat terminates below the rim of the vat, but is not submerged in water or solution. (NOTE: If the float has stuck and it is submerged at the time of the inspection it is a five (5) point debit.)
2. <u>Permanent in-line high pressure pump (power washer):</u> Without acceptable protection, such as: a. Properly functioning low-pressure cut-off switch with a properly located test valve; and b. Other methods acceptable to the State Water Control Authority.	2. <u>Portable high pressure water pump (power washer):</u> Without acceptable protection, such as: a. Separate water supply or reservoir; b. Properly functioning low-pressure cut-off switch with a properly located test valve; and c. Other methods acceptable to the applicable Government Water Control Authority. (NOTE: Lack of a valve or improperly located valve, used to test the low-pressure cut-off switch is a two (2) point debit.)
3. Cleaner, sanitizer and udder wash injectors (pumps) with water supply connection not properly protected and supply container of greater than one (1) gallon size. Submerged inlet(s) in other chemical containers (i.e., bottles and/or containers of Roundup, 2-4D, etc.), regardless of the size of the chemical container.	

Major (5 point)	Minor (2 point)
4. Anti-siphon vent-type backflow preventer with vent plugged.	
5. Use of non-functional or improper devices to protect against submerged inlets and/or cross-connections.	
6. Stock tank(s) utilizing center ground pipe as an overflow, where the overflow is flooded and not draining.	
7. Discharge hose connecting potable water system directly to the sewer system or manure handling system (i.e., water line terminating below the flood rim of a floor drain).	

RECLAIMED WATER NOT MEETING THE FOLLOWING CRITERIA:

(Appendix D., VI. - Water Reclaimed from Heat Exchanger Processes or Compressors on Grade “A” Dairy Farms)

Major (5 point)

- 1. Sampled before initial approval;**
- 2. Sampled at least once in each six (6) month period;**
- 3. Proper construction of the storage tank (i.e., protected from contamination);**
- 4. No cross-connections between reclaimed water and non-potable water; and**
- 5. Approved chemicals used if water is treated.**