

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

2013 Revision

Includes the:

- ◆ CONSTITUTION AND BYLAWS OF THE NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS
- ◆ MEMORANDUM OF UNDERSTANDING BETWEEN THE U.S. FOOD AND DRUG ADMINISTRATION AND THE NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS
- ◆ RELATED DOCUMENTS



**U. S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
AND THE
NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS**

PREFACE

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

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

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

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

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SECTION I. PURPOSE

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

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

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

SECTION II. SCOPE

A. PRODUCTS COVERED

Agreements adopted by the NCIMS shall apply to Grade “A” raw milk and/or milk products for pasteurization, heat-treated products, pasteurized, ultra-pasteurized, aseptically processed and packaged low-acid milk and/or milk products, and/or retort processed after packaged low-acid milk and/or milk products, condensed and dry milk products, and whey and/or whey products produced under the NCIMS program.

B. SUPERVISION REQUIREMENTS

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

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

SECTION III. 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.

A. **ADVERSE ACTION:** A re-inspection, re-rating or withdrawal of certification of an individual IMS listed shipper.

B. **AREA RATING:** An area rating, if used, shall apply to raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging and retort processed after packaging. An area rating consists of more than one (1) producer group operating under the supervision of a single Regulatory Agency and which is rated as a single entity. An individual dairy farm shall only be included in one (1) IMS Listing.

C. **ASEPTIC PROCESSING AND PACKAGING SYSTEM (APPS):** For the purposes of this document, the Aseptic Processing and Packaging System (APPS) in a milk plant is comprised of the processes and equipment used to process and package aseptic Grade "A" low-acid milk and/or milk products. The Aseptic Processing and Packaging System (APPS) shall be regulated in accordance with the applicable requirements of 21 CFR Parts 108, 110 and 113. The Aseptic Processing and Packaging System (APPS) shall begin at the constant level tank and end at the discharge of the packaging machine, provided that the Process Authority may provide written documentation which will clearly define additional processes and/or equipment that are considered critical to the commercial sterility of the product.

D. **BULK TANK UNIT (BTU):** A dairy farm or group of dairy farms from which raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging and/or retort processed after packaging is collected under the routine supervision of one (1) Regulatory Agency and rated as a single entity and given a Sanitation Compliance and Enforcement Rating. An individual dairy farm shall only be included in one (1) IMS Listing.

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

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

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

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

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

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

K. **IMS LISTED SHIPPER**: An interstate milk shipper (BTU, receiving station, transfer station, or milk plant), which has been certified by a Rating Agency as having attained the Sanitation Compliance and Enforcement Ratings necessary for inclusion on the *IMS List*. The ratings are based on compliance with the requirements of the *Grade "A" PMO* and were made in accordance with the procedures set forth in the *Methods of Making Sanitation Ratings of Milk Shippers (MMSR)*. For milk plants that produce aseptically processed and packaged Grade "A" low-acid milk and/or milk products and/or retort processed after packaged Grade "A" low-acid milk and/or milk products, prior to the milk plant participating in the NCIMS Aseptic Processing and Packaging Program and/or Retort Processed after Packaging Program, respectively, the 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 Retort Processed after Packaging Program.

L. **INDIVIDUAL RATING**: An individual rating is the rating of a single producer group, milk plant, receiving station, and/or transfer station under the supervision of a single Regulatory Agency. Milk plants producing Grade "A" condensed and/or dried milk and/or milk products

and/or Grade “A” condensed and/or dry whey and/or whey products may be rated separately from the same milk plant producing other Grade “A” milk and/or milk products, provided each listing holds a separate permit. Milk plants that produce aseptically processed and packaged Grade “A” low-acid milk and/or milk products, and/or retort processed after packaged Grade “A” low-acid milk and/or milk products and pasteurized and/or ultra-pasteurized Grade “A” milk and/or milk products shall be rated separately. Provided that an NCIMS HACCP milk plant listing that produces aseptically processed and packaged Grade “A” low-acid milk and/or milk products and/or retort processed after packaged Grade “A” low-acid milk and/or milk products shall have only an NCIMS HACCP listing. An individual dairy farm shall only be included in one (1) IMS Listing.

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

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

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

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

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

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

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

T. **MEMORANDUM OF MILK ORDINANCE EQUIPMENT COMPLIANCE (M-b)**: A memorandum issued by PHS/FDA that provides a notice of PHS/FDA's review of equipment related to compliance with the *Grade "A" PMO* to PHS/FDA Regional staff and Regulatory/Rating Agencies.

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

V. **MILK PLANT**: A milk plant is any place, premises, or establishment where milk and/or milk products are collected, handled, processed, stored, pasteurized, ultra-pasteurized, aseptically processed and packaged, retort processed after packaged, condensed, dried, packaged, or prepared for distribution.

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

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

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

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

AA. **RETORT PROCESSED AFTER PACKAGING SYSTEM (RPPS)**: For the purposes of this document, the Retort Processed after Packaging System (RPPS) in a milk plant is comprised of the processes and equipment used to retort process after packaging low-acid Grade "A" milk and/or milk products. The Retort Processed after Packaging System (RPPS) shall be regulated in accordance with the applicable requirements of 21 CFR Parts 108, 110 and 113. The Retort Processed after Packaging System (RPPS) shall begin at the container filler and end at the palletizer, provided that the Process Authority may provide written documentation which will clearly define additional processes and/or equipment that are considered critical to the commercial sterility of the milk and/or milk product.

BB. **REGULATORY/RATING AGENCY PROGRAM EVALUATION**: An evaluation of a Regulatory/Rating Agency's program by PHS/FDA. This shall include check ratings of IMS Listed Shippers, an assessment of a Regulatory/Rating Agency's administrative procedures and records, adoption of the *Grade "A" PMO* (or equivalent laws and regulations), and compliance with NCIMS *Procedures*.

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

Executive Board and the Third Party Certifier (TPC).

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

SECTION IV. OVERSIGHT AND RESPONSIBILITIES

A. PHS/FDA RESPONSIBILITIES

1. Standardization of Personnel

PHS/FDA shall standardize at least every three (3) years the rating procedures of:

a. PHS/FDA Regional personnel who:

1.) Meet the qualification requirements of the PHS/FDA Milk Safety Program;

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

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

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

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

2. Training

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

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

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

3. Regulatory/Rating Agency Program Evaluations

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

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

2.) Identification of regulatory responsibilities:

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

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

4.) Identification of IMS responsibilities:

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

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

- A.) Adequate proof of disposition of contaminated loads.

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

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

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

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

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

A.) Milk Sampling:

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

B.) Milk Hauling and Transportation:

- 1.) The issuing of milk tank truck permits,
- 2.) Milk tank truck inspection (adequacy and frequency),
- 3.) Actions taken against those milk tank trucks or milk transportation

- companies not in compliance,
- 4.) Forwarding results of milk tank truck inspections, performed on milk tank trucks permitted by another Regulatory Agency, to that Regulatory Agency in a timely manner,
 - 5.) Follow-up actions taken when a violative milk tank truck inspection report is received from another Regulatory Agency regarding a milk tank truck permitted by this Regulatory Agency,
 - 6.) Inspection, enforcement and permitting program for unattached milk tank truck cleaning facilities, and
 - 7.) Adequacy of associated records.

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

4. Laboratory Evaluations

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

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

5. Electronic Publication of Sanitation Compliance and Enforcement Ratings

a. PHS/FDA shall provide an electronic publication of the *IMS List* on their web site. The electronic *IMS List* is available at <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/MilkSafety/FederalStatePrograms/InterstateMilkShippersList/default.htm>. The Sanitation Compliance Ratings of IMS listed milk shippers, the Enforcement Ratings of Regulatory Agencies and the IMS Listed shippers' expiration

rating dates contained in the electronic publication are certified by the Rating Agency to be those established by ratings conducted in accordance with the *MMSR* by certified SROs when FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT is signed and submitted to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs for publication.

Milk plants, receiving stations and transfer stations shall achieve a Sanitation Compliance Rating of 90 percent (90%) or higher, except as cited in Section VIII., C.,5. for HACCP listings, in order to be eligible for a listing on the *IMS List*. Sanitation Compliance Rating scores for transfer and receiving stations and milk plants will not be identified on the *IMS List*.

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

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

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

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

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

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

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

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

7. Interpretations and Editorial Updates

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

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

1. PHS/FDA is requested or determines the necessity to issue an M-a.
2. PHS/FDA develops the draft M-a, with a proposed implementation date, after seeking input from appropriate sources.
3. PHS/FDA disseminates the draft M-a to all Regulatory and Rating Agencies and the Executive Board with provisions for a thirty (30) day written comment period from the date of dissemination. The date the draft M-a was actually distributed by PHS/FDA to all Regulatory and Rating Agencies and the Executive Board shall be the date of dissemination from which all timelines are calculated. When calculating the timelines, the date of dissemination is not counted as one (1) of the days.
4. All comments shall be submitted to the Executive Secretary, NCIMS Executive Board.
5. The Executive Secretary shall forward comments to PHS/FDA MST and the Executive Board within fifteen (15) days of the end of the comment period.
6. The NCIMS Executive Board may, within seventy-five (75) days of the dissemination of the draft M-a, with the majority of the Board consenting, request PHS/FDA to consider modifying the draft M-a as provided by the Board.
7. Within one hundred and five (105) days of the dissemination of the draft M-a, PHS/FDA shall provide to the NCIMS Executive Secretary sufficient copies of each draft M-a for submission to the NCIMS voting delegates for their approval or disapproval. After receipt from PHS/FDA of the draft M-a, the NCIMS Executive Secretary shall forward within fifteen (15) days a copy of the draft M-a to the current NCIMS voting delegates, along with a ballot and instructions for returning their vote. The Executive Secretary shall include a copy of the comments and the minutes covering the discussion between PHS/FDA and the Executive Board. All ballots shall contain a date fifteen (15) days from the date the ballot was mailed or sent (if by other means) by which time, the ballot shall be received by the NCIMS Executive Secretary to be counted.
8. The NCIMS Executive Secretary may use any available method for delivering copies of each draft M-a and the voting ballots including, but not limited to: (i) the mail; (ii) private carriers; (iii) facsimile; (iv) email; or (v) other electronic means. The Executive Secretary has fifteen (15) days from the end of the voting period to forward the results (votes per State) to PHS/FDA.
9. An M-a shall not become effective unless it receives the approval from a simple majority of the returned ballots of the NCIMS voting delegates.
10. PHS/FDA shall, at the next duly convened Conference, submit a Proposal, incorporating the requirements of any M-a, issued between Conferences, into the appropriate document(s).

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

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

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

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

b. In order to make effective use of PHS/FDA Regional Office personnel, the random selection of shippers to be check rated shall be selected in advance and assignments scheduled in each State and/or TPC’s jurisdiction. Selection of dairy farms shall be made from records provided at the time of the check rating.

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

d. In any case a check rating cannot be conducted with a greater frequency than the official rating or listing.

e. For action to be taken if the PHS/FDA check rating indicates the listed rating is not justified, refer to Section IV., B., 7.c. For the purpose of these *Procedures* and all related forms, the terms “listed rating”, “official rating” and “published rating” shall mean the most recent rating, which is accompanied by written permission from the shipper to

publish, and submitted to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs by the Rating Agency.

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

g. Enforcement Ratings shall be conducted as part of check ratings.

B. STATE AND TPC RESPONSIBILITIES

1. Ratings and Single-Service Containers and Closures Manufacturer Listings

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

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

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

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

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

immediately withdrawn from the *IMS List* and the shipping State or TPC shall immediately notify all receiving States and/or TPCs and the appropriate PHS/FDA Office or PHS/FDA MST for TPCs.

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

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

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

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

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

k. When a certified manufacturer of Single-Service Containers and Closures for Milk and Milk Products changes status because of permit suspension and/or revocation or the withdrawal of their listing based upon observed violations that cannot ensure the sanitary quality of their single-service containers and/or closures that may lead to a potential public health concern involving the contamination of milk and/or milk products packaged within them, the shipping State or TPC shall immediately notify all known receiving States and/or TPCs and the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs.

When an existing listing is no longer valid because a listed single-service containers and closures manufacturer's permit is revoked, the State or TPC shall within five (5) days request PHS/FDA to withdraw the shipper from the *IMS List*.

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

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

2. Enforcement Ratings

Enforcement Ratings shall be conducted as part of Milk Sanitation Ratings.

3. Laboratory Evaluation

a. If written split sample results of the laboratories/Certified Industry Supervisor (CIS) used by certified interstate milk shippers are not received by PHS/FDA LPET within sixteen (16) months of the last previous split sample date, PHS/FDA LPET shall notify the appropriate PHS/FDA Regional Office in writing to send a written withdrawal of the accreditation of the laboratory(ies) concerned. A copy of the PHS/FDA Regional Office notice or PHS/FDA LPET notice for TPCs to the Milk Laboratory Control Agency to withdraw accreditation shall be sent to the Regulatory and/or Rating Agency. The Milk Laboratory Control Agency shall then inform the laboratory(ies), the Regulatory Agency and/or Rating Agency in writing of the action.

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

4. Response to Regulatory/Rating Agency Program Evaluations

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

5. Request for Emergency Consideration

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

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

6. Reports to Database

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

7. Challenges and Remedies

a. Complaints from Receiving States or TPCs

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

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

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

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

A.) Notify the receiving State(s) and/or TPC(s) and appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs that the complaint has been resolved;

B.) Withdraw the certification of the shipper and notify the receiving State(s) and/or TPC(s) and the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs of such action; or

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

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

A.) Notify PHS/FDA, the State and/or TPC making the complaint. Such notification shall be considered by PHS/FDA as tantamount to the withdrawal of

the present certification of the interstate shipper involved.

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

b. Complaints from Shipping States and/or TPCs

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

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

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

1.) Dairy Farms (Raw Milk)

A.) Action to be Taken

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

DAIRY FARMS (RAW MILK)

LISTED RATING	RE-RATING	WITHDRAW CERTIFICATION
100 to 90	84 to 80	79 or less
89 to 84	83 to 80	79 or less
83	82 to 80	79 or less
82	81 to 80	79 or less
81 or less	80	79 or less

B.) Re-Rating

When check rating data indicates that the Sanitation Compliance Rating of a listed shipper's dairy farms requires a re-rating, PHS/FDA shall formally notify

the Rating Agency that a re-rating of the dairy farms shall be required within sixty (60) days.

C.) Withdrawal of Certification

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

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

A.) Action to be Taken

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

MILK PLANTS, RECEIVING STATIONS AND/OR TRANSFER STATIONS

LISTED RATING	REINSPECTION	WITHDRAW CERTIFICATION
100 to 90	80	79 or less

B.) Reinspection

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

C.) Withdrawal of Certification

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

3.) Single-Service Containers and Closures For Milk and Milk Products

A.) Withdrawal of Certification

When PHS/FDA audit data indicates violations that cannot ensure the sanitary quality of single-service containers and/or closures that may lead to a potential public health concern involving the contamination of milk and/or milk products packaged within them requires a withdrawal of certification, the Rating Agency upon written recommendation of PHS/FDA, shall immediately withdraw the current certification of the shipper and notify such shipper, PHS/FDA, and all known receiving States thereof, in accordance with Section IV., B., 1.k. In case of withdrawal, a new certification shall be made in not less than thirty (30) days and not to exceed sixty (60) days, unless the Rating Agency has reason to believe a new certification within a lesser time period, would result in an acceptable listing. The effective date for action shall be determined from the date of the letter of notification by the Rating Agency. Such letter shall be dated within five (5) working days following the date of the official notification.

4.) If a Rating Agency fails to take the required action outlined in Section IV., B., 7.c.1.), 7.c.2.) and 7.c.3), calling for immediate notification of all known receiving States and/or TPCs when the current certification of a listed shipper is to be withdrawn as recommended by PHS/FDA, PHS/FDA after a reasonable lapse of time (not to exceed five (5) days), shall provide all participating States and TPCs with the check rating scores results or audit findings for single-service containers and closures

listings. The State or TPC which failed to take the required action shall be identified in the next listing of the *IMS List* as not being in compliance with Section IV., B., 7.c.1.), 7.c.2.) and 7.c.3).

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

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

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

SECTION V. QUALIFICATIONS AND CERTIFICATIONS

A. SUPERVISION REQUIREMENTS

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

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

3. Sampling procedures and laboratory examinations are a fundamental and basic component of supervision. The surveillance of sample collection procedures shall be conducted as prescribed in the *Grade “A” PMO*. Samples from each dairy farm and each pasteurization milk plant shall be examined for the prescribed tests at the frequency prescribed in the PHS/FDA recommended *Grade “A” PMO*.

B. PROCEDURES FOR REQUESTING A MILK SANITATION RATING

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

C. SANITATION COMPLIANCE AND ENFORCEMENT RATINGS REQUIRED

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

1. Sanitation Compliance Ratings on dairy farms, transfer stations, receiving stations, pasteurization plants, condensed and dry milk plants and whey plants.
2. Enforcement Rating of the Regulatory Agency.

D. MILK SANITATION RATING PERSONNEL

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

1. Have submitted to PHS/FDA a written request for certification including the following: applicant name and contact information, education, training, work experience, list of training courses attended and categories for which certification are being requested.
2. Have been certified by PHS/FDA as a SRO and hold a valid certificate of qualification in one (1) or any combination of the following categories: milk pasteurization plants, including HACCP and/or aseptic processing and packaging, and/or retort processed after packaging, if appropriate, dairy farms and transfer/receiving stations, including HACCP if appropriate. The PHS/FDA shall issue a certificate, valid for three (3) years, to each individual who meets the criteria listed below, as applicable. Certification of a SRO shall qualify that SRO to perform ratings or HACCP listings, if applicable, upon the request of that State's or TPC's Regulatory/Rating Agency as long as the SRO's certification is valid.
3. A SRO applicant for initial certification shall be evaluated by PHS/FDA personnel in an independent side-by-side comparison of dairy facilities using the items listed on the appropriate inspection or evaluation report form. The applicant and PHS/FDA personnel shall be in agreement at least eighty percent (80%) of the time on each listed item. Comparison evaluations shall be performed on at least the following number of dairy facilities:
 - a. Twenty-five (25) producer dairies. Milking time evaluations should be included.
 - b. Five (5) pasteurization milk plants. Milk plants of varying sizes using, vat, HTST and HHST pasteurization; ultra-pasteurization; aseptic processing and packaging; and/or retort processed after packaging, if applicable, should be included in these evaluations. One (1) transfer or receiving station may also be included as one (1) of the required five (5) pasteurization milk plants.
 - c. One (1) dry milk plant, if applicable. The dry milk plant may be used as one (1) of the required five (5) pasteurization plants.

- d. If HACCP certified for plants, receiving or transfer stations, in addition to meeting the requirements listed above for pasteurization plants for a SRO, one (1) mock-listing audit conducted separate from an official HACCP listing audit is required. (Refer to Section VIII., E.6. for additional HACCP certification procedures.)
 - e. One (1) single service container and closure manufacturing, if applicable.
 - f. Five (5) receiving and/or transfer stations if certification is only for these types of facilities.
4. The requirements listed in 3. above will be dependant on the applicant's range of responsibilities and the category(ies) in which they are being certified.
 5. Applicants shall also have attended a course on "Milk Pasteurization Controls and Tests" and demonstrate proficiency in applying equipment tests in at least one (1) pasteurization plant, including demonstrating knowledge of product flow through individual pasteurization systems.
 6. To conduct ratings of aseptic processing and packaging milk plants and/or retort processed after packaging milk plants, the applicant shall have completed a training course that is acceptable to the NCIMS and PHS/FDA addressing the procedures for conducting the rating and the implementation of the NCIMS Aseptic Processing and Packaging Program or the NCIMS Retort Processed after Packaging Program, respectively.
 7. Applicants shall demonstrate the ability to conduct and compute Sanitation Compliance and Enforcement Ratings by completing all of the necessary forms.
 8. A certified SRO shall be re-certified once each three (3) years by PHS/FDA personnel in an independent side-by-side comparison of dairy facilities using the items listed on the appropriate inspection or evaluation report form. The applicant and PHS/FDA personnel shall be in agreement at least eighty percent (80%) of the time on each listed item. Comparison evaluations shall be performed on at least the following number of dairy facilities:
 - a. Ten (10) producer dairies. Milking time evaluations should be included.
 - b. Three (3) pasteurization milk plants. Milk plants of varying sizes using, vat, HTST and HHST pasteurization; ultra-pasteurization; aseptic processing and packaging; and/or retort processed after packaging, if applicable, should be included in these evaluations.
 - c. One (1) dry milk plant, if applicable. The dry milk plant may be used as one (1) of the required three (3) pasteurization milk plants.
 - d. If HACCP certified for milk plants, receiving or transfer stations, in addition to meeting the requirements listed above for pasteurization milk plants for a SRO, one (1)

re-certification audit is required. The re-certification audit can be done independent as a mock-listing audit or as part of an official HACCP listing audit, at the discretion of the PHS/FDA personnel and SRO. (Refer to Section VIII., E.6. for additional HACCP certification procedures.)

e. One (1) single service container and closure manufacturing plant, if applicable.

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

9. The requirements listed in 8. above will be dependant on a SROs range of responsibilities and the category(ies) in which they are being certified.

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

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

12. A SRO shall not have direct responsibility for the routine regulatory inspection and enforcement or regulatory auditing of the shipper to be rated or listed. Directors, administrators, etc. may be certified as SROs.

E. DRUG RESIDUE COMPLIANCE

A shipper desiring a rating of their supply shall comply with Appendix N. of the *Grade “A” PMO*.

F. SAMPLING SURVEILLANCE PERSONNEL

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

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

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

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

- a. Five (5) bulk milk hauler/samplers during a routine milk pick-up at a producer dairy.
- b. One (1) plant sampler that collects raw and finished product samples and single service containers/closures at one (1) pasteurization plant, if applicable.
- c. One (1) industry plant sampler that collects a raw milk sample from a milk tank truck at one (1) pasteurization plant, if applicable.
- d. Hold a valid certificate of qualification as a SRO, LEO, or, in the case of a State or TPC Regulatory Supervisor, hold a valid certificate as a SSO.

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

5. The SSO may delegate the inspection of bulk milk hauler/samplers, who collect samples of raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging from individual dairy farms, to other qualified State or TPC Regulatory Agency personnel or certified industry personnel as outlined in Section 5 of the *Grade "A" PMO*.

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

The SSO may delegate the inspection of Dairy Plant Samplers and Industry Plant Samplers to other qualified State or TPC Regulatory Agency personnel.

When delegation of sampling surveillance responsibilities is necessary, the SSO certified by PHS/FDA, shall initially certify responsible individuals following the same procedures that govern SSO certification listed in a. below. Individuals shall be re-certified every three (3) years in accordance with the procedures listed in c. below. Reports of all joint evaluations shall be submitted to PHS/FDA.

- a. Initial Certification: The applicant for the delegation of sampling surveillance responsibilities shall be evaluated by a PHS/FDA certified SSO in an independent side-by-side comparison of sampling procedure observations using the items listed on the appropriate inspection or evaluation report form. The applicant and SSO shall be in

agreement at least eighty percent (80%) of the time on each listed item. Comparison evaluations shall be performed on at least the following number of bulk milk hauler/samplers and plant samplers at dairy facilities:

- 1.) Five (5) bulk milk hauler/samplers during a routine milk pick-up at a producer dairy.
 - 2.) One (1) plant sampler that collects raw and finished product samples and single service containers/closures at one (1) pasteurization plant, if applicable.
 - 3.) One (1) industry plant sampler that collects a raw milk sample from a milk tank truck at one (1) pasteurization plant, if applicable.
- b. The requirements listed above will be dependent on the applicant's range of responsibilities and the category(ies) in which they are being certified.
- c. Re-certification: A certified applicant for the delegation of sampling surveillance responsibilities shall be re-certification once each three (3) years by a PHS/FDA certified SSO in an independent side-by-side comparison of sampling procedure observations using the items listed on the appropriate inspection or evaluation report form. The applicant and SSO shall be in agreement at least eighty percent (80%) of the time on each listed item. Comparison evaluations shall be performed on at least the following number of bulk milk hauler/samplers and plant samplers at dairy facilities:

- 1.) Two (2) bulk milk hauler/samplers during a routine milk pick-up at a producer dairy.
 - 2.) One (1) plant sampler that collects raw and finished product samples and single service containers/closures at one (1) pasteurization plant, if applicable.
 - 3.) One (1) industry plant sampler that collects a raw milk sample from a milk tank truck at one (1) pasteurization plant, if applicable.
- d. The requirements listed above will be dependent on the applicant's range of responsibilities and the category(ies) in which they are being certified.

G. MILK LABORATORY EVALUATION PERSONNEL

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

1. Have been certified and approved by PHS/FDA as a LEO per the requirements and criteria listed in the most recent edition of the *EML*. (Refer to Section 3 of the *EML*)
2. Holds a valid certificate or provisional endorsement of qualification.

3. Shall not fail, without cause, to attend the PHS/FDA Regional Milk Seminar, when offered, and, in addition, attended at least one (1) Milk Laboratory Evaluation Officer's Workshop or other training courses judged by PHS/FDA LPET to be equivalent.

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

1. Certification Hearing Panel Members

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

- a. The Regional Food and Drug Director or designee.
- b. The Director of the Division of Federal-State Relations or designee.
- c. The Director of the Division of Plant and Dairy Food Safety or designee.

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

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

- a. The facts and the reasons that are the basis for the revocation;
- b. Deadline for submitting a request for a hearing;
- c. Where to send a request for a hearing; and
- d. The date revocation will be effective if a hearing is not requested.

3. Request for a Hearing

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

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

SSO, or LEO raises any genuine and substantial issues of fact relevant to whether certification should be revoked.

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

4. Hearings

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

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

The Certification Hearing Panel will have the opportunity to question the PHS/FDA Standard, the SRO, SSO, or LEO, and any witnesses.

5. Decision

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

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

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

I. AREA RATINGS

1. Area ratings shall be made at a frequency of not less than once every twenty-four (24) months.
2. If a shipper's supply is included in an area rating which has received a Sanitation Compliance Rating of ninety percent (90%) or more, the shipper may be listed without an individual rating, provided that an individual rating shall be furnished upon request of the receiving State(s) and/or TPC(s).
3. If the Enforcement Rating is less than ninety percent (90%), the shipper may be listed. A re-rating of the area shall be conducted within six (6) months of the date of the rating after the Rating Agency receives written notification from an authorized representative of the Regulatory Agency indicating that the area is in substantial compliance. A re-rating of the area, which includes both a Sanitation Compliance and Enforcement Rating, shall be completed in no more than fifteen (15) days from the date of receipt of the notification.

J. INDIVIDUAL RATINGS

1. Individual ratings shall be made at a frequency of not less than once every twenty-four (24) months.
2. If an IMS listed shipper receives a Sanitation Compliance Rating of less than ninety percent (90%), a re-rating shall be conducted after written notification from an authorized representative of the IMS listed shipper to the Rating Agency that the IMS listed shipper is in substantial compliance. A re-rating shall be completed in no more than fifteen (15) days, from the date of receipt of the notification, unless the Rating Agency has a reason to believe a new rating within a lesser time would result in an acceptable rating.
3. If an aseptic or retort milk plant has any ACLE identified by a SRO, PHS/FDA Regional Milk Specialist, or PHS/FDA MST personnel as not being in compliance on FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM 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), the listing shall be immediately denied or withdrawn.
4. If an IMS listed shipper receives an Enforcement Rating of less than ninety percent (90%), the shipper may be listed and a re-rating of both the Sanitation Compliance and Enforcement shall be completed by the Rating Agency within six (6) months of the date of the rating, after the Rating Agency receives written notification from an authorized representative of the Regulatory Agency indicating that the IMS listed shipper is in substantial compliance. A re-

rating of the IMS listed shipper, which includes both a Sanitation Compliance and Enforcement Rating, shall be completed in no more than fifteen (15) days from the date of receipt of the notification.

K. RE-RATINGS

Whenever a rating results in a request for a re-rating, the effective date for the re-rating shall be determined from the date of the letter of notification by the Rating Agency. Such letter is to be dated within five (5) working days following the date of the rating.

L. DENIAL OF RATINGS

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

SECTION VI. STANDARDS

A. POINTS BEYOND THE LIMITS OF THE ROUTINE INSPECTION

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

B. RECIPROCITY FOR THE PURPOSE OF NCIMS AGREEMENTS

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

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

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

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

For the purpose of these *Procedures* and NCIMS in total, each participating non-U.S. country or political subdivision thereof shall be considered as a State with all the rights, duties,

responsibilities, and privileges of a State, providing the governing regulatory body of such non-U.S. country or political subdivision thereof shall meet the requirements of Part A. of this Section by establishing a MOU with PHS/FDA, which provides an acceptable basis for NCIMS to verify equivalence in the State or Local area concerned.

The determination that a foreign country's public health regulatory program and the government oversight of that program has an equivalent effect on the safety of the regulated milk or milk product is the responsibility of PHS/FDA. PHS/FDA shall confer with NCIMS prior to finalizing a determination of equivalence. The foreign government shall provide adequate assurance that the level of public health protection provided by the NCIMS program is met. When PHS/FDA determines that a foreign country's milk regulatory program is equivalent, PMO defined milk and milk products from that country are accepted in the IMS program.

E. **MILK SANITATION STANDARDS**

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

F. **RATING PROCEDURES**

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

G. **SAMPLING PROCEDURES**

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

H. **LABORATORY EVALUATION PROCEDURES**

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

I. **LABORATORY PROCEDURES**

Laboratory procedures used to examine milk and milk products of interstate milk shippers shall conform to the procedures in the current revisions of the FDA/NCIMS 2400 Forms and the *OMA*, using only methods approved by the NCIMS. Vitamin testing shall be performed

in a laboratory, which has been accredited by PHS/FDA and which is acceptable to the Regulatory Agency using test methods acceptable to PHS/FDA and other official methodologies that give statistically equivalent results to the PHS/FDA methods.

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

REGULATORY/RATING AGENCY PROGRAM EVALUATIONS

- A. PHS/FDA shall evaluate the inspection, supervisory, and rating work of Regulatory and Rating Agencies triennially to determine whether milk regulations are being interpreted and enforced in accordance with the provisions of the *Grade "A" PMO*.
- B. Any State or TPC in substantial non-compliance as determined by PHS/FDA shall be referred to the NCIMS Executive Board for determination of listing on a separate page in the *IMS List*. The State or TPC upon notification of PHS/FDA and the NCIMS Executive Board shall have an opportunity to address the NCIMS Executive Board to explain why they believe they shall not be so listed. If such listing is required, annual evaluations shall be conducted until substantial compliance as determined by PHS/FDA is achieved. Any State or TPC not in substantial compliance a second consecutive year shall be notified by PHS/FDA and provided an opportunity for a hearing by the NCIMS Executive Board. The NCIMS Executive Board, as a result of the hearing, may determine that the State or TPC shall not be an active participant in future NCIMS Conferences until substantial compliance is achieved.

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

A. PURPOSE AND SCOPE

1. Purpose

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

2. Products Covered Under HACCP Listings

Agreements adopted by the NCIMS shall apply to Grade "A" raw milk and/or milk products for pasteurization, heat-treated products, pasteurized, ultra-pasteurized, aseptically processed and packaged low-acid milk and/or milk products, and/or retort

processed after packaging low-acid milk and/or milk products, condensed and dry milk products, and whey and/or whey products produced under the NCIMS program. Listings made under the NCIMS voluntary HACCP listing system described in this Section, may be made for milk plants, receiving stations and transfer stations.

3. Supervision Requirements

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

B. HACCP DEFINITIONS:

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

1. **AUDIT:** An evaluation of the entire milk plant, receiving station, or transfer station facility, and NCIMS HACCP System to ensure compliance with the NCIMS HACCP System and other NCIMS regulatory requirements, with the exception of the Aseptic Processing and Packaging System (APPS) for aseptic processing and packaging milk plants and Retort Processed after Packaging System (RPPS) for retort processed after packaging milk plants, respectively.

2. **CERTIFIED MILK SANITATION RATING OFFICER (SRO):** The definition in Section III. shall apply as written except that, for purposes of this Section, a SRO may be certified to make HACCP listings. A SRO who has been certified to make HACCP listings does not have direct responsibility for the routine regulatory audits of the shipper to be listed.

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

4. **PHS/FDA AUDIT:** An evaluation conducted by PHS/FDA of the entire milk plant, receiving station, or transfer station facility to ensure compliance with the NCIMS HACCP System and other NCIMS regulatory requirements, with the exception of the Aseptic Processing and Packaging System (APPS) for aseptic processing and packaging milk plants and Retort Processed after Packaging System (RPPS) for retort processed after packaging milk plants, respectively.

5. **HACCP LISTED SHIPPER**: A milk plant, receiving station, or transfer station that has been certified by a SRO. The listing is based on compliance with the NCIMS HACCP Program.
6. **HACCP LISTING**: An inclusion in the *IMS List–Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers (IMS List)* based on a SROs evaluation of a milk plant’s, receiving station’s, or transfer station’s NCIMS HACCP Program and other applicable NCIMS requirements.
7. **LISTING AUDIT**: An evaluation conducted by a Milk Sanitation Rating Officer (SRO) of the entire milk plant, receiving station or transfer station facility to ensure compliance with the NCIMS voluntary HACCP Program and other NCIMS regulatory requirements, with the exception of the Aseptic Processing and Packaging System (APPS) for aseptic processing and packaging milk plants and Retort Processed after Packaging System (RPPS) for retort processed after packaging milk plants, respectively.
8. **REGULATORY/RATING AGENCY PROGRAM EVALUATION**: Definition BB. in Section III shall apply as written, except that for purposes of this Section the words "check ratings of IMS Listed Shippers" shall include "PHS/FDA audits of IMS Listed Shippers".

C. **PHS/FDA HACCP RESPONSIBILITIES**

1. **Standardization of Personnel**

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

- a. PHS/FDA Regional personnel who:
 - 1.) Meet the qualification requirements of the PHS/FDA Milk Safety Program;
 - 2.) Comply with the directives of the PHS/FDA Milk Safety Program as administered by the PHS/FDA MST; and
 - 3.) Shall not fail, without cause, to attend the PHS/FDA Regional Milk Seminar when offered, the PHS/FDA Regional Milk Specialists Conference, and attended at least one (1) training course on “Special Problems in Milk Protection” or other training courses judged by the PHS/FDA to be equivalent.
 - 4.) PHS/FDA personnel responsible for PHS/FDA HACCP audits and Regulatory/Rating Agency Program Evaluations in States and TPCs participating in the NCIMS HACCP Program shall, at a minimum, be required to meet the same level of training and certification required for SROs who make HACCP listing audits.
- b. SROs who comply with E. 4. of this Section.

2. HACCP Training

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

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

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

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

d. Specialized Training for HACCP Auditing and Listing Procedures

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

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

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

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

3. Regulatory/Rating Agency Program Evaluations

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

4. Laboratory Evaluations

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

5. Electronic Publication of Sanitation Compliance and Enforcement Ratings

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

a. PHS/FDA shall provide an electronic publication of the *IMS List* on their web site. The electronic *IMS List* is available at [http://www.fda.gov/Food/Food Safety/Product-SpecificInformation/MilkSafety/FederalStatePrograms/InterstateMilkShippersList/default.htm](http://www.fda.gov/Food/Food%20Safety/Product-SpecificInformation/MilkSafety/FederalStatePrograms/InterstateMilkShippersList/default.htm). The HACCP listings and IMS Listed shipper's expiration listing dates contained in the electronic publication are certified by the Rating Agency to be those established by HACCP audits conducted in accordance with the *MMSR* by certified SROs when FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT is signed and submitted to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs for electronic publication.

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

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

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

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

PHS/FDA shall provide a list of PHS/FDA Regional Milk Specialists and SROs whose HACCP listing methods and interpretations of the PHS/FDA recommended *Grade "A" PMO* have been evaluated and certified by PHS/FDA on the *IMS List*.

7. Interpretations and Editorial Updates

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

8. PHS/FDA Audits of HACCP Listings

a. PHS/FDA shall conduct, each year, PHS/FDA audits of HACCP listed shippers. To conduct audits of HACCP/aseptic processing and packaging milk plants and/or retort processed after packaging milk plants, the PHS/FDA Regional Milk Specialist and/or PHS/FDA MST personnel for TPCs shall have completed a training course that is acceptable to the NCIMS and PHS/FDA addressing the procedures for conducting audits and the implementation of the NCIMS Aseptic Processing and Packaging Program and/or

the NCIMS Retort Processed after Packaging Program, respectively. Within a State or a TPC conducting the NCIMS voluntary HACCP Program, PHS/FDA audits shall be conducted of a representative number of IMS HACCP listed shippers. The selection of shippers to be audited in a given State or a TPC's jurisdiction shall be made randomly.

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

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

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

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

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

g. If dairy farms are listed with a HACCP listed milk plant, receiving station or transfer station, the farms shall be check rated in conjunction with the PHS/FDA audit.

h. PHS/FDA shall conduct on-site milk plant, receiving station and transfer station audits of the HACCP compliance status of listed interstate milk shippers. These PHS/FDA HACCP audits shall be conducted using the procedures for HACCP listing audits as described in the *MMSR*. These audits shall be used in the overall Regulatory/Rating Agency Program Evaluation. Provided, that for NCIMS HACCP listed milk plants producing aseptically processed and packaged Grade "A" low-acid milk and/or milk products and/or retort processed after packaging Grade "A" low-acid milk and/or milk products, PHS/FDA HACCP audits shall be conducted using the procedures identified in the NCIMS Aseptic Processing and Packaging Program or the

NCIMS Retort Processed after Packaging Program, respectively, related to the inspection/auditing and regulation of the APPS and RPPS, respectively, as described in the *Grade "A" PMO* and *MMSR*, along with the completion of FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND/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. PHS/FDA shall review the Regulatory Agency records for the milk plant, receiving station or transfer station being audited. In the event that there is reason to doubt the safety of any Regulatory Agency's milk and/or milk products that are HACCP listed, PHS/FDA shall immediately investigate the Milk Safety Program and may evaluate/audit the milk plants, receiving stations or transfer stations affected. This applies even if the HACCP listing of the milk plant, receiving station or transfer station being audited is sustained.

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

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

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

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

D. NCIMS HACCP RESPONSIBILITIES

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

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

a. The Rating Agency of the shipping State or TPC shall certify the results of HACCP listing audits of each interstate milk shipper to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs, which in turn, shall transmit the

HACCP listing audits to the PHS/FDA Headquarters Office for inclusion on the *IMS List*. (Refer to Section IV., A., 5.) The HACCP listing audit results, together with other pertinent information, shall be forwarded on an appropriate form (FORM FDA 2359j).

c. When the Sanitation Compliance status of a listed shipper's supply changes as a result of a new listing made within the twenty-four (24) month eligibility period, the most recent listing and FORM FDA 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT and FORM FDA 2359n-NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT, shall apply and shall be submitted to PHS/FDA. Provided that for NCIMS HACCP listed milk plants producing aseptically processed and packaged Grade "A" low-acid milk and/or milk products and/or retort processed after packaging Grade "A" low-acid milk and/or milk products, FORM FDA 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) shall also be completed and submitted to PHS/FDA.

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

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

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

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

2. NCIMS HACCP Enforcement Responsibilities

A NCIMS HACCP System Regulatory Agency review shall be conducted and FORM FDA 2359n-NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT shall be completed and provided to PHS/FDA as a part of all NCIMS HACCP listings.

Based on this report, if PHS/FDA finds there may be reason to doubt the safety of the State's or TPC's milk and/or milk products that are NCIMS HACCP listed, PHS/FDA

shall immediately investigate the State's or TPC's Milk Safety Program and may evaluate/audit the milk plants, receiving stations or transfer stations affected. This applies even if FORM FDA 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT finds that the listing of the milk plant, receiving station or transfer station is satisfactory.

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

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

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

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

3. Laboratory Evaluation

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

4. Response to Regulatory/Rating Agency Program Evaluations

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

6. Reports to Database

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

7. Challenges and Remedies

a. Complaints from Receiving States and/or TPCs

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

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

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

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

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

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

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

b. Complaints from Shipping States and/or TPCs

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

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

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

1.) Producer Dairies (Raw Milk)

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

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

A.) Action to be Taken

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

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

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

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

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

B.) Re-Audit

If deficiencies and/or non-conformities are significant to the point that timely correction is necessary, but do not require an immediate withdrawal of certification, the deficiencies and/or non-conformities shall be corrected and the correction confirmed by a re-audit by an appropriate listing official. The period of time allowed to correct the HACCP System deficiencies and/or non-

conformities shall be specified by the PHS/FDA Regional Milk Specialist and/or PHS/FDA MST personnel for TPCs in writing to the State or TPC. A re-audit is not required if the deficiencies and/or non-conformities are immediately corrected, or are minor and can be corrected within a time period, which will neither present a risk to the public health nor result in milk and/or milk product adulteration.

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

If the HACCP System deficiencies and/or non-conformities have been corrected, the Rating Agency shall notify the Regional Office of PHS/FDA or PHS/FDA MST for TPCs and further action shall not be necessary.

C.) Withdrawal of Certification

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

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

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

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

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

iv.) Milk is received from a supply other than a NCIMS listed source or from a listed source with a Sanitation Compliance Rating below ninety percent (90%).

2.) Significant deficiencies involving one (1) or more CLE's constitute grounds for withdrawal of a HACCP 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 marked on the audit report as a CLE or used to justify the removal of a listing. In this case, professional judgment should be exercised to allow the milk plant, receiving station or transfer station to retain its listing and benefit from the observation by making the necessary corrections to their system.

NOTE: CLE's are noted on FORM FDA 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 HACCP Program:

1. **HAZARD ANALYSIS:** Flow Diagram and Hazard Analysis conducted and written for each kind or group of milk and/or milk products processed.
2. **HACCP PLAN:** HACCP Plan prepared for each kind or group of milk and/or milk products processed.
3. **HACCP PLAN CRITICAL LIMITS (CL's):** CL's are adequate to control the hazard identified.
4. **HACCP PLAN CORRECTIVE ACTION:** Corrective action taken for milk and/or milk products produced during a deviation from CL's defined in the HACCP Plan.
5. **HACCP PLAN VERIFICATION AND VALIDATION:** Calibration of Critical Control Point (CCP) process monitoring instruments performed as required and at the frequency defined in the HACCP Plan.
6. **HACCP PLAN RECORDS:** Information on HACCP records not falsified.
7. **OTHER NCIMS REQUIREMENTS:** Including a milk supply from a NCIMS listed source(s) with a Sanitation Compliance Rating(s) of ninety percent (90%) or better and a drug residue control program implemented.
8. **HACCP SYSTEM AUDIT FOLLOW-UP ACTIONS:** A series of observations that lead to a finding of a potential HACCP System failure that is likely to result in a compromise to milk and/or milk product safety.

3.) A HACCP aseptic listing that includes an aseptically processed and packaged Grade "A" low-acid milk and/or milk products plant and/or a HACCP retort listing that includes a retort processed after packaging Grade "A" low-acid milk and/or milk products plant shall be requested to be withdrawn when any ACLE is identified as not being in compliance on FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND/OR RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products).

4.) When PHS/FDA audit data indicates that the milk plant, receiving station and/or transfer station requires a withdrawal of certification, the Rating

Agency, upon written recommendation of the PHS/FDA, shall immediately withdraw the current certification of the shipper and notify such shipper, PHS/FDA, and all known receiving States and/or TPCs thereof. In case of withdrawal, a new listing shall be made in not less than thirty (30) days and not to exceed sixty (60) days, unless the Rating Agency has reason to believe a new listing within a lesser time period would result in an acceptable listing. The effective date for action shall be determined from the date of the letter of notification by the Rating Agency. Such letter shall be dated within five (5) working days following the date of the official notification.

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

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

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

D.) Imminent Health Hazard

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

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

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

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

E. QUALIFICATIONS AND CERTIFICATIONS

1. Supervision Requirements

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

a. Supervision of the milk supply, condensed and dry milk products, whey and whey products to be audited for interstate certification shall be based on the criteria and procedures for Grade “A” standards set forth in Section VI., and procedures for Grade “A” standards set forth in Section VI., E., or regulations pertaining to supervision substantially equivalent thereto.

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

2. Procedure for Requesting a HACCP Listing

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

3. HACCP Listing

a. An acceptable HACCP listing shall be substituted for an acceptable Sanitation Compliance and Enforcement Rating for a milk plant, receiving station or transfer station participating in the NCIMS HACCP Program. FORM FDA 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT and FORM FDA 2359n-NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT shall be completed as a part of all milk plant, receiving station or transfer station HACCP listing audits. Provided that for NCIMS HACCP listed milk plants producing aseptically processed and packaged Grade “A” low-acid milk and/or milk products and/or retort processed after packaging Grade “A” low-acid milk and/or milk products, FORM FDA 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) shall be completed as a part of all HACCP aseptic and/or HACCP retort listing audits.

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

4. HACCP Listing Personnel

HACCP listings shall be made by qualified SROs who:

- a. Have been certified by PHS/FDA as a SRO and hold a valid certification of qualification to perform HACCP listing audits.
- b. Have attended at least one (1) training course in the auditing of milk plant HACCP Systems and NCIMS listing for the period of qualification.
- c. Have, during the three (3) year period for which certified, participated in at least one (1) Regional Milk Seminar and, in addition, attended at least one (1) training course on “Special Problems in Milk Protection” or other training course judged by the PHS/FDA to be equivalent.
- d. Do not have direct responsibility for the routine regulatory audits of the shipper to be listed.

5. Drug Residue Compliance

A shipper desiring a listing audit of their supply shall comply with Appendix N. of the *Grade “A” PMO*.

6. Certification Procedure for SROs Who Will Conduct HACCP Listing Audits

a. Candidate Background

1.) Training and Experience

A.) The Candidate shall provide a statement describing their background and experience that qualifies them to perform this work.

B.) Candidates are encouraged to gain practical milk plant experience in the application of HACCP and in conducting milk plant NCIMS HACCP audits by working with SROs that are certified to perform NCIMS HACCP Listings audits whenever practical.

C.) The Candidate shall complete a basic HACCP training course that is acceptable to the NCIMS and PHS/FDA; NCIMS HACCP Orientation; as well as training in general auditing requirements for the auditing of milk plants, receiving stations and transfer stations under the NCIMS HACCP Program.

D.) Candidate shall be a certified SRO for milk plants.

b. Original Certification Process

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

A standardized PHS/FDA Regional Milk Specialist, qualified to conduct HACCP Audits, shall accompany the Candidate during the course of one (1) mock-listing audit conducted separate from an official HACCP listing audit. The Candidate may be certified to conduct HACCP listings after successfully completing one (1) mock-listing audit, with the certification valid for three (3) years. In the case of an original HACCP certification, the date of expiration of the other SRO certification shall be automatically extended to correspond with the original HACCP certification expiration date.

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

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

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

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

c. Continuous Certification

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

1.) Milk Plant Technical Knowledge

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

During the three (3) year certification period, the SRO, certified to conduct NCIMS HACCP listings, shall complete the minimum training requirements established to maintain proficiency regarding the NCIMS voluntary HACCP Program including having attended at least one (1) training course in the auditing of milk plant HACCP

Systems and NCIMS listing for the period of qualification. The NCIMS HACCP Implementation Committee has developed and accepted for this required training both a comprehensive multi-day course presented by members of the NCIMS HACCP Implementation Committee and an abbreviated individual instruction that may be presented to individuals or small groups by any of the HACCP Certified FDA Regional Milk Specialists.

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

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

During the three (3) year certification period, a PHS/FDA Regional Milk Specialist shall accompany the SRO during the course of at least one (1) recertification listing audit. The recertification listing audit can be done independent as a mock-listing audit or as part of an official HACCP listing audit, at the discretion of the PHS/FDA REGIONAL MILK SPECIALIST and SRO. This decision shall be made prior to the beginning of the recertification listing audit. In the absence of an agreement, the recertification listing audit shall be conducted during a mock listing audit. The standardizing official (PHS/FDA Regional Milk Specialist) shall accompany as a “silent observer” during this recertification listing audit. The PHS/FDA Regional Milk Specialist shall evaluate the SROs HACCP knowledge and NCIMS HACCP auditing skills. Particular attention shall be given to the SROs observations, evaluation, and decision making skills related to planning and conducting the listing or mock-listing audit, identifying and recording the findings, communicating with industry representatives, and arriving at an audit listing or mock-listing audit determination. The PHS/FDA Regional Milk Specialist will categorize the SROs HACCP knowledge and NCIMS HACCP auditing skills into one (1) of the following three (3) categories:

- A.) The SRO is recertified to conduct NCIMS HACCP Listing Audits; or
- B.) The SRO is recertified with written recommendations identifying areas that need improvement; or
- C.) The SRO is not recertified.

NOTE: The cause shall be documented and provided to the SRO and the Rating Agency.

d. Paperwork Review

FORM FDA 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT, with attachments, FORM FDA 2359n-NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT, and

FORM FDA 2359o-PERMISSION FOR PUBLICATION (*Interstate Milk Shipper's Listing*) shall be submitted with FORM FDA 2359i for each NCIMS HACCP Listing Audit to the PHS/FDA Regional Office for quality assurance review. Provided that for NCIMS HACCP listed milk plants producing aseptically processed and packaged Grade "A" low-acid milk and/or milk products and/or retort processed after packaging Grade "A" low-acid milk and/or milk products, FORM FDA 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) shall also be completed and submitted for quality assurance review.

These reviews will be used to enhance uniformity and strengthen each individual's skills and will be used to assist in identifying needs for future training.

7. Sampling Surveillance Personnel

Section V., F. shall apply as written.

8. Milk Laboratory Evaluation Personnel

Section V., G. shall apply as written.

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

a. Individual milk plants, receiving stations or transfer stations participating in the NCIMS HACCP listing process shall be audited for listing at a frequency of not less than once every twenty-four (24) months.

b. If an audit for a HACCP listing is unsatisfactory, another audit shall be conducted after written notification from an authorized representative of the IMS Listed shipper to the Rating Agency that the IMS Listed shipper is in substantial compliance. The audit shall be completed in not more than fifteen (15) days from the date of receipt of the notification, unless the Rating Agency has a reason to believe a new listing within a lesser time would result in an acceptable listing.

10. Re-Audits

Whenever a listing audit results in a request for a re-audit, the effective date for the re-audit shall be determined from the date of the letter of notification by the Rating Agency. Such letter is to be dated within five (5) working days following the date of the listing audit.

11. Denial of Listings

Requests for HACCP listings of shippers, which are not under supervision as described

in E. 1. of this Section, shall be denied.

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

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

1. Points Beyond the Limits of Routine Inspection

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

5. Milk Sanitation Standards

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

6. HACCP Listing Audit Procedures

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

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

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

1. Regulatory/Rating Agency Program Evaluations

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

SECTION IX. PROCEDURES GOVERNING THE NCIMS VOLUNTARY INTERNATIONAL CERTIFICATION PROGRAM

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

A. PURPOSE AND SCOPE

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

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

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

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

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

B. PROCEDURES

1. Operation of the NCIMS voluntary ICP

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

- a. Comply with all of the applicable requirements of the *Grade “A” PMO* and related NCIMS documents. The regulation and rating of MCs shall be in accordance with the applicable requirements of the NCIMS Grade “A” Milk Safety Program for the purpose of listing those complying on the *IMS List*.
 - b. Continue to assure the same level of milk safety provided within the NCIMS Grade “A” Milk Safety Program.
 - c. Provide a means for NCIMS Member States to accept Grade “A” milk and/or milk products from NCIMS voluntary ICP IMS Listings.
2. Application by Prospective TPCs
- a. The NCIMS Executive Board shall make an initial announcement seeking applications from non-governmental individuals or organizations wishing to participate in the NCIMS voluntary ICP as a TPC. Prospective TPCs shall complete and submit the official NCIMS voluntary ICP application form along with all of the appropriate documentation to the ICP Committee. The ICP Committee shall confirm with each applicant, the receipt of the application form and whether it is complete enough to be warranted for consideration as submitted or if additional information shall be required.
 - b. All documents that are utilized and exchanged within the NCIMS voluntary ICP shall be in English or translated into English by the submitter.
3. Review of Applications, Selection and Official Notification of TPCs
- a. The ICP Committee is responsible to review all valid application forms from qualified prospective TPCs. This review shall evaluate the quality and strength of each application on the basis of the applicant’s response to the requests for information on the application form. This review shall also evaluate each application based on the TPC identified personnel’s knowledge and experience with the requirements of the NCIMS Grade “A” Milk Safety Program and the responsibilities and duties of a Regulatory/Rating/Laboratory Control Agencies providing the regulatory, rating and laboratory functions within the NCIMS Grade “A” Milk Safety Program. The ICP Committee shall make recommendations to the NCIMS Executive Board of qualified applicants for participation in the NCIMS voluntary ICP.
 - b. The NCIMS Executive Board may request additional information concerning the ICP Committee’s recommendations. If the NCIMS Executive Board has a reason to dispute any of the ICP Committee’s recommendations, they may request that the ICP Committee reconvene to consider additional information that may be relevant to their recommendations.
 - c. All applicants shall be notified in writing, which may include mail, facsimile, email or other electronic means, by the Chair of the NCIMS Executive Board as to the status of

their application and whether or not they have been selected to participate as a TPC in the NCIMS voluntary ICP.

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

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

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

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

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

i. If a TPC has not IMS listed any milk shippers within two (2) years of the signed and dated LOU, the ICP Committee Chair shall request a meeting with the TPC to discuss why their LOU shall continue to remain valid. The meeting shall take place at a time, location and manner (in person or via teleconference) agreed upon by the ICP Committee Chair and the TPC. If an agreement cannot be reached, the meeting shall take place at a reasonable time, location and manner as determined by the ICP Committee Chair.

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

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

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

C. **THIRD PARTY CERTIFIER (TPC) RESPONSIBILITIES**

1. **Required Signed and Dated Agreements/Commitments**

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

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

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

A signed and dated MOA shall be submitted to the ICP Committee Chair and PHS/FDA MST prior to the initial rating/certification of any milk shipper, or official laboratory, or

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

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

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

2. Qualifications of TPC Personnel

a. Regulatory Personnel

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

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

b. Milk Sanitation Rating Personnel

TPC personnel conducting rating/listing activities shall meet the qualification and certification requirements set forth in Section V, D, and Section VIII, E. 4, if applicable, of this document. SROs cannot have direct responsibility for the routine inspection and enforcement or regulatory auditing of the milk shipper to be rated or listed.

c. Sampling Surveillance Personnel

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

d. Milk Laboratory Evaluation Personnel

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

e. NCIMS HACCP Program Personnel

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

f. NCIMS Aseptic/Retort Program Personnel

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

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

3. Code of Ethics

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

a. The TPC:

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

- 2.) Shall not be financially affiliated with a manufacturer, supplier or vendor of milk and/or milk products regulated under the NCIMS;
 - 3.) Shall not charge fees contingent or based upon results from the TPC inspection, rating and certification activities; and
 - 4.) Shall hold all personnel, including contractors, to the same conflict of interest standards.
- b. The TPC and its Personnel:
- 1.) Shall act with honesty and integrity;
 - 2.) Shall act impartially and shall not give preferential treatment to any organization(s) or individual(s);
 - 3.) Shall not discriminate because of race, religion, national origin or gender;
 - 4.) Shall not hold financial interest(s) that conflict with the conscientious and impartial performance of their duties;
 - 5.) Shall not engage in financial transactions using Regulatory/Rating derived information or allow the improper use of such information to further any private interest;
 - 6.) Shall not disclose or use confidential or privileged information for personal benefit or for financial gain. The TPC and its personnel shall maintain strict confidentiality of proprietary information learned through their Regulatory/Rating oversight activities;
 - 7.) Shall avoid conflicts of interest or the appearance of a conflict of interest. The TPC and its personnel shall not participate in any matter in which they, or their spouse or dependents, have a private interest which may directly or indirectly affect or influence the performance of their duties.
 - 8.) Shall perform only the activities within the scope of their responsibilities, training and/or certification within the context of the NCIMS Grade “A” Milk Safety Program;
 - 9.) Shall endeavor to avoid any actions creating the appearance that they are violating the ethical tenets set forth in this Section. Whether particular circumstances create an appearance that these tenets have been violated shall be determined from the perspective of a reasonable person with the knowledge of the relevant facts; and

10.) The TPC, TPC personnel, their spouses and dependents shall not solicit or accept any gift or other items of monetary value for their duties beyond the agreed upon contract value from the regulated industry or entity seeking Regulatory/Rating activities whose interests may be substantially affected by the performance or nonperformance of their duties.

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

4. Performance of Duties and Responsibilities

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

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

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

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

D. MILK COMPANY (MC) RESPONSIBILITIES

1. Required Signed and Dated Agreements/Commitments

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

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

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

A MC shall have the option of terminating a signed and dated MOA if, at any time, in the MC's sole judgment, a conflict of interest exists or is imminent. Termination shall be in

accordance with the notification requirements addressed in Item 8 of the signed and dated MOA. The MC shall be aware and fully understand that if a signed and dated MOA is terminated after they have been listed on the *IMS List* they shall be immediately withdrawn from the *IMS List* and removed from the NCIMS voluntary ICP.

2. The MC shall comply with the signed and dated MOA and all applicable requirements of the NCIMS Grade “A” Milk Safety Program and the NCIMS voluntary ICP.
3. The MC shall allow unannounced inspections, during reasonable working hours, of all facilities included in the NCIMS voluntary ICP.
4. The MC shall provide access to the TPC of all required records relating to the provisions and requirements of the NCIMS Grade “A” Milk Safety Program and the NCIMS voluntary ICP. They shall also provide access to the TPC for all required pasteurization equipment testing and the collection of all required milk and/or milk products and milk containers, if applicable, and the required sampling of all applicable water system(s), including recirculated water systems.
5. Along with all of the other requirements as cited in the NCIMS documents, a MC seeking listing on the *IMS List*, shall provide documentation, acceptable to the TPC, the ICP Committee, and PHS/FDA MST, that demonstrates their compliance with the provisions of Section 8. Animal Health and Appendix A. Animal Disease Control of the *Grade “A” PMO* and the relevant USDA/APHIS requirements for tuberculosis and brucellosis.
6. All documents that are utilized and exchanged within the NCIMS voluntary ICP shall be in English or translated into English by the MC. These documents include all forms, contracts and written communication between the TPC and the regulated MC. The MC shall provide an interpreter during all official inspections, ratings/listings, training, and accreditation/certification activities.

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

1. Third Party Certifier (TPC)

Compliance with the requirements of the NCIMS voluntary ICP shall be determined by PHS/FDA MST and LPET. Failure to adequately comply with the regulatory and enforcement provisions of the NCIMS Grade “A” Milk Safety Program; the requirements of the NCIMS voluntary ICP; requirements for IMS listing; Code of Ethics; etc. can result in the removal of the TPC from the NCIMS voluntary ICP.

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

- a. If a TPC is found to be in non-compliance with the requirements set forth in the documents of the NCIMS Grade “A” Milk Safety Program by PHS/FDA MST and/or LPET, the TPC shall be subject to procedures addressing their removal from the NCIMS voluntary ICP.
- b. If a TPC ceases to provide oversight of all of their IMS listed MCs for purposes of the NCIMS voluntary ICP, both the TPC and the MCs shall immediately notify the ICP Committee Chair and PHS/FDA MST and/or LPET. Both the TPC and MCs shall immediately be removed from the NCIMS voluntary ICP and the MCs shall immediately be withdrawn from the *IMS List* by PHS/FDA MST and/or LPET. Within fifteen (15) days of a TPC ceasing to provide this required MC oversight, the TPC shall transfer all existing records to PHS/FDA MST in a manner acceptable to PHS/FDA MST.
- c. When there is evidence, found during PHS/FDA check ratings or a triennial Regulatory/Rating Agency Program Evaluation, that the TPC is in non-compliance with the applicable requirements set forth in the documents of the NCIMS Grade “A” Milk Safety Program, the TPC shall be referred to the NCIMS Executive Board in accordance with Section IV, A. 3. b of this document. The TPC and MC(s) listed by the TPC can be subject to withdrawal by PHS/FDA MST and/or LPET from the *IMS List*.
- d. Violators of any of the required Code of Ethics’ tenets by a TPC or their personnel shall be subject to removal from participation in the NCIMS voluntary ICP by the Executive Board.

2. Milk Company (MC)

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

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

- a. If a MC’s IMS listed milk shipper changes status due to non-compliance or a change in the Sanitation Compliance Rating to less than ninety percent (90%), the TPC shall immediately notify the PHS/FDA MST and all known receiving Member States and/or TPCs. The MC’s IMS listed milk shipper shall immediately be withdrawn from the *IMS List* by PHS/FDA MST.
- b. If a TPC ceases to provide the required oversight of an IMS listed MC for purposes of the NCIMS voluntary ICP, both the TPC and the MC shall immediately notify the ICP Committee Chair and PHS/FDA MST and/or LPET. The MC, including all associated

facilities, shall immediately be removed from the NCIMS voluntary ICP and the MC shall also immediately be withdrawn from the *IMS List* by PHS/FDA MST and/or LPET. Within fifteen (15) days of a TPC ceasing to provide this required MC oversight, the TPC shall transfer all existing records to PHS/FDA MST in a manner acceptable to PHS/FDA MST.

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

F. **CONFIDENTIALITY**

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

SECTION X. APPLICATION OF CONFERENCE AGREEMENTS

A. **IMPLEMENTATION OF CHANGES**

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

1. The transcript of the second voting day shall be forwarded to PHS/FDA within forty-five (45) days of the close of the Conference.
2. PHS/FDA shall review the transcript and within ninety (90) days of receipt, notify the Conference Chair of those issues with which they do or do not concur. The changes involved, that have been concurred with shall be effective within one (1) year of the electronic publication of the affected documents or notification to the States and TPCs by *IMS-a*, following the Conference at which the changes were approved.
3. Those issues with which PHS/FDA does not concur shall be referred to the NCIMS Executive Board for further discussion (within thirty (30) days if possible). If mutual concurrence is obtained, the changes shall be effective within one (1) year of the electronic

publication of the affected documents or notification to the States and TPCs by IMS-a, following the Conference at which the changes were approved, unless otherwise mutually agreed upon by PHS/FDA and the NCIMS Executive Board.

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

B. EDITORIAL CHANGES TO NCIMS CONFERENCE DOCUMENTS

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

1. Incorporating language from Proposals adopted by the voting delegates into their respective documents;
2. Incorporating language from any Proposal that does not include the exact language to be incorporated but does provide some direction for determining the text to be incorporated in the document (For Example: Section IV. A. 6. shall apply as written except that, for purposes of this Section the word “rating” shall be replaced with “listing”.);
3. Correcting misspelled words;
4. Correcting capitalization of words;
5. Correcting the use of punctuation within documents;
6. Correcting paragraph or Section numbering schemes;
7. Correcting incorrect citations or other references within a document;
8. Correcting the incorrect use of terms used in any Proposal (For Example: Using the term “rating” instead of “listing”.);
9. Correcting the inconsistent use of defined terms when referencing facilities, persons or equipment subject to any requirement contained in any of the documents (For Example: Adding “receiving station and transfer station” after “milk plant” if the Section requirements were intended to be applicable to all three.);

10. Changing incomplete sentences into complete sentences without changing the meaning or intent of the original language;
11. Consistently using acronyms within documents after they have been cited where the term or phrase first occurs in each document;
12. Deleting or changing references within NCIMS conference documents if a document is deleted or combined with another document to ensure accurate references;
13. Deleting any language that would extend the regulatory oversight to products outside the scope of the Grade “A” NCIMS Program;
14. Modifying any definition that is in conflict with a previously established definition in any NCIMS document to be consistent with the established definition and limited to the extent that the editorial changes do not alter the meaning or intent of the original language passed by the voting delegates; or
15. Providing consistent references to Document Titles, Committee Names, Agency Names, Agency Identifications, Position Names, Reporting Forms, citations of Documents and citations of Sections within Documents.

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

C. REVIEW AND APPROVAL OF EDITORIAL CHANGES

1. After receipt of the transcript of the second voting day PHS/FDA shall prepare an IMS-a document detailing the actions of the NCIMS Conference and shall incorporate the language from all Proposals passed by the voting delegates into the appropriate NCIMS conference documents.
2. PHS/FDA shall prepare an electronic version of each IMS-a and NCIMS conference document detailing the actions of the NCIMS Conference for review by the NCIMS Documents Review Committee that strikes out text to be deleted and underlines text to be inserted. The NCIMS Documents Review Committee shall have a minimum of ten (10) business days to review the changes and respond back to PHS/FDA with any concerns. Review of each IMS-a and NCIMS conference document detailing the actions of the NCIMS Conference shall continue until both the NCIMS Documents Review Committee and PHS/FDA concur on the IMS-a and NCIMS conference document or concurrence cannot be reached.
3. Those issues on which the NCIMS Documents Review Committee and PHS/FDA do not concur shall be referred to the NCIMS Executive Board for further discussion. If the NCIMS

Executive Board and PHS/FDA reach agreement on a proposed solution, the IMS-a or NCIMS conference document being considered shall require approval by a minimum of two-thirds (2/3) affirmative vote of the NCIMS Executive Board members before being released for publication.

4. The NCIMS Executive Board shall review and approve all editorial changes to NCIMS conference documents by a minimum of two-thirds (2/3) affirmative vote of the NCIMS Executive Board members. Editorial changes that did not raise any concerns of the NCIMS Documents Review Committee may be combined and voted on as one (1) motion by the NCIMS Executive Board.

D. **TRAINING COURSE DEVELOPMENT**

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

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

LETTER OF INTENT (LOI):

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

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

Milk Company

Signature of Most Responsible Party

Name

Title

Date

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

Third Party Certifier

Signature of Most Responsible Party

Name

Title

Date

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

MEMORANDUM OF AGREEMENT (MOA)

NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS
VOLUNTARY INTERNATIONAL CERTIFICATION PROGRAM

MEMORANDUM OF AGREEMENT
BETWEEN A
THIRD PARTY CERTIFIER
AND
A MILK COMPANY

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

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

- All required regulatory inspections and related enforcement;
- All required pasteurization system equipment testing;
- All required sampling and analysis of Grade “A” raw, pasteurized, ultra-pasteurized, aseptically processed and packaged milk and/or milk products, and/or retort processed after packaging milk and/or milk products; and milk containers, if applicable;
- All ratings/listings of shippers of Grade “A” milk and/or milk products; and
- Laboratory certification/approval program activities required for compliance with all applicable NCIMS Grade “A” Milk Safety Program requirements.

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

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

milk and/or milk products to be imported would be covered under FIMA.

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

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

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

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

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

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

Compliance with the requirements of the NCIMS voluntary ICP shall be determined by the FDA MST and LPET. Failure to adequately comply with the regulatory and enforcement provisions of

the Grade “A” Milk Safety Program; the requirements of the NCIMS voluntary ICP; requirements for IMS listing; the required Code of Ethics; etc. may result in the removal of {Third Party Certifier} from the NCIMS voluntary ICP.

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

- a. If a TPC is found to be in non-compliance with the requirements set forth in the documents of the NCIMS Grade “A” Milk Safety Program by PHS/FDA MST and/or LPET, the TPC shall be subject to procedures addressing their removal from the NCIMS voluntary ICP.
- b. If a TPC ceases to provide the required oversight of an IMS listed MC for purposes of the NCIMS voluntary ICP, both the TPC and the MC shall immediately notify the ICP Committee Chair and PHS/FDA MST and/or LPET. The MC, including all associated facilities, shall immediately be removed from the NCIMS voluntary ICP and the MC shall also immediately be withdrawn from the *IMS List* by PHS/FDA MST and/or LPET. Within fifteen (15) days of a TPC ceasing to provide this required MC oversight, the TPC shall transfer all existing records to PHS/FDA MST in a manner acceptable to PHS/FDA MST.
- c. If a TPC ceases to provide oversight of all of their IMS listed MCs for purposes of the NCIMS voluntary ICP, both the TPC and the MCs shall immediately notify the ICP Committee Chair and PHS/FDA MST and/or LPET. Both the TPC and MCs shall immediately be removed from the NCIMS voluntary ICP and the MCs shall immediately be withdrawn from the *IMS List* by PHS/FDA MST and/or LPET. Within fifteen (15) days of a TPC ceasing to provide this required MC oversight, the TPC shall transfer all existing records to PHS/FDA MST in a manner acceptable to PHS/FDA MST.
- d. When there is evidence, found during PHS/FDA check ratings or a triennial Regulatory/Rating Agency Program Evaluation, that the TPC is in non-compliance with the applicable requirements set forth in the documents of the NCIMS Grade “A” Milk Safety Program, the TPC shall be referred to the NCIMS Executive Board in accordance with Section IV, A. 3. b of the *Procedures*. The TPC and MC(s) listed by the TPC can be subject to withdrawal by PHS/FDA MST and/or LPET from the *IMS List*.
- e. If a MC’s IMS listed milk shipper changes status due to non-compliance or a change in the Sanitation Compliance Rating to less than ninety percent (90%), the TPC shall immediately notify the PHS/FDA MST and all known receiving Member States and/or TPCs. The MC’s IMS listed milk shipper shall immediately be withdrawn from the *IMS List* by PHS/FDA MST.
- f. When there is evidence that the MC or it’s servicing laboratory is not meeting the applicable requirements of the Grade “A” PMO and/or the EML, respectively, as determined by the TPC, or the ICP Committee, and/or PHS/FDA MST and/or LPET, the

MC's IMS listing(s) is subject to withdrawal from the *IMS List*. The TPC or the ICP Committee shall immediately notify PHS/FDA MST and/or LPET, respectively. In the case that PHS/FDA MST and/or LPET makes this determination based upon the results of a check rating or a laboratory evaluation, the MC is subject to suspension and/or removal from the NCIMS voluntary ICP until compliance, as determined by PHS/FDA MST and/or LPET, is achieved. With this determination, PHS/FDA MST and/or LPET, respectively, shall notify all known receiving Member States.

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

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

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

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

The MC shall have the option of terminating this MOA if, at any time, in the MC's sole judgment, a conflict of interest exists or is imminent. The TPC shall advise the MC of any activity, employment or business arrangement contemplated by the TPC that may be relevant to this Paragraph. Termination shall be in accordance with the notification requirements in Item 8. of this Agreement. The MC understands that if this MOA is terminated after they have been listed on the *IMS List* that their IMS Listings shall be immediately withdrawn from the *IMS List* and the MC shall be immediately removed from the NCIMS voluntary ICP.

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

8.) **Termination of MOA by Notice:** Either party may terminate this MOA upon [number] days notice by registered or certified mail, return receipt requested, addressed to the other party. If either party terminates this MOA, both the TPC and the MC shall immediately notify the ICP Committee Chair and FDA MST. Upon the TPC ceasing to provide oversight of the MC, the

CONSTITUTION OF THE NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

ARTICLE I ----- ORGANIZATION

- SECTION 1. The name of the entity shall be "The National Conference On Interstate Milk Shipments", hereinafter referred to as the Conference.
- SECTION 2. The Conference shall be directed by and shall be in the control of the various States who join together to stipulate the Conference's Procedures.
- SECTION 3. The Conference shall meet at least biennially during odd numbered years with additional meetings as the need arises.

ARTICLE II ----- MISSION

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

- SECTION 1. Adopting sound, uniform procedures, which will be accepted by participating Rating and Regulatory Agencies.
- SECTION 2. Promoting mutual respect and trust between Rating and Regulatory Agencies of producing and receiving States and Third Party Certifiers.
- SECTION 3. Utilizing Public Health Service/Food and Drug Administration (PHS/FDA) personnel for training programs and using that Agency as a channel for the dissemination of information among Rating and Regulatory Agencies for the objective of promoting uniformity among the States and Third Party Certifiers.
- SECTION 4. Acquainting producers, processors, and consumers with the purpose of the Conference through the media of meetings, conferences, workshops, press releases, publications, and by utilization of facilities and personnel of educational institutions, trade associations, Rating and Regulatory Agencies and other groups that are willing to assist in the dissemination of such information.

ARTICLE III ----- AFFILIATION AND REGISTRATION

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

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

- Subd. 2. Applying to the Executive Secretary for affiliation on forms provided and paying the annual affiliation fee.
- SECTION 2. Persons may not attend and/or take part in the biennial or special meeting of the Conference until they have registered their name, address, company, or Agency with the Executive Secretary and paid the registration fee.
- SECTION 3. Payment of registration fees as are required in Article I, Section 9. of the *Bylaws* shall be a part of registration.
- SECTION 4. All persons affiliated with the Conference as prescribed in this Article are entitled to be on an official list to receive copies of the Conference proceedings and other Conference matters determined by the Board to be of interest to all persons affiliated with the Conference.

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

- SECTION 1. The voting delegates, of the Conference, are representatives of the State Rating Agencies, State Regulatory Agencies, and like representatives from the District of Columbia, participating U.S. Trust Territories and each participating non-U.S. country or political subdivisions thereof, as identified in Article VII, Section 4., Subdivision 3. of the *Bylaws*.
- SECTION 2. An individual must be affiliated with the Conference to be eligible to serve as an Officer of the Conference, on the Board, on Committees or Councils or as Program Chair. Individuals must be in attendance and registered at the Conference at which they are appointed or elected or shall have been registered or attended the Conference immediately preceding the one at which they are appointed or elected. The requirement in respect to the consumer representative, Committees and Councils may be waived by the unanimous consent of the Board.
- SECTION 3. The voting delegates of the biennial meeting of the Conference shall elect its Executive Board, hereinafter called the Board.
- SECTION 4. The Board shall be composed up to twenty-six (26) members as follows:
- Four (4) members from Group I (Eastern States); Six (6) members from Group II (Central States) (two (2) at large); Four (4) members from Group III (Western States); all to be elected by the General Assembly by majority vote (General Assembly is defined as qualified voting delegates, assembled at a biennial or special meeting of the Conference); plus one

(1) member at large from each of Groups I (PHS/FDA) and III (United States Department of Agriculture (USDA)), appointed as outlined in the following Section; plus one (1) non-voting member at large representing consumers, appointed by the Chair and confirmed by the Board; plus one (1) non-voting representative from the Third Party Certifiers, appointed by the Chair and confirmed by the Board; plus the immediate Past Chair, the Program Chair, Chair of the NCIMS Liaison Committee, and the three (3) Council Chairs who are appointed by the Chair and confirmed by the Board; and one (1) representative each from the International Dairy Foods Association (IDFA) and the National Milk Producers Federation (NMPF). The Program Chair, Chair of the NCIMS Liaison Committee, the three (3) Council Chairs, the immediate Past Chair and the representatives from IDFA and NMPF, except as otherwise provided, shall serve on the Board as non-voting members. Each elected member of the Board shall serve through three (3) biennial meetings of the Conference. Full term Board members may succeed themselves, unless re-election would extend the total terms of consecutive service to more than twelve (12) years.

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

Subd. 1. Group I -- Eastern States

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

Subd. 2. Group II -- Central States

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

Subd. 3. Group III -- Western States

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

Subd. 4. Other Membership

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

SECTION 6. The Board shall elect a Chair and a Vice Chair from its membership after each biennial meeting of the Conference and they may retain their position at the pleasure of the Board as long as they are officially members of the Board. If the Chair cannot perform the duties, the Board shall again elect a Chair. The Board shall retain the services of an Executive Secretary. The Executive Secretary shall be bonded, shall not have a vote on the Board and in biennial or special meetings of the Conference; but shall perform all duties required in Article IV of the *Bylaws*. The compensation of the Executive Secretary shall be set by the Board.

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

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

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

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

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

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

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

Subd. 1. Council Chairs and Vice Chairs shall after appointment serve through two (2) consecutive biennial meetings of the Conference.

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

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

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

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

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

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

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

BYLAWS OF THE NATIONAL CONFERENCE
ON INTERSTATE MILK SHIPMENTS

ARTICLE I ----- DUTIES OF THE BOARD

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

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

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

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

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

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

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

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

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

SECTION 8. An elected Board membership vacancy occurring between Conferences shall remain vacant until the next Conference. The vacancy shall be filled by a qualified registrant who is nominated by the Nominating Committee or from the floor in General Assembly and is elected by the voting delegates.

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

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

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

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

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

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

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

ARTICLE II ----- DUTIES OF THE CHAIR

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

Section 1. of the *Bylaws*.

- SECTION 2. The Chair shall assist the Executive Secretary in arranging all Conferences.
- SECTION 3. The Chair, with the approval of the Board, shall appoint qualified Conference registrants to Standing Committees, including the Constitution and Bylaws, Documents Review Committee, HACCP Implementation Committee, Laboratory, Methods of Making Sanitation Ratings, Liaison, Single-Service Container and Closure, Technical Engineering Review, Scientific Advisory, Hauling Procedures, Other Species and International Certification Program Committees, and Councils as is necessary to carry out the mission of the Conference.
- SECTION 4. The Chair shall appoint Study and Ad hoc Committees as directed by the voting delegates or the Board.
- SECTION 5. The Chair shall assure that at least one half (1/2) the voting membership of Standing Committees, Ad hoc Committees and Study Committees as set forth in Article II, Sections 3. and 4. of the *Bylaws*, shall be composed of Rating and Regulatory Agencies, provided the membership of the Nominating Committee, Resolutions Committee and Constitution and Bylaws Committee shall consist in whole from State Rating and State Regulatory Agencies. The Nominating Committee shall be composed as set forth in Article I, Section 5. of the *Bylaws*.
- SECTION 6. The Chair shall assure that PHS/FDA may provide a non-voting consultant to Standing committees, Ad hoc committees or Study committees, provided PHS/FDA shall not provide any consultant to the Nominating Committee, Resolutions Committee, NCIMS Liaison Committee and Constitution and Bylaws Committee.
- SECTION 7. The Chair with the approval of the Board shall appoint Council Chairs and Vice Chairs as outlined in Article IV, Section 11. of the *Constitution*.
- SECTION 8. The Chair shall appoint Council consultants as required in Article II, Section 13. of the *Bylaws*.
- SECTION 9. The Chair shall appoint a Local Arrangements Committee to assist in planning the physical facilities for the next Conference.
- SECTION 10. The Chair may retain the services of a parliamentarian to rule on Parliamentary Procedures at Board meetings and during the delegate business meetings of the Conference.

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

SECTION 12. The Chair shall appoint a Program Chair.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

SECTION 5. The Chair of each Council shall appoint four (4) alternate Council members representing a dairy processor, a dairy producer, a Regulatory Agency and a Rating Agency for review and approval by the NCIMS Executive Board prior to each Conference. Alternate Council members shall be seated to cast votes during periods of temporary absence of Council members and shall be designated to replace Council members for the entire Conference if they cannot attend. Alternates must be affiliated with the current Conference and meet the same eligibility requirements to serve on a Council as the member for whom they will temporarily replace. Alternates shall be required to be in attendance at the Conference and be present at each Council meeting, even if not called upon by the Council Chair to temporarily replace an existing Council member. Alternates are only eligible to replace existing Council members from the same stakeholder group and shall be seated for the entire Conference as a temporary replacement for the original Council member. Council Chairs are encouraged to consider Council alternates when recommending permanent Council replacements to the Board for approval.

ARTICLE VII ----- RULES OF THE CONFERENCE

SECTION 1. All Conferences shall be at least two (2) days' duration.

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

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

Subd. 1. Call to order by the Chair.

- Subd. 2. Roll call of States and the announcement of the names of the delegates who will vote for each State in General Assembly.
- Subd. 3. Report of the Executive Secretary.
- Subd. 4. Unfinished business.
- Subd. 5. Appointment of the Nominating Committee.
- Subd. 6. Conference program, PHS/FDA report, Council Chair reports, the annual audit report and other new business.
- Subd. 7. Report of the Nominating Committee at least four (4) hours before voting.
- Subd. 8. Election of Board Members. In addition to the nominees selected by the Nominating Committee, nominations may be made from the floor of the delegate business meeting, if nominees qualify for the position to be filled.
- Subd. 9. Report of the Resolutions Committee.
- Subd. 10. Authorization by the voting delegates for the Board to conclude and implement any current unfinished action requiring PHS/FDA concurrence not specifically obtained during the Conference.
- Subd. 11. Adjourn.

SECTION 4. Rules of the delegate business meeting.

- Subd. 1. Robert's Rules of Order shall prevail, unless specific rules are established.
- Subd. 2. Each State or other entity listed in Subdivision 3. of this Section, shall be entitled to one (1) full vote or two (2) one-half (1/2) votes in the delegate business meeting.
- Subd. 3. Only a registrant at the Conference, who is a representative of a State Rating Agency or a State Regulatory Agency responsible for the enforcement of sanitation laws for Grade "A" milk and milk products, Grade "A" condensed and dry milk products and Grade "A" whey and whey products, or a like representative from the District of Columbia, or a participating U.S. Trust Territory, or a participating non-U.S. country or political subdivision thereof, is entitled to be a voting delegate. When any State is represented by both Rating and Regulatory Agencies, the vote may be cast together as one (1) vote or separately as one-half (1/2) vote each, provided that any State represented by both Rating and Regulatory

delegates certified in compliance with the provisions of Subdivision 4. of this Section may during any delegate business meeting, reassign its one-half (1/2) vote privilege to the other duly certified State delegate by giving written notice of such action to the Chair. When any State is represented by only one (1) Agency, the voting delegate at the Conference may cast a full vote for that State. Each voting delegate at the Conference may cast a vote only for the voting delegate's own State. Delegates and/or alternates will not be allowed to vote at the Conference from a State, which fails to honor the reciprocity provisions set forth in Section VI., paragraphs A. and B. of the *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments*.

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

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

- a. Its officially designated responsibility whether as State Rating Agency only, or as State Regulatory Agency only, or both as identified in Article VII, Section 4., Subdivision 3. of the *Bylaws*.
- b. The name of the delegate and the alternate and the authority they represent.
- c. Designation of the vote to which they are entitled, whether one-half (1/2) vote or one (1) vote.

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

- Subd. 5. State delegates shall record their names with the Executive Secretary, and shall cast their votes in the General Assembly when their State's name is called by announcing "yes" or "no" one (1) vote, or "yes" or "no" one-half (1/2) vote.
- Subd. 6. Voting in General Assembly shall be recorded as "yes" or "no".
- Subd. 7. A delegate may pass when the State's name is called for the purpose of caucusing and then shall vote when the second roll is called.
- Subd. 8. To adopt in General Assembly:
- a. A delegate quorum must be present.
 - b. A delegate quorum is defined as the registered voting delegates from at least two-thirds (2/3) of the States which have designated official delegates for the Conference, as identified in Section 4., Subdivisions 3. and 4. of this Article.
 - c. Adoption of motions involving actions not otherwise covered in this *Constitution* and *Bylaws* shall require a simple majority vote of the delegate quorum.
 - d. Adoption of a motion involving a new procedure in the *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments* shall require a simple majority vote of the delegate quorum with the vote to be taken on the second delegate voting day of the biennial or special meeting of the Conference; and
 - e. In order to change a procedure in the *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments*, adopted at any previous biennial or special meeting of the Conference, two (2) ballots are required on the motion for change. The first ballot shall be made on the first delegate voting day of the Conference, and shall require a majority vote of the delegate quorum. If the motion for change carries on the first ballot, the second consideration shall then be made on the second delegate voting day of the Conference. For the proposed change in procedure of the *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments* to be finally adopted, the second ballot shall

require at least a two-thirds (2/3) affirmative vote of the delegate quorum.

ARTICLE VIII ----- AMENDMENTS TO THE BYLAWS

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

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

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

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

BACKGROUND

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

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

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

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

PURPOSE

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

AGREEMENT

The FDA and NCIMS have agreed upon the following principles:

- A. The Interstate Milk Shippers Program shall be governed by the provisions of the current FDA Publication No. 72-2022, Procedures Governing the Cooperative Federal-State Program for Certification of Interstate Milk Shippers*, and by the documents referenced therein. Copies of all governing documents are available for review in the office of the Food and Drug Administration, Hearing Clerk.
- B. The responsibilities of the NCIMS, the participating States, and FDA for execution of the Interstate Milk Shippers Program shall be as stated in the above referenced Procedures Manual.
- C. Failure on the part of any certified state milk sanitation rating officer, state milk laboratory survey officer, or state sampling surveillance officer to comply with the provisions of this Memorandum or the Procedures Manual shall be sufficient cause for FDA to proceed to a hearing to provide said rating officer, laboratory survey officer, or sampling surveillance officer an opportunity to show cause why his/her certification or approval should not be revoked.
- D. It shall be the right of the NCIMS and each participating State to request and receive consultation with the appropriate representative of the FDA to discuss the provisions of this Memorandum or problems encountered in the execution of the provisions of the Procedures Manual. The initial contact office at FDA for all inquiries pertaining to the Program is Bureau of Foods (HFF-415)**, FDA, 200 C Street, S.W., Washington, D.C. 20204.
- E. It shall be the right of the FDA to request and receive consultation with appropriate officials of the NCIMS or any of its member States to discuss the provisions of this Memorandum or problems encountered in the execution of the provisions of the Procedures Manual. The Executive Board of NCIMS can be contacted by FDA personnel through the Bureau of Foods (HFF-415)** at the address indicated in paragraph D, above.
- F. Problems of interpretation regarding provisions of the Procedures Manual and the documents referenced therein, or their application, shall be subject to resolution by mutual agreement of the parties.
- G. Changes in the provisions of the Procedures Manual and the documents referred to therein shall be mutually concurred in by NCIMS and FDA.
- H. This Memorandum of Understanding may be modified by mutual consent of the parties and may be terminated by either party upon a thirty (30) day advance written notice to the other. Any modification or notice of termination will be published in the Federal

Register.

For the FDA.

Dated: August 5, 1977.

Donald Kennedy,
Commissioner of
Food and Drugs.

For the NCIMS.

Dated: June 28, 1977.

H. H. Vaux
Chairman, NCIMS.

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

Dated: September 12, 1977.

Joseph P. Hile
Associate Commissioner
for Compliance

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

* Current document is titled: Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments.

**Note: HFF-415 mail symbol for Dairy and Lipid Technology Branch, DFT, Bureau of Foods is now HFS-316, Center for Food Safety and Applied Nutrition, Milk Safety Team, 5100 Paint Branch Parkway, College Park, MD 20740.

RELATED DOCUMENTS

Grade “A” Pasteurized Milk Ordinance, Current Edition.

Methods of Making Sanitation Ratings of Milk Shippers, Current Edition.

Evaluation of Milk Laboratories, Current Edition.

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

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

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

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

Marshall, Robert T., *Standard Methods for the Examination of Dairy Products*. American Public Health Association, Washington, DC 20005, Current Edition.

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

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

Standard Methods for the Examination of Water and Wastewater, American Public Health Association, Washington, DC 20005, Current Edition.

FDA/NCIMS 2400 Forms, USPHS/FDA, U.S. Department of Health and Human Services, Bedford Park, Illinois 60501, Current Edition.