FDA U.S. FOOD & DRUG ADMINISTRATION

OFFICE OF REGULATORY AFFAIRS

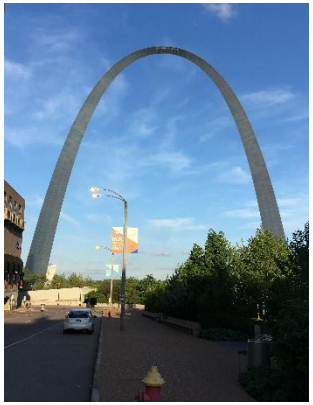
2019 NCIMS CONFERENCE ACTIONS

RESULTS OF THE 2019 NCIMS

37th NCIMS

April 26 - May 1, 2019

St. Louis, Missouri



RESULTS OF THE 2019 NCIMS

397 REGISTERED

- State/Regulatory- 131
- Federal (FDA and USDA) - 53
- Industry - 208
- Academia- 3
- 131 (33%) First Time Attendees

RESULTS OF THE 2019 NCIMS

5 REGISTERED

- **FOREIGN COUNTRIES**
  - **CANADA**
  - **ISRAEL**
  - **AUSTRALIA**
  - **COSTA RICA**
  - **IRELAND**

RESULTS OF THE 2019 NCIMS

VOTING DELEGATES:

48 STATES AND PUERTO RICO SENT DELEGATES

(Alaska and Arkansas not in attendance)

RESULTS OF THE 2019 NCIMS

75 PROPOSALS WERE DELIBERATED

(98) in 2017

- COUNCIL I – 23 Proposals
- COUNCIL II – 42 Proposals
- COUNCIL III – 8 Proposals
- JOINT COUNCIL – 2 Proposals

RESULTS OF THE 2019 NCIMS

COUNCIL I: (23 Proposals)

- NO ACTION – 12
- PASSED AS SUBMITTED – 6
- PASSED AS AMENDED – 5

RESULTS OF THE 2019 NCIMS

COUNCIL II: (42 Proposals)

- NO ACTION – 23
- PASSED AS SUBMITTED – 6
  FDA/NCIMS 2400 FORMS - 3
- PASSED AS AMENDED – 13
  FDA/NCIMS 2400 FORMS- 2

RESULTS OF THE 2019 NCIMS

COUNCIL III: (8 Proposals)

- NO ACTION – 1
- PASSED AS SUBMITTED – 2
- PASSED AS AMENDED – 5

RESULTS OF THE 2019 NCIMS

JOINT COUNCIL: (2 Proposals)

- NO ACTION – 0
- PASSED AS SUBMITTED – 0
- PASSED AS AMENDED – 2

RESULTS OF THE 2019 NCIMS

39 PROPOSALS PASSED

- **REVISED FDA FORMS:**
  - **2399a-Bulk Milk Hauler/Sampler Evaluation Report (4/11):**
    - **Council II – To make necessary corrections and report back in 2021**

RESULTS OF THE 2019 NCIMS

39 of 75 PROPOSALS PASSED

- **3 PROPOSALS ASSIGNMENT TO STUDY COMMITTEES OR A PILOT PROGRAM**
  - **Proposal JC-1**
  - **Proposal 112**
  - **Proposal 114**

RESULTS OF THE 2019 NCIMS

ASSIGNMENT TO A STUDY COMMITTEES OR A PILOT PROGRAM

- **Proposal 112**

The filling of cultured products made in one Grade "A" facility and transported to another Grade "A" facility to be repackaged without being repasteurized.

RESULTS OF THE 2019 NCIMS

ASSIGNMENT TO A STUDY COMMITTEES OR A PILOT PROGRAM

- **Proposal 114**
  - **This proposal requests the NCIMS Chair assign an NCIMS standing committee, special committee, or ad hoc committee as approved by the NCIMS Executive Board involving UV disinfection and other to study the safety of water….**

RESULTS OF THE 2019 NCIMS

ASSIGNMENT TO A STUDY COMMITTEES OR A PILOT PROGRAM

- **Proposal JC 1**

- **The assigned committee is charged to work cooperatively with FDA to develop a pilot program which will establish a regulatory framework to find efficiencies in inspection activities for facilities that manufacture both Grade "A" and non-Grade "A" products and be implemented by FDA and the participating States.**

RESULTS OF THE 2019 NCIMS

IMS-a-52 (to be issued)

ACTIONS OF THE 2019 NCIMS CONFERENCE

RESULTS OF THE 2019 NCIMS

IMS-a-52

STATES THAT CAN LEGALLY ENFORCE THE ACTIONS FROM THE 2019 NCIMS CONFERENCE BASED ON THE ISSUANCE OF THIS IMS-a, THEIR EFFECTIVE DATE IS:

ONE (1) YEAR AFTER THE ISSUANCE DATE OF IMS-a-52 (11/??/2019)

RESULTS OF THE 2019 NCIMS

IMS-a-52

STATES THAT CAN LEGALLY ENFORCE THE ACTIONS FROM THE 2019 NCIMS CONFERENCE BASED ON THE ISSUANCE OF THE ELECTRONIC PUBLICATION OF THE AFFECTED DOCUMENT(S), THEIR

EFFECTIVE DATE IS:

ONE (1) YEAR AFTER THE ISSUANCE DATE OF THE AFFECTED DOCUMENT(S).

RESULTS OF THE 2019 NCIMS

NOTE:

UNDERLINED TEXT IS NEW WORDING THAT WAS IN THE PASSED PROPOSAL.

TEXT ~~STRUCK THROUGH~~ IS EXISTING TEXT IN THE DOCUMENTS THAT WAS DELETED IN THE PASSED PROPOSAL.

RESULTS OF THE 2019 NCIMS

5/28/2019- OFFICIAL TRANSCRIPT WAS RECEIVED BY FDA

8/25/2019- DEADLINE DATE FOR FDA'S CONCUR/NON-CONCUR LETTER (90 days after receipt of transcript.)

RESULTS OF THE 2019 NCIMS

- **FDA CONCURRED WITH ALL PROPOSALS EXCEPT THE FOLLOWING PROPOSALS:**

- **Proposal 206**
- **JC-1**
- **Proposal 210**
- **Proposal 211**

RESULTS OF THE 2019 NCIMS

FDA NON-CONCERRED: PROPOSALS:

- **Proposal 206**

To clarify primacy of the FDA/NCIMS 2400 forms over SMEDP and OMA in the PMO

RESULTS OF THE 2019 NCIMS

FDA NON-CONCERRED: PROPOSALS:

- **Proposal JC-1**

Appendix T compliance would have to be determined once every thirty-six (months) by a federal check rating or by a state rating.

RESULTS OF THE 2019 NCIMS

FDA NON-CONCERRED: PROPOSALS:

- **Proposal 210**

V. REQUIREMENTS FOR USING AN APPROVED ON-TANKER FARM BULK MILK TANK ASEPTIC ~~SAMPLING SYSTEM~~ SAMPLER FOR MULTIPLE AND/OR SINGLE FARM PICKUPS

RESULTS OF THE 2019 NCIMS

FDA NON-CONCERRED: PROPOSALS:

- **Proposal 211**

V. REQUIREMENTS FOR THE SAMPLING OF RAW SHEEP MILK THAT HAS BEEN FROZEN PRIOR TO BEING TESTED FOR APPENDIX N. DRUG RESIDUE

RESULTS OF THE 2019 NCIMS

FDA NON-CONCERRED: PROPOSALS:

- **Proposal 211**

VI. REQUIREMENTS FOR SANITIZING SAMPLING COCKS AND IN-LINE SAMPLE POINTS

RESULTS OF THE 2019 NCIMS

FDA NON-CONCERRED: PROPOSALS:

- **Proposal 210 & 211**

V. REQUIREMENTS FOR USING AN APPROVED ON-TANKER FARM BULK MILK TANK ASEPTIC SAMPLER FOR MULTIPLE AND/OR SINGLE FARM PICKUPS

VI. REQUIREMENTS FOR SANITIZING SAMPLING COCKS AND IN-LINE SAMPLE POINTS

VII. REQUIREMENTS FOR THE SAMPLING OF RAW SHEEP MILK THAT HAS BEEN FROZEN PRIOR TO BEING TESTED FOR APPENDIX N. DRUG RESIDUE

VIII. MILK TANK TRUCK PERMITTING AND INSPECTION

RESULTS OF THE 2019 NCIMS

JOINT COUNCIL

(2 Proposals)

RESULTS OF THE 2019 NCIMS

Proposal JC 1

1. **Allows the States the option of conducting Appendix T inspections (During State Ratings) with Agreement with FDA** – Changes made to the PMO, MMSR and Procedures

RESULTS OF THE 2019 NCIMS

Proposal JC 1

2. Liaison Committee and FDA to draft and implement a pilot study to:

1. Establish regulatory framework to find efficiencies in dual-grade firms.
2. Determine the eligibility criteria for pilot consideration, the types of non-Grade "A" products manufactured in dual-grade facilities, the resource needs and potential hurdles likely to be encountered.
3. Maximize state and federal resources and to create greater efficiencies through its obligations under the Food Safety Modernization Act.

RESULTS OF THE 2019 NCIMS

Proposal JC 1

PMO (Page 21)

SECTION 5. INSPECTION OF DAIRY FARMS AND MILK PLANTS

3. …

c. Inspections of a milk plant for compliance with Appendix T. of this *Ordinance* may be conducted by the Regulatory Agency at least once every thirty-six (36) months. Inspection for compliance by the Regulatory Agency can only occur after the completion of either the Grade "A" PMO Preventive Controls Training for Regulatory/Rating Agencies or the Preventive Controls for Human Food Regulators Course (FD254).

RESULTS OF THE 2019 NCIMS

Proposal JC 1

PROCEDURES (Page 26)

F. **FOOD SAFETY PLAN COMPLIANCE**
An IMS listed milk plant shall comply with the applicable Food Safety Plan requirements cited in Appendix T. of the *Grade "A" PMO* as determined once every thirty-six (36) months ~~on~~ by a PHS/FDA check rating or, upon agreement between a State Rating Agency and FDA, by a state rating. Check ratings, state ratings, and any required re-inspection to determine compliance with Appendix T. shall be conducted only by personnel who have completed either the PHS/FDA *Grade "A" PMO* Preventive Controls training for Regulatory/Rating Agencies or the Preventive Controls for Human Food Regulators Course (FD254).

RESULTS OF THE 2019 NCIMS

Proposal JC 1

MMSR (page 14)

NOTE: If a re-inspection is required following a PHS/FDA check rating or state rating because of the milk plant not being in substantial compliance with Appendix T. of the *Grade "A" PMO*, then the milk plant shall upon re-inspection ~~initially~~ be determined to be in substantial compliance with Appendix T. of the *Grade "A" PMO* and ~~upon re-inspection then~~ shall achieve a Sanitation Compliance Rating of ninety percent (90%) or higher on the re-inspection in order to be eligible for a listing on the *IMS List*.

RESULTS OF THE 2019 NCIMS

Proposal JC 1

MMSR (Page 13)

2. FOOD SAFETY PLAN COMPLIANCE – PROCEDURES FOR DETERMINING MILK PLANT COMPLIANCE

During a PHS/FDA check rating/audit, or a state rating/audit upon agreement between a State Rating agency and FDA, it is necessary to determine compliance of the milk plant with the requirements of Appendix T. Preventive Controls for Human Food Requirements for Grade "A" Milk and Milk Products of the *Grade "A" PMO* related to the requirement that the milk plant shall have a written food safety plan. The following criteria are to be used in making that determination:

RESULTS OF THE 2019 NCIMS

Proposal JC 1

MMSR (Page 14)

If the milk plant is determined not to be in substantial compliance with Appendix T. of the *Grade "A" PMO* by a check rating, the milk plant shall not be immediately removed from the *IMS List* and PHS/FDA shall formally notify the Rating Agency that a re-inspection/re-audit of the milk plant shall be required within sixty (60) days. If the milk plant is determined not to be in substantial compliance with Appendix T of the Grade "A" PMO as determined by a state rating, the milk plant shall not be immediately removed from the *IMS List* and the Rating Agency shall conduct a re-inspection/re-audit of the milk plant within sixty (60) days of the initial rating.

RESULTS OF THE 2019 NCIMS

Proposal JC 1

MMSR (Page 14)

NOTE: If a re-inspection/re-audit is required following a PHS/FDA check rating/audit or a state rating/audit because of the milk plant not being in substantial compliance with Appendix T. of the *Grade "A" PMO*, then the milk plant upon re-inspection shall ~~initially~~ be determined to be in substantial compliance with Appendix T. of the *Grade "A" PMO* and ~~then~~ shall achieve a Sanitation Compliance Rating of ninety percent (90%) or higher on the re-inspection or shall receive an acceptable listing audit for NCIMS HACCP milk plants on a re-audit in order to be eligible for a listing on the *IMS List*.

RESULTS OF THE 2019 NCIMS

Proposal JC 1

The Liaison Committee requests the Chair to assign this proposal to an NCIMS standing committee, special committee, or ad hoc committee as approved by the NCIMS Executive Board.

The assigned committee is charged to work cooperatively with FDA to develop a pilot program which will establish a regulatory framework to find efficiencies in inspection activities for facilities that manufacture both Grade "A" and non-Grade "A" products and be implemented by FDA and the participating States.

RESULTS OF THE 2019 NCIMS

Proposal JC 1

In developing the details of the inspectional model(s) to pilot, the assigned committee will, at least, consider: the regulatory authorities of state regulatory agencies, the eligibility criteria for pilot consideration, the types of non-Grade "A" products manufactured in dual-grade facilities, the resource needs and potential hurdles likely to be encountered, and the metrics for evaluating success.

RESULTS OF THE 2019 NCIMS

Proposal JC 1

When implemented, the pilot program will meet the Agency's commitment to the NCIMS of identifying additional ways to maximize State and Federal resources and to create greater efficiencies through its obligations under the FDA Food Safety Modernization Act while maintaining the high safety of the U.S. milk supply.

RESULTS OF THE 2019 NCIMS

Proposal JC 1

FDA shall inform and confer with the assigned committee to answer questions and address concerns to provide clarity and transparency at a frequency determined by the NCIMS Executive Board. A complete report of the pilot program will be shared at the 2021 Conference.

RESULTS OF THE 2019 NCIMS

Proposal JC 1

In recognition that FDA is strongly committed to developing and implementing the dairy inspection pilot program and stands ready to work in a collaborative spirit on the framework for this pilot program immediately with the assigned committee, the Liaison Committee requests an effective date of the receipt and acceptance of FDA concurrence at the next NCIMS Executive Board meeting after the Conference.

RESULTS OF THE 2019 NCIMS

Proposal JC 2

This Proposal contains modifications to the PMO, Methods, Procedures and EML documents that address the regulation and rating of milk plants producing Grade "A" fermented, high acid shelf-stable milk and/or milk products.

RESULTS OF THE 2019 NCIMS

Proposal JC 2

PMO, Page vi:

This edition of the *Ordinance* contains sanitary standards for Grade "A" raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, ~~or~~ retort processed after packaging **or fermented high acid shelf stable processing and packaging** and Grade "A" milk and/or milk products defined in Section 1.

RESULTS OF THE 2019 NCIMS

Proposal JC 2

PMO, Page xvii - Abbreviations and Acronyms:

AQFPSS (Aseptic-Qualified Filler and Product Sterilizer System)
FHA (Fermented High Acid)

RESULTS OF THE 2019 NCIMS

Proposal JC 2

PMO, SECTION 1. DEFINITIONS …

B. **ASEPTIC-QUALIFIED FILLER AND PRODUCT STERILIZER SYSTEM (AQFPSS):** A filler and product sterilizer and associated equipment which are used for aseptic processing and packaging as defined in 21 CFR 113.3(a). This system will be described within filings for aseptic low acid products that have been filed with and reviewed by the Food Processing Evaluation Team in FDA/CFSAN's Office of Food Safety. The aseptic-qualified filler (which includes the package sterilizer) is operated as described within the Form FDA 2541g filing submission.

RESULTS OF THE 2019 NCIMS

Proposal JC 2

PMO, SECTION 1. DEFINITIONS (*Continued*)

The aseptic-qualified product sterilizer is operated in a manner that is sufficient to destroy the vegetative cells of microorganisms of public health significance and those of non-health significance capable of reproducing in the food under conditions of ambient storage. The scope of the AQFPSS includes the filler and product sterilizer described within the Form FDA 2541g filing submission and any other equipment or processes which will be defined in written documentation provided by the Process Authority that are critical to maintain the safety of the product.

RESULTS OF THE 2019 NCIMS

Proposal JC 2

PMO, SECTION 1. DEFINITIONS …*Page 4:*

R. FERMENTED HIGH (CULTURED)ACID SHELF STABLE MILK AND/OR MILK PRODUCTS: Grade "A" Fermented High Acid (FHA) shelf-stable milk and/or milk products are Grade "A" milk and/or milk products that have been pasteurized and fermented (cultured) to pH 4.6 or lower, which may contain safe and suitable ingredients, and

RESULTS OF THE 2019 NCIMS

Proposal JC 2

PMO, SECTION 1. DEFINITIONS *…Page 4:*

R-1. which are thermally processed and packaged in accordance with the Process Authority's recommendations using an Aseptic-Qualified filler and Product Sterilizer System (AQFPSS) to achieve shelf-stability and then stored and distributed under normal non-refrigerated conditions and subject to all requirements of Appendix S of the PMO, or

RESULTS OF THE 2019 NCIMS

Proposal JC 2

PMO, SECTION 1. DEFINITIONS *…Page 4: (continued)*

R-2. which are processed and packaged in accordance with all applicable provisions of the PMO to achieve shelf stability and then stored and distributed under normal non-refrigerated conditions.

RESULTS OF THE 2019 NCIMS

Proposal JC 2

PMO, SECTION 1. DEFINITIONS …*Page 4:*

Note: This does not include acidified milk and/or milk products, such as acidified milk and acidified sour cream.

RESULTS OF THE 2019 NCIMS

Proposal JC 2

PMO, SECTION 1. DEFINITIONS …*Page 4:*

S. FERMENTED HIGH ACID SHELF STABLE PROCESSING AND PACKAGING: For the purpose of this *Ordinance* Fermented High Acid Shelf Stable Processing and Packaging is the processing and packaging of Grade "A" fermented high acid shelf stable milk and/or milk products on an AQFPSS.

RESULTS OF THE 2019 NCIMS

Proposal JC 2

PMO, SECTION 1. DEFINITIONS …(*continued)*

The Grade “A” fermented high acid shelf stable milk and/or milk products shall be subjected to a process that is sufficient to destroy the vegetative cells of microorganisms of public health significance and those of non-health significance capable of reproducing in the food under conditions of ambient storage. Fermented High Acid Shelf Stable Processing and Packaging shall conform to the applicable requirements of 21 CFR Part 117.

RESULTS OF THE 2019 NCIMS

Proposal JC 2

PMO, Page 393:

APPENDIX S. ASEPTIC PROCESSING AND PACKAGING PROGRAM, ~~AND~~ RETORT PROCESSED AFTER PACKAGING PROGRAM AND FERMENTED HIGH ACID SHELF STABLE PROCESSING AND PACKAGING PROGRAM

The Aseptic Processing and Packaging Program is designed to include all Grade "A" low-acid (21 CFR Part 113) aseptically processed and packaged milk and/or milk products.

The Retort Processed after Packaging Program is designed to include all Grade "A" low-acid (21 CFR Part 113) retort processed after packaged milk and/or milk products.

The Fermented High Acid Shelf Stable Processing and Packaging Program is designed to include all Grade "A" fermented high acid shelf stable processed and packaged milk and/or milk products.

RESULTS OF THE 2019 NCIMS

Proposal JC 2

PMO, Page 393:

APPENDIX S. ASEPTIC PROCESSING AND PACKAGING PROGRAM, ~~AND~~ RETORT PROCESSED AFTER PACKAGING PROGRAM AND FERMENTED HIGH ACID SHELF STABLE PROCESSING AND PACKAGING PROGRAM

NOTE: Retort processed after packaging low-acid milk and/or milk products as addressed in the definition of Milk Products of this *Ordinance* shall be considered to be Grade "A" milk and/or milk products if they are used as an ingredient to produce any milk and/or milk product defined in the definition of Milk Products of this *Ordinance*; or if they are labeled as Grade "A" as described in Section 4. of this *Ordinance*.

RESULTS OF THE 2019 NCIMS

Proposal JC 2

PMO, Page 393:

- **ASEPTIC PROCESSING AND PACKAGING PROGRAM, ~~AND~~**

RETORT PROCESSED AFTER PACKAGING PROGRAM AND FERMENTED HIGH ACID SHELF STABLE PROCESSING AND PACKAGING PROGRAM

GRADE "A" PMO/CFR COMPARISON SUMMARY REFERENCE

RESULTS OF THE 2019 NCIMS

Proposal JC 2

PMO, Section 7. Items	**Aseptic Program/Retort Program/ Fermented High Acid Shelf Stable Program**	**Authority**
1p. Floors – Construction	Floor drains are not required in storage rooms for aseptic processed and packaged low-acid milk and/or milk products, ~~and~~ retort processed after packaged low-acid milk and/or milk products and fermented high acid, shelf stable milk and/or milk products.	PMO
2p. Walls and Ceiling – Construction	Ceiling requirements are exempt in aseptically processed and packaged low-acid milk and/or milk products, ~~and~~ retort processed after packaged low-acid milk and/or milk products and fermented high acid milk and/or milk products dry storage rooms. (Same as for dry milk or milk products.)	PMO

RESULTS OF THE 2019 NCIMS

Proposal JC 2

PMO, Section 7. Items	**Aseptic Program/Retort Program/ Fermented High Acid Shelf Stable Program**	**Authority**
3p. Doors and Windows	**None**	**PMO**
4p. Lighting and Ventilation	**None**	**PMO**
5p. Separate Rooms	Fabrication of containers and closures for aseptic processed and packaged low-acid milk and/or milk products, ~~and~~ retort processed after packaged low-acid milk and/or milk products and fermented high acid shelf stable milk and/or milk products within the APPS, ~~and/or~~ RPPS, or AQFPSS, respectively, is exempt.	PMO

RESULTS OF THE 2019 NCIMS

Proposal JC 2

6p. Toilet – Sewage Disposal Facilities	None	PMO
7p. Water Supply*	The APPS, ~~and/or~~ RPPS, or AQFPSS**, respectively, is exempt, but shall comply with the CFR.	PMO/CFR
8p. Handwashing Facilities	None	PMO
9p. Milk Plant Cleanliness	None	PMO
10p. Sanitary Piping*	The APPS, ~~and/or~~ RPPS, and/or **, respectively, is exempt, but shall comply with the CFR.	PMO/CFR

RESULTS OF THE 2019 NCIMS

Proposal JC 2

11p. Construction and Repair of Containers and Equipment*	The APPS, ~~and/or~~ RPPS, or AQFPSS, respectively, is exempt, but shall comply with the CFR. Paper, plastics, foil, adhesives and other components of containers and closures used in the packaging of milk and/or milk products that have been aseptically processed and packaged, ~~or~~ retort processed after packaged or fermented high acid shelf stable processed and packaged are not required to comply with Appendix J. of this Ordinance; are not required to originate from an IMS Listed Source; and are subject to the requirements of the CFR.	PMO/CFR
12p. Cleaning and Sanitizing of Containers and Equipment*	The APPS, ~~and/or~~ RPPS, or AQFPSS**, respectively, is exempt, but shall comply with the CFR.	PMO/CFR

RESULTS OF THE 2019 NCIMS

Proposal JC 2

13p. Storage of Cleaned Containers and Equipment*	The APPS, ~~and/or~~ RPPS, or AQFPSS**, respectively, is exempt, but shall comply with the CFR.	PMO/CFR
14p. Storage of Single-Service Containers, Utensils and Materials	None	PMO

RESULTS OF THE 2019 NCIMS

Proposal JC 2

15p.(A) Protection from Contamination*	The APPS, ~~and/or~~ RPPS, or AQFPSS**, respectively, is exempt, but shall comply with the CFR.	PMO/CFR
15p.(B) Protection from Contamination - Cross Connections*	The APPS, ~~and/or~~ RPPS, or AQFPSS**, respectively, is exempt, but shall comply with the CFR. APPS, ~~and/or~~ RPPS and/or AQFPSS equipment is exempt from the separation requirements of the PMO in relationship to instrumented steam blocks between milk and milk products and cleaning and/or chemical sanitizing solutions.	PMO/CFR -

RESULTS OF THE 2019 NCIMS

Proposal JC 2

16p. Pasteurization and Aseptic Processing and Packaging (A) through (D)*	The APPS, ~~and/or~~ RPPS, or AQFPSS, respectively, is exempt, but shall comply with the CFR. The Regulatory Agency is not required to conduct the quarterly equipment testing and sealing of aseptic and/or processing equipment. Records and recording charts are not required to be reviewed during routine inspections, ratings or check ratings. **Provided that records and recording charts of the AQFPSS shall be evaluated in accordance with FHA CLE #5.**	CFR

RESULTS OF THE 2019 NCIMS

Proposal JC 2

PMO Appendix S (page 395)

*__NOTE:__ In areas of the milk plant where these Items are dedicated only to the APPS, ~~and/or~~ RPPS, or AQFPSS, respectively, as defined by this *Ordinance*, these Items shall be inspected and regulated in accordance with the applicable FDA regulations (21 CFR Parts 108, 113 and 117).

__NOTE: Only portions of the AQFPSS that are included in the FDA Form 2541g filing will be exempt from this requirement. Any additional equipment not included in the Form FDA 2541gfiling submission will be inspected per the PMO.__**

RESULTS OF THE 2019 NCIMS

Proposal JC 2

MMSR, Page 3:

15. FERMENTED HIGH ACID SHELF STABLE CRITICAL LISTING ELEMENT: An Item on FORM FDA 2359xxx-NCIMS ASEPTIC PROGRAM COMMITTEE - CRITICAL LISTING ELEMENTS for Grade "A" fermented high-acid shelf-stable milk and/or milk products - pH of 4.6 or below obtained by fermentation using live and active cultures. The identification of any Fermented High Acid Shelf Stable Critical Listing Element by a Milk Sanitation Rating Officer (SRO) or PHS/FDA Milk Specialist as not being in compliance, shall cause a listing to be immediately denied or withdrawn.

RESULTS OF THE 2019 NCIMS

Proposal JC 2

MMSR, Page 18:

NOTE: In the case of a HACCP aseptic listed milk plant, ~~and/or~~ HACCP retort listed milk plant, and/or HACCP fermented high acid shelf stable milk plant, the identification of any ~~A~~CLE element on FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND/OR PACKAGING PROGRAM AND RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products) or FORM FDA 2359xxx-NCIMS ASEPTIC PROGRAM COMMITTEE - CRITICAL LISTING ELEMENTS for Grade "A" fermented high-acid shelf-stable milk and/or milk products - pH of 4.6 or below obtained by fermentation using live and active cultures by a SRO or PHS/FDA Milk Specialist as not being in compliance shall also constitute an ~~A~~CLE deficiency under the NCIMS HACCP System, whereby a listing shall be immediately denied or withdrawn.

RESULTS OF THE 2019 NCIMS

Proposal JC 2

MMSR, Page 19:

1.) Inspection Criteria

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

B.) The …

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

RESULTS OF THE 2019 NCIMS

Proposal JC 2

Procedures, Page 21:

C.) Withdrawal of Listed Rating

When check rating data indicates that the Sanitation Compliance Rating of a milk plant, receiving station and/or transfer station requires a withdrawal of their listed rating, … letter of notification by the Rating Agency. Such letter shall be dated within five (5) working days following the date of the official notification by PHS/FDA. A withdrawal of a listed rating is also required if an aseptic, ~~or~~ retort, or fermented high acid shelf stable milk plant has any ~~Aseptic~~ Critical Listing Element ~~(ACLE)~~ (CLE) 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) or on FORM FDA 2359xxx-NCIMS ASEPTIC PROGRAM COMMITTEE - CRITICAL LISTING ELEMENTS for Grade "A" fermented high-acid shelf-stable milk and/or milk products - pH of 4.6 or below obtained by fermentation using live and active cultures following the procedures cited above.

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RESULTS OF THE 2019 NCIMS

Proposal JC 2

Procedures, Page 35:

Insert after 3 and renumber 4.

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

RESULTS OF THE 2019 NCIMS

Proposal JC 2

Joint Council_2_2019_Appendix_1

NCIMS ASEPTIC PROGRAM COMMITTEE - CRITICAL LISTING ELEMENTS for Grade "A" fermented high-acid shelf-stable milk and/or milk products - pH of 4.6 or below obtained by fermentation using live and active cultures

(To be included with NCIMS State Ratings/HACCP Listings and FDA Check Ratings/Audits.)

MILK PLANT: FHA Yogurt **DATE OF INSPECTION/RATING:** 10/25/2018

ADDRESS: Main Street, USA
LICENSE PERMIT NUMBER: _____

REGULATORY OR RATING AGENCY: _____

EXPLANATION OF CONCERNS NOTED REGARDING CRITICAL LISTING ELEMENTS UNDER THE NCIMS ASEPTIC PROGRAM COMMITTEE
(Use additional sheets as necessary.)

RESULTS OF THE 2019 NCIMS

Proposal JC 2

- **A narrative description shall be provided as a part of all NCIMS Aseptic Program Committee State Ratings/HACCP Listings and FDA Check Ratings/Audits. This report shall include an evaluation of the following requirements:**

1. Does the milk plant have a FDA Low Acid Canned Foods (LACF) Food Canning Establishment (FCE)

RESULTS OF THE 2019 NCIMS

Proposal JC 2

2. Are the milk plant's Grade "A" fermented high-acid (FHA) shelf-stable milk and/or milk product(s) produced using an Aseptic-Qualified Filler and Product Sterilizer System (AQFPSS) which is under a current FDA LACF 2541g (Food Process Filing for Low Acid Aseptic Systems)?

RESULTS OF THE 2019 NCIMS

Proposal JC 2

3. Are the milk plant's process recommendations for its Grade "A" fermented high-acid shelf-stable milk and/or milk product(s) developed by a recognized process authority qualified as having expert knowledge of aseptic processes?

RESULTS OF THE 2019 NCIMS

Proposal JC 2

4. Have the milk plant's process recommendations for its Grade "A" fermented high-acid shelf-stable milk and/or milk product(s) been reviewed [with no objections] by the Regulatory Agency prior to production of these products?

RESULTS OF THE 2019 NCIMS

Proposal JC 2

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

RESULTS OF THE 2019 NCIMS

Proposal JC 2

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

RESULTS OF THE 2019 NCIMS

Proposal JC 2

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

RESULTS OF THE 2019 NCIMS

COUNCIL I

RESULTS OF THE 2019 NCIMS

PROPOSAL 106

This proposal provided clarification on the emptying and cleaning of storage tanks as identified by item 12p within the PMO.

RESULTS OF THE 2019 NCIMS

PROPOSAL 106

PMO, Item 12p

- Otherwise, **storage tanks** shall be cleaned when emptied and shall be emptied at least every seventy-two (72) hours ~~and shall be cleaned prior to first use. For the purpose of determining compliance with this provision the 72-hour time frame shall begin when milk first enters the storage tank after cleaning~~. **The seventy-two (72) hour period of time starts when milk first enters a cleaned and sanitized storage tank.** Records shall be available to ~~**verify**~~ **document** that milk storage in these tanks does not exceed seventy-two (72) hours.

RESULTS OF THE 2019 NCIMS

PROPOSAL 108

This proposal adds language to Item 16p.(B)2.f.(2)ii. and Appendix H that will allow use of the partial homogenization for producing the milk and/or milk products.

RESULTS OF THE 2019 NCIMS

PROPOSAL 108

Page 102, PMO, Item 16p.(B)

When a homogenizer is used in conjunction with a timing pump, and both are located upstream of the holding tube, it shall be ~~either~~ **one of the following**:

ii) Of smaller capacity than **and located after** the timing pump: …

iii. Of smaller capacity than and located before the timing pump when used to homogenize some but not all of the milk and/or milk product: In which case the unhomogenized milk and/or milk product shall mix with the homogenized milk and/or milk product before the timing pump and an unrestricted, open, homogenizer by-pass line shall be used to connect the unhomogenized milk and/or milk product line with the homogenized milk and/or milk product line. The homogenizer by-pass line shall be at least the same or larger diameter than the inlet piping feeding the timing pump.

RESULTS OF THE 2019 NCIMS

PROPOSAL 108

Page 102, PMO, Item 16p.(B)

NOTE: For those systems that do not homogenize all milk or milk products and wish to utilize a by-pass line to **completely** by-pass the homogenizer while processing such milk or milk product, the by-pass line shall be connected with valves that are so designed that both lines cannot be open at the same time. This may be accomplished… **. Milk and/or milk products cannot be labeled "homogenized" if some or all of the milk and/or milk product bypasses the homogenizer as described in the this note of f.2.iii above.**

RESULTS OF THE 2019 NCIMS

PROPOSAL 109

This proposal allows for milk pasteurization plants to list either their **name and location or their milk plant code** on their milk ***pasteurization charts***.

RESULTS OF THE 2019 NCIMS

PROPOSAL 109

PMO 16p.(D) Pasteurization Records

Page 106:

(7) Quarterly, the time accuracy of the recording thermometer, as determined by the Regulatory Agency, or…

(10) Signature or initials of the operator; and

(11) Name **and location** of the milk plant **or their milk plant code**.

RESULTS OF THE 2019 NCIMS

PROPOSAL 111

This proposal made the extended the filling and **cooling exceptions** to **cup set yogurt**.

RESULTS OF THE 2019 NCIMS

PROPOSAL 111

PMO 17p. Cooling of Milk and/or Milk Products

Page 113:

1. All yogurt products at all milkfat levels, cultured in the cup after filling (cup set) and being moved out of the culturing room when reaching a pH 4.8 or below and with a pH of 4.6 or below within twenty-four (24) hours and cooled to 7°C (45°F) or less within ninety-six (96) hours of being moved out of the culturing room;**

~~1.~~**2.** Cultured sour cream at all milkfat levels with a pH of 4.70 or below* and cooled to 7°C (45°F) or less within one hundred sixty eight (168) hours of filling**;

RESULTS OF THE 2019 NCIMS

PROPOSAL 112

This proposal requested to allow the repacking of yogurt from one Grade “A” milk plant to another Milk Plant **without having to be repasteurized** at the plant of final packaging

STUDY COMMITTEE

RESULTS OF THE 2019 NCIMS

PROPOSAL 113

This proposal adds a "flow control **system**" as an alternative to a "flow control **valve**" in Appendix D and Appendix H for controlling performance in UV light systems used to treat water.

RESULTS OF THE 2019 NCIMS

PROPOSAL 113

Added the term “flow control system” as an alternative to “flow control valve” for UV Light water treatment systems.

2017 PMO Appendix D page 182:

- 6. An automatic flow control system or valve, accurate within the expected pressure range, shall be installed to restrict flow ~~to the maximum design flow of the treatment unit~~ so that the entire volume of water receives the minimum dose required above.

2017 PMO Appendix D page 183

- 6. An automatic flow control system or valve, accurate within the expected pressure range, shall be installed to restrict flow ~~to the maximum design flow of the treatment unit~~ so that the entire volume of water receives the minimum dose required above.

2017 PMO Appendix H page 282

- 4. An automatic flow control system or valve, accurate within the expected pressure range, shall be installed to restrict flow ~~to the maximum design flow of the treatment unit~~ so that all particles receive the minimum dose listed above.

RESULTS OF THE 2019 NCIMS

PROPOSAL 114

This proposal was combined with proposals 114,115 and 116 which all involved UV Light water treatment and other technologies to produce disinfected and/or Past. Equiv. Water as prescribed in Section VII, Appendix D and H.

STUDY COMMITTEE

RESULTS OF THE 2019 NCIMS

PROPOSAL 117

A proposal submitted in 2017 requested the Chair assign a committee to evaluate item 16p and App H of the PMO to make editorial corrections and to make them more uniform and accurate.

RESULTS OF THE 2019 NCIMS

PROPOSAL 117

Main edits;

1. **Milk and/or Milk Products (>100x)**
2. **The terms “Holder” or “Tubular Holder” in reference to a vat is a “pasteurizer” or “holding tube” as referenced**
3. **HTST/HHST pasteurizers now called “Continuous Flow Pasteurization”**

RESULTS OF THE 2019 NCIMS

PROPOSAL 117

PMO, pages 90 – 108

ITEM 16p. PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING, AND RETORT PROCESSED AFTER PACKAGING

In all cases, except for the specific exemptions provided for in **ADMINISTRATIVE PROCEDURES** #3, pasteurization of raw milk and / or milk product shall be performed before the raw milk and / or milk product enters the reverse osmosis (RO), ultra-filtration (UF), evaporator or condensing equipment and shall be performed in the milk plant where the processing is done. All condensed milk and / or milk products transported to a milk plant for drying shall be re-pasteurized at the milk plant at which it is dried. …

RESULTS OF THE 2019 NCIMS

PROPOSAL 117

PMO, Page 92

(3) The RO or UF system shall be equipped with temperature monitoring and recording devices that ~~comply with the applicable specifications outlined in Appendix H. of this *Ordinance*~~ are acceptable to the Regulatory Agency. At a minimum, milk and / or milk product temperature shall be monitored and recorded prior to entering the system,…

RESULTS OF THE 2019 NCIMS

PROPOSAL 117

PMO, Page 93

(2) The MF system shall be equipped with temperature monitoring and recording devices that ~~comply with the applicable specifications outlined in Appendix H of this Ordinance~~ are acceptable to the Regulatory Agency. At a minimum, milk and / or milk product temperature shall be monitored and recorded prior to entering the MF system and within the circulating retentate loop of each module just prior to the circulation pump; and

RESULTS OF THE 2019 NCIMS

PROPOSAL 117

PMO, Page 95

1. TIME AND TEMPERATURE CONTROLS FOR BATCH PASTEURIZERS

a. Temperature Difference: The pasteurizer shall be so designed that the simultaneous temperature difference between the milk and / or milk product, at the center of the coldest milk and / or milk product and the warmest milk and / or milk product in the vat, will not exceed 0.5ºC (1ºF) at any time during the holding period. The vat shall be provided with adequate agitation,… .

RESULTS OF THE 2019 NCIMS

PROPOSAL 117

PMO, Page 96

b. "The Just-Closed Position" shall mean that closed position of a plug-type valve in which the flow into or out of the ~~holder~~ pasteurizer is barely stopped, or any position within 2 millimeters (0.078 of an inch) thereof as measured along the maximum circumference of the valve seat.

RESULTS OF THE 2019 NCIMS

PROPOSAL 117

PMO, Page 97

5. RECORDING THERMOMETER CHARTS

All recording thermometer charts shall comply with all the applicable requirements of Item 16p.(D)1. of this *Ordinance*.

- **ITEM 16p.(B) ~~HIGH-TEMPERATURE-SHORT-TIME (HTST)~~ CONTINUOUS-FLOW PASTEURIZATION**

PUBLIC HEALTH REASON

RESULTS OF THE 2019 NCIMS

PROPOSAL 117

PMO, Page 97

2. **AUTOMATIC MILK CONTROLLER**

Automatic Milk and/or Milk Product-Flow Controls: ~~The term "automatic milk or milk product-flow controls" shall mean those safety devices which control the flow of milk or milk product in relation to the temperature of the milk or milk product or heating medium and/or pressure, vacuum or other auxiliary equipment. Milk or milk product-flow controls shall not be considered as part of the temperature control equipment. Milk or milk product flow controls shall be of the flow-diversion type, which automatically cause the diversion of the milk or milk product in response to a sub-legal pasteurization temperature. At sub-legal temperatures, FDDs return the milk or milk product to the raw milk or milk product side of the heating system continuously until legal pasteurization temperatures are obtained, at which time, the device restores forward-flow through the pasteurizer.~~

RESULTS OF THE 2019 NCIMS

PROPOSAL 117

Continue PMO, Page 97

2. **AUTOMATIC MILK CONTROLLER**

…..

- Milk and / or milk product controls must have a Flow Diversion Device (FDD) which automatically causes the diversion of the milk and / or milk product in response to a sub legal pasteurization condition.
- The controls shall include logic to meet the applicable requirements of Item 16p.(B), Item 16p.(C) and Appendix H. of this *Ordinance* and perform the applicable tests listed in Item 16p.(D)2. and Appendix I. of this *Ordinance*.

- The controls vendor shall provide to the Regulatory Agency documentation including a user manual with testing procedures and instructions necessary to supplement those in this *Ordinance*.

RESULTS OF THE 2019 NCIMS

PROPOSAL 117

PMO, Page 98

(6) The FDD shall be located downstream from the ~~holder~~ holding tube. The flow-control sensor shall be located in the milk and / or milk product line not more than 46 centimeters (18 inches) upstream from the inlet of the FDD.

(7) The FDD may be located downstream from the regenerator and/or cooler section, provided, that ~~when the FDD is located downstream from the regenerator and/or cooler section, the FDD shall be automatically prevented from assuming the forward-flow position until all product-contact surfaces between the holding tube and FDD have been held at or above the required pasteurization temperature continuously and simultaneously for at least the required pasteurization time as defined in the definition of Pasteurization of this *Ordinance*.~~ the system complies with the criteria for downstream FDDs in Appendix H of this *Ordinance*.

RESULTS OF THE 2019 NCIMS

PROPOSAL 117

PMO, Page 99

(11) If the area between the divert and leak-detect valve seats is not self-draining when the FDD is in the diverted position,… or if the holding time in diverted-flow through an unrestricted divert valve line is longer than the required pasteurization time as specified in the definition of Pasteurization of this *Ordinance*.; ~~and except that, no time delay is required in pasteurization systems in which the FDD is located downstream from the pasteurized regenerator and in which all forward-flow product-contact surfaces of the FDD are sanitized, or sterilized during the normal start-up process.~~

RESULTS OF THE 2019 NCIMS

PROPOSAL 117

PMO, Page 99

(12) In the case of HHST pasteurizing systems utilizing temperatures and holding times to meet the definition of ultra-pasteurization (UP) of this *Ordinance*, the FDD may be located downstream of the regenerator and/or cooler section. Said FDD may alternatively be a system of the "Steam-Block Type" as described in Appendix H. of this *Ordinance*. ~~This FDD system shall allow for the flow of water and/or milk or milk product to the constant-level tank through appropriate valves and coolers during sterilization and when diverted.~~

RESULTS OF THE 2019 NCIMS

PROPOSAL 117

PMO, Page 99

(13)When switching to the "CIP" position, the FDD shall move to the divert position and shall remain in the diverted-flow position for at least ten (10) minutes, regardless of temperature, and for HTST pasteurization systems the booster pump cannot run during this ten (10) minute time delay.

RESULTS OF THE 2019 NCIMS

PROPOSAL 117

PMO, Page 99

C. Milk and / or Milk Product-Flow Controller Instrumentation: The following requirements shall be met with respect to the instrumentation of the milk and / or milk product-flow controller:

(1) The thermal-limit-controller, with sensor located at the outlet of the holding tube, shall be set and sealed so that forward-flow of milk and / or milk product cannot start unless the temperature at the controller sensor is above the required pasteurization temperature as defined in the definition of Pasteurization of this *Ordinance* for the milk and / or milk product~~,~~ and the process used, nor continue ~~during descending temperatures~~ when the temperature is below the required pasteurization temperature. ~~The~~ A seal shall be applied by the Regulatory Agency after testing, and shall not be removed without immediately notifying the Regulatory Agency. The pasteurization system shall be so designed that no milk and/or milk product can ~~be bypassed around~~ bypass the controller sensor. The controller sensor ~~that~~ shall not be removed from its proper position during the pasteurization process. The cut-in and cut-out milk and / or milk product temperatures, as shown by the indicating thermometer, shall be determined at the beginning of each day's operation and entered ~~upon~~ on the recorder chart daily by the milk plant operator.

RESULTS OF THE 2019 NCIMS

PROPOSAL 117

PMO, Page 99

(2) ~~In the case of pasteurization systems, with the FDD located downstream from the regenerator and/or cooler section, additional temperature controllers and timers shall be inter-wired with the thermal-limit-controller, and the control system shall be set and sealed so that forward-flow of milk or milk product cannot start until all product-contact surfaces between the holding tube and FDD have been held at or above the required pasteurization temperature, continuously and simultaneously for at least the required pasteurization time as defined in the definition of Pasteurization of this *Ordinance*. The control system shall also be set and sealed so that forward-flow cannot continue when the temperature of the milk or milk product in the holding tube is below the required pasteurization temperature.~~

- ~~Provided, that for~~ For pasteurization systems used for the processing of milk and / or milk products labeled as UP, it is not necessary to set and seal the thermal-limit controller at or above 138ºC (280ºF). Also, provided that these systems shall meet all the public health control requirements for HHST pasteurization systems, and that the recorder-controller chart shows that the UP milk and / or milk product has been processed at a minimum temperature of 138ºC (280ºF), and has been verified by the Regulatory Agency to have a calculated holding time of at least two (2) seconds. ~~The~~ A seal, if required,

RESULTS OF THE 2019 NCIMS

PROPOSAL 117

PMO, Page 100

d. Holding Tube:

(1) Holding tubes shall be designed to provide for the holding of every particle of the milk and / or milk product for at least the pasteurization time required in the definition of Pasteurization of this *Ordinance* for the milk and / or milk product and the process used.

(2) The holding tube…, at any time during the holding period, will not be greater than 0.5ºC (1ºF). This requirement may be assumed to have been satisfied, without testing, in ~~tubular holders~~ holding tubes of 17.8 centimeters (7 inches) or smaller diameter that are free of any fittings through which the milk and / or milk product may not be thoroughly swept.

RESULTS OF THE 2019 NCIMS

PROPOSAL 117

PMO, Page 100

(7) The holding time for HHST pasteurization systems shall be determined from the pumping rate rather than by the salt conductivity test, because of the short holding tube. The holding tube length shall be such that the fastest flowing particle~~,~~ –of any milk and / or milk product~~,~~ will not traverse the holding tube in less than the required holding time. Since laminar flow~~,~~ (the fastest flowing particle travels twice as fast as the average flowing particle)~~,~~ can occur in the holding tube during pasteurization of high-viscosity milk and / or milk products, holding tube lengths ~~are~~ shall be calculated as twice the length required to hold the average flow for the required holding time ~~standard~~.

RESULTS OF THE 2019 NCIMS

PROPOSAL 117

PMO, Page 101

f. Flow-Promoting Devices:

(1) The pump or pumps and other equipment, which may produce flow through the holding tube, shall be located upstream from the holding tube, provided that pumps and other flow-promoting devices, may be located downstream from the holding tube, if means are provided to eliminate negative pressure between the holding tube and the inlet to such equipment. When vacuum equipment is located downstream from the holding tube, an effective vacuum breaker, plus an automatic means of preventing a negative pressure in the line between ~~the~~ a FDD located at the end of the holding tube and the vacuum chamber, shall be acceptable.

RESULTS OF THE 2019 NCIMS

PROPOSAL 117

PMO, Page 102

The ~~timing pump~~ holding time shall be ~~of the~~ controlled by a positive-displacement type timing pump or ~~shall comply with the specifications for~~ a magnetic flow meter based timing ~~systems~~ system as outlined in Appendix H. of this *Ordinance*.

RESULTS OF THE 2019 NCIMS

PROPOSAL 117

PMO, Page 103

- (5) The holding time shall be tested ~~in both forward and diverted flow~~ by the Regulatory Agency initially; semiannually thereafter; after any alteration or replacement that may affect the holding time; and whenever the seal of the speed setting has been broken. For pasteurization systems utilizing a timing pump, the holding time shall be tested in both forward and diverted flow.

RESULTS OF THE 2019 NCIMS

PROPOSAL 117

PMO, Page 104

•ITEM 16p.(C) PASTEURIZERS EMPLOYING REGENERATIVE HEATING PUBLIC HEALTH REASON

- To prevent contamination of the pasteurized milk and / or milk product in regenerators, the raw milk and / or milk product shall always be under less pressure than the pasteurized milk and / or milk product or the heat-transfer medium. ~~In the case of milk or milk product-to-milk or milk product regenerators, this~~ This requirement is necessary to prevent contamination of the pasteurized milk and / or milk product by the raw milk and / or milk product ~~if~~ should flaws ~~should~~ develop in the metal or in the gasketed joints separating the raw and pasteurized milk and / or milk product.

RESULTS OF THE 2019 NCIMS

PROPOSAL 117

PMO, Page 105

- 8. ~~All~~ When the raw milk and / or milk product pump(s) are shut down, all raw milk and / or milk product in the raw regenerator(s) shall automatically drain freely into the constant-level tank or to the floor. ~~when the raw milk or milk product pump(s) are shut down and the raw milk or milk product connection(s) at the regenerator(s) is disconnected.~~

RESULTS OF THE 2019 NCIMS

PROPOSAL 117

PMO, Page 106

OPTION II: Pasteurizers with the FDD located downstream of the regenerator and / or cooling section and with milk and / or milk product-to-water-to-milk and / or milk product regenerators ~~may also be~~ constructed, installed and operated such that the pasteurized milk and / or milk product in the regenerator will be under greater pressure than the heat-transfer-medium in the pasteurized milk and / or milk product ~~side~~ section of the regenerator, shall comply with the following or equally satisfactory specifications:

RESULTS OF THE 2019 NCIMS

PROPOSAL 117

PMO, Page 107

2. The heat-transfer-medium pump shall be wired so that it cannot operate unless the timing pump and / or other flow promoting devices ~~is~~ are in operation.

RESULTS OF THE 2019 NCIMS

PROPOSAL 117

PMO, Page 107

1. **PASTEURIZATION RECORDS:**

All temperature and flow rate pasteurization recording charts or alternative records, acceptable to FDA and the Regulatory Agency, in place of charts, shall be:

a. Reviewed, dated and signed or initialed by or under the oversight of a PCQI within seven (7) working days after the records were created;

b. Onsite ~~and shall be reviewed~~ for review by the Regulatory Agency during each regulatory inspection for at least the previous three (3) months …

The use of such charts shall not exceed the time limit for which they are designed. Overlapping of recorded data shall be a violation of this Item. The following information shall also be entered on the charts or ~~other~~ alternative records acceptable to FDA and the Regulatory Agency in place of charts as applicable:

RESULTS OF THE 2019 NCIMS

PROPOSAL 117

PMO, Page 108

b. HTST and HHST Pasteurizers: Recording thermometer charts shall contain all the information specified in Subitem a. above, except (4), and (5), and in addition, shall include the following:

(2) The cut-in and cut-out milk and / or milk product temperatures, as shown by the indicating thermometer and recorded daily by the operator, at the beginning of the run (HTST only), and initialed quarterly by the Regulatory Agency, or in the case of milk plants regulated under the NCIMS voluntary HACCP Program, a qualified industry person acceptable to the Regulatory Agency; and

(3) ~~Number~~ through (6) from above shall also be recorded immediately after a chart has been changed.

RESULTS OF THE 2019 NCIMS

PROPOSAL 117

PMO, Page 227 – 235

APPENDIX H. CONTINUOUS FLOW PASTEURIZATION SYSTEMS (EQUIPMENT AND PROCEDURES) AND OTHER EQUIPMENT

- **~~I. HTST~~ CONTINUOUS FLOW PASTEURIZATION**
  - **OPERATION OF HTST PASTEURIZATION SYSTEMS**

RESULTS OF THE 2019 NCIMS

PROPOSAL 117

PMO, Page 227

NOTE: Some operators prefer to bypass the raw ~~regenerator~~ regenerator(s) when starting. Under this system, cold raw milk and / or milk product is drawn directly through the timing pump, step 3, and into the heater section. The remaining steps are performed without exception. This bypass arrangement facilitates and speeds up the starting operation. After forward-flow has been established at the FDD, the bypass, which may be manually or automatically controlled, is not used and the raw milk and / or milk product flows through the regenerator.

RESULTS OF THE 2019 NCIMS

PROPOSAL 117

PMO, Page 227:

4. The raw milk and / or milk product is pumped through the heater section, where hot water or steam on opposite sides of thin stainless steel surfaces heats the milk and / or milk product to a temperature at or above ~~72°C (161°F).~~ the minimum pasteurization temperature required for that product.

RESULTS OF THE 2019 NCIMS

PROPOSAL 117

PMO, Page 229

- For some systems, it will be necessary to bypass the raw regenerator during start-up and when the FDD is in the diverted-flow position. Care shall be taken in the design of such bypass systems to assure that a dead-end does not exist. A dead-end could allow milk and / or milk product to remain at ambient temperature for long periods of time and allow bacterial growth in the milk and / or milk product. Caution shall also be observed with such bypass systems and any valves used in them so that raw milk and / or milk product will not be trapped, under pressure in the raw regenerator plates, and not have free drainage back to the constant-level tank when shutdown occurs.

RESULTS OF THE 2019 NCIMS

PROPOSAL 117

PMO, Page 230

- **THE USE OF LIQUID INGREDIENT INJECTION WITHIN HTST SYSTEMS**

•

• Milk and / or milk product flavoring slurries, condensed milk and / or milk products, and cream or skim for standardization and similar ingredients may be injected at a point after the last regenerator and before the timing pump, if all of the following conditions are met:

•

1. The slurry injection valve(s) is (are) closed and the slurry pump is de-energized:
   a. When the FDD is in the "Inspect" mode;
   b. When the timing pump, if present, is not in operation; ~~and~~
   c. When the temperature is below the required minimum legal pasteurization temperature and the FDD is not in the fully diverted position~~.~~; and
   d. For MFMBTS, when the flow requirements are not satisfied (high flow, low flow or loss of signal) and the FDD is not in the fully diverted position.

RESULTS OF THE 2019 NCIMS

PROPOSAL 117

PMO, Page 231

NOTE: The slurry pump may remain energized provided:

1. A spring-to-close and air-to-open blocking valve is located between the slurry injection pump and the slurry injection valve(s) described in 2 below.

3. The slurry injection valve(s) is (are) of the fail-safe type, spring-to-close and air-to-open, and are "block-and-bleed" design with a full port open to the atmosphere or a single-bodied double seat mixproof valve design between the HTST isolation seat and the slurry pump when slurry is not being injected.

RESULTS OF THE 2019 NCIMS

PROPOSAL 117

PMO, Page 233

6. For HTST pasteurization systems, when the legal flow rate has been reestablished, following an excessive flow rate, a time delay shall be instituted, which shall prevent the FDD from assuming the forward-flow position for at least a minimum of fifteen (15) or twenty-five (25) seconds depending upon the product being pasteurized and the temperature being utilized. The time delay shall be tested and sealed by the Regulatory Agency. For HHST pasteurization systems, when the legal ~~holding time~~ flow rate has been reestablished, following an excessive flow rate, a time delay at least as long as the legal ~~flow rate~~ holding time shall be instituted, which shall prevent the FDD from assuming the forward-flow position until at least the legal holding time within the holding tube has been reestablished. In the case of HHST systems with the FDD located after the final cooler, this time delay shall be built into the sequence logic that requires all conditions for legal pasteurization to be satisfied and that legal pasteurization temperature exists from the holding tube to the FDD, before the FDD can assume the forward-flow position.

RESULTS OF THE 2019 NCIMS

PROPOSAL 117

PMO, Page 235

THE USE OF FDD LOCATED DOWNSTREAM OF REGENERATORS AND COOLER SECTIONS

•

The FDD may be located downstream from the regenerator and/or cooler section, provided that the following criteria are met:

1. The FDD shall be automatically prevented from assuming the forward-flow position until all product-contact surfaces between the holding tube and FDD have been held at or above the required pasteurization temperature continuously and simultaneously for at least the required pasteurization time as defined in the definition of Pasteurization of this Ordinance.

RESULTS OF THE 2019 NCIMS

PROPOSAL 117

PMO, Page 235 (continued)

2. Additional temperature controllers and timers shall be inter-wired with the thermal-limit-controller, and the control system shall be set and sealed so that forward-flow of milk and / or milk product cannot start until all product-contact surfaces between the holding tube and FDD have been held at or above the required pasteurization temperature, continuously and simultaneously for at least the required pasteurization time as defined in the definition of Pasteurization of this Ordinance . The control system shall also be set and sealed so that forward-flow cannot continue when the temperature of the milk or milk product in the holding tube is below the required pasteurization temperature. For these pasteurization systems, daily measurement by the operator of the cut-in and cut-out temperatures is not required.

RESULTS OF THE 2019 NCIMS

PROPOSAL 117

PMO, Page 235 (continued)

In addition, for continuous flow pasteurization systems which have the FDD located downstream from the regenerator and/or cooler, the following apply:

1. When the pasteurization system is inter-wired or computer controlled to thoroughly clean the system, including the divert pipeline before the re-starting of production, a cooling section, which is not self-draining, may be present in the divert pipeline.

2. In pasteurization systems in which all forward-flow product-contact surfaces of the FDD are sanitized, or sterilized during the normal start-up process the time delay in 16p(B)2.b.11 is not required.

RESULTS OF THE 2019 NCIMS

PROPOSAL 117

PMO, Page 235 (continued)

3. The requirements of paragraphs (2), (3), (5), (7) and (8) of Section 16p(C) MILK AND / OR MILK PRODUCT-TO-MILK AND / OR MILK PRODUCT REGENERATIVE HEATING may be eliminated. Provided, that a differential pressure controller is used to monitor the highest pressure in the raw milk and / or milk product side of the regenerator and the lowest pressure in the pasteurized side of the regenerator, and the controller is interlocked with the FDD and is set and sealed so that whenever improper pressures occur in the regenerator, forward-flow of milk and / or milk product is automatically prevented and shall not start again until all milk and / or milk product-contact surfaces between the holding tube and FDD have been held at or above the required pasteurization temperature, continuously and simultaneously for at least the required pasteurization time as defined in the definition of Pasteurization of this Ordinance.

RESULTS OF THE 2019 NCIMS

PROPOSAL 117

PMO, Page 235 (continued)

4. When the differential pressure controller is installed and wired to control the FDD as described in paragraph 3. of this Section, the raw milk and / or milk product booster pump may be permitted to run at all times. Provided, that the timing pump, if present, is in operation.

RESULTS OF THE 2019 NCIMS

PROPOSAL 117

PMO, Page 278

VII. CRITERIA FOR STEAM-BLOCK TYPE FDD SYSTEMS

2. The steam-block zones shall be temperature - monitored and shall alarm when the temperature ~~falls below 121°C (250°F)~~ indicates there is liquid present in the steam-block.

RESULTS OF THE 2019 NCIMS

PROPOSAL 118

A proposal submitted in 2017 requested the Chair assign a committee to examine compliance issues with AMIs and to identify solution to better align these systems with the applicable "R" items of the PMO.

RESULTS OF THE 2019 NCIMS

PROPOSAL 118

- The subcommittee determined that Appendix Q of the PMO contains, in some instances, **redundant language** when compared to Section 7
- The consensus of the subcommittee is that U.S. dairy farms utilizing AMI technology should **not be regulated any differently** than other dairy farms in the U.S.
- It was decided to work on **incorporating language from Appendix Q into Section 7** and then remove Appendix Q.
- Appendix Q **computer control language** that was identified as necessary was revised and that language was placed in a **new Section within Appendix H**.

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APPENDIX Q. ~~OPERATION OF AUTOMATIC MILKING INSTALLATIONS FOR THE PRODUCTION OF GRADE "A" RAW MILK FOR PASTEURIZATION, ULTRA- PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING~~

[RESERVED]..... 385

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PMO, Page 36

ITEM 1r. ABNORMAL MILK

Lactating animals which show evidence of the secretion of milk with abnormalities in one (1) or more quarters, based upon bacteriological, chemical or physical examination, shall be milked last or with separate equipment and the milk shall be discarded. AMIs shall ~~have the capability to~~ identify and discard milk from animals that are producing milk with abnormalities. Lactating animals producing contaminated milk, that is, lactating animals which have been treated with, have consumed chemical, medicinal or radioactive agents, which are capable of being secreted in the milk and which, in the judgment of the Regulatory Agency, may be deleterious to human health, shall be milked last or with separate equipment and the milk disposed of as the Regulatory Agency may direct. ~~(For applicability to Automatic Milking Installations (AMIs), refer to Appendix Q. of this *Ordinance*.)~~

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PROPOSAL 118

PMO, Page 36

ITEM 1r. ABNORMAL MILK ADMINISTRATIVE PROCEDURES

5. AMIs shall have the capability to identify and discard milk from animals that are producing milk with abnormalities. Monitoring and controlling functions related to the identification and discarding of milk with abnormalities, shall comply with the criteria set forth in Appendix H of this *Ordinance*.

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PROPOSAL 118

PMO, Page 36

ITEM 1r. ABNORMAL MILK ADMINISTRATIVE PROCEDURES

8. Milk without abnormalities may be diverted for other uses and the parts of the milking system that came into contact with this milk are not required to be cleaned and sanitized prior to use for milk to be offered for sale.

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PROPOSAL 118

PMO, Page 37

ITEM 2r. MILKING BARN, STABLE OR PARLOR – CONSTRUCTION

A milking barn, stable or parlor shall be provided on all dairy farms in which the milking herd shall be housed during milking time operations. ~~(For applicability to AMIs, refer to Appendix Q. of this *Ordinance*.)~~ The areas used for milking purposes shall:

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PMO, Page 37

5. Provide sufficient air space and air circulation to prevent condensation and excessive odors. In the case of AMI milking unit rooms, all ventilation air shall come from outside the cattle housing area.

ADMINISTRATIVE PROCEDURES

9. Air circulation is sufficient to minimize odors and to prevent condensation upon walls and ceilings. For AMI milking unit rooms, the ventilation air shall come from outside the cattle housing area.

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PROPOSAL 118

PMO, Page 38

ITEM 3r. MILKING BARN, STABLE OR PARLOR – CLEANLINESS

Feed shall be stored in a manner that will not increase the dust content of the air or interfere with the cleaning of the floor. ~~(For applicability to AMIs, refer to Appendix Q. of this *Ordinance*.)~~ Surcingles, or belly straps, milk stools and antikickers shall be kept clean and stored above the floor.

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PROPOSAL 118

PMO, Page 38

ITEM 3r. MILKING BARN, STABLE OR PARLOR – CLEANLINESS

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

4. Outside surfaces of ~~pipeline systems~~ all milking and clean-in-place (CIP) equipment located in the milking barn, stable or parlor are reasonably clean.

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PROPOSAL 118

PMO, Page 51

ITEM 12r. UTENSILS AND EQUIPMENT – STORAGE

All containers, utensils and equipment used in the handling, storage or transportation of milk, unless stored in sanitizing solutions, shall be stored to assure complete drainage and shall be protected from contamination prior to use. Provided, that pipeline milking equipment such as milker claws, inflations, weigh jars, meters, milk hoses, milk receivers, tubular coolers, plate coolers, ~~and~~ milk pumps and AMI milking equipment which are designed for CIP cleaning and other equipment~~, as accepted by FDA,~~ which meets these criteria, may be stored in the milking barn or parlor, provided this equipment is designed, installed and operated to protect the product and solution-contact surfaces from contamination at all times.

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PMO, Page 52

12r. ADMINISTRATIVE PROCEDURES

1. All milk containers, utensils and equipment, including milking machine vacuum hoses, are stored in the milkhouse in a sanitizing solution, or on racks, until used. Pipeline milking equipment such as milker claws, inflations, weight jars, milk hoses, milk receivers, tubular coolers, plate coolers ~~and~~ milk pumps and AMI milking equipment which are designed for CIP cleaning and other equipment~~, as accepted by FDA,~~ which meets these criteria, may be CIP cleaned, sanitized and stored in the milking barn or parlor, provided this equipment is designed, installed and operated to protect the product and solution contact surfaces from contamination at all times. ~~Some of the parameters~~ Parameters to be considered in determining protection are:

c. Adequate and properly located lighting and ventilation.

i. Provided, AMI milking unit rooms shall have positive air ventilation systems in operation whenever the milking system is being cleaned and/or sanitized.

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PROPOSAL 118

PMO, Page 53

ITEM 13r. MILKING – FLANKS, UDDERS AND TEATS

ADMINISTRATIVE PROCEDURES

NOTE: Additional alternative udder preparation methods, including those used on AMIs, may also be used once they have been evaluated by FDA and found acceptable. A copy of the FDA acceptance will be available for distribution to regulatory agencies, FDA and other interested parties. Verification of an AMI's control functions responsible for proper teat preparation shall comply with the criteria set forth in Appendix H of this *Ordinance*.

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PROPOSAL 118

PMO, Page 54

ITEM 14r. PROTECTION FROM CONTAMINATION

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. Equipment and operations are so located within the milking barn and milkhouse as to prevent overcrowding and contamination of cleaned and sanitized containers, utensils and equipment by splash, condensation or manual contact.
2. During the teat preparation process of an AMI, the teat cups (inflations) shall be adequately shielded to prevent contamination.
3. During milking and milkhouse operations, pipelines and equipment, used to contain or conduct milk, shall be effectively separated from tanks/silos and/or circuits containing cleaning and/or sanitizing solutions. In addition, AMIs shall provide separation between milk with abnormalities and milk intended for sale. This can be accomplished by:

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PROPOSAL 118

PMO, Page 54

ITEM 14r. PROTECTION FROM CONTAMINATION

ADMINISTRATIVE PROCEDURES

3. The valve vent, including piping between blocking valves, is not cleaned until milk has been removed or isolated, except in the case of a properly designed and operated system. This drainable opening to the atmosphere may be cleaned while milk is isolated by one (1) of the blocking valves. A properly designed and operated system shall incorporate the following:

i) During CIP, ~~a valve actuation of~~ the valve blocking the cleaning/sanitizing solution ~~blocking valve~~ may be ~~used~~ pulsed open for cleaning the valve vent, including piping between blocking valves, provided the blocking valves are fail-safe and the vent is self-draining and free from restrictions. Other means of preventing ~~there shall not be~~ pressurization of cleaning solutions on ~~the exterior of~~ the valve isolating milk may be individually evaluated and found to be acceptable by FDA and the Regulatory Agency. ~~that can equal or exceed the pressure of the milk being isolated, and~~

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PROPOSAL 118

PMO, Page 55

ITEM 14r. PROTECTION FROM CONTAMINATION

ADMINISTRATIVE PROCEDURES

6. Controls for the fail-safe system are tested and secured as directed by the Regulatory Agency. ~~in order to prevent unauthorized changes.~~ Testing verification procedures shall comply with the criteria set forth in Appendix H of this *Ordinance*.

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PROPOSAL 118

PMO, Page 59

ITEM 18r. RAW MILK COOLING

Raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging shall be cooled to 10ºC (50ºF) or less within four (4) hours ~~or less, of the commencement of the first milking, and to 7ºC (45ºF) or less, two (2) hours or after the completion of milking.~~ after starting the milking operation. The milk shall then be cooled within two (2) more hours to 7ºC (45ºF) or less. Provided, that the blend temperature after the first milking and subsequent milkings does not exceed 10ºC (50ºF).

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PROPOSAL 118

PMO, Page 59

ITEM 18r. RAW MILK COOLING

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. Raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging shall be cooled to 10ºC (50ºF) or less within four (4) hours ~~or less, of the commencement of the first milking, and to 7ºC (45ºF) or less, two (2) hours or after the completion of milking.~~ after starting the milking operation. The milk shall then be cooled within two (2) more hours to 7ºC (45ºF) or less. The start of the milking operation is the moment when milk is first transferred to an empty, clean and sanitized farm bulk milk tank, silo or direct load milk tank truck. Provided, that the blend temperature after the first milking and subsequent milkings does not exceed 10ºC (50ºF).

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PROPOSAL 118

PMO, Page 283

Add new section X. to Appendix H

X. CRITERIA FOR THE EVALUATION OF COMPUTERIZED SYSTEMS FOR AUTOMATIC MILKING INSTALLATIONS (AMIs) FOR GRADE "A" PUBLIC HEALTH CONTROLS

BACKGROUND

AMIs have computerized systems that are programmed for monitoring and/or controlling various sensors, instrumentation and the operational state of various devices such as pumps and valves. The following criteria are to be used for the evaluation of AMI computerized systems requirements within Items 1r, 13r and 14r of this *Ordinance*.

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PROPOSAL 118

PMO, Page 283

CRITERIA

1. A verification of all computerized system's control functions responsible for properly detecting and diverting abnormal milk; proper teat preparation; and the fail-safe valve system(s) providing separation between milk with abnormalities and milk intended for sale; and between cleaning/sanitizing solutions and milk intended for sale shall be conducted and documented at the commissioning of the computer system and at additional frequencies as deemed necessary by the Regulatory Agency.

2. This verification means the visual observation by Regulatory Agency personnel; or documentation indicating the testing that was completed by the AMI manufacturer; or other means accepted by the Regulatory Agency.

3. A manufacturer's written or electronic documentation addressing the computerized system's monitoring and controlling functions shall explain the devices controlled, the sensors or instruments monitored, and testing procedures. This document will be available to regulatory agencies, FDA and other interested parties upon request.

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PROPOSAL 118

PMO, Page 385-388

APPENDIX Q. ~~OPERATION OF AUTOMATIC MILKING INSTALLATIONS FOR THE PRODUCTION OF GRADE "A" RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING~~ [RESERVED]

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PROPOSAL 120

Clarifies that test 9.2.1 and 9.2.3. do not apply to spiral tubular regenerators such as those in Spyrotherm and Unitherm HHST pasteurization systems.

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PROPOSAL 120

PMO, Page 301

9.2 DIFFERENTIAL PRESSURE CONTROLLER

Application: Test 9.2.1 applies to all differential pressure controllers used to control the operation of booster pumps within HTST pasteurization systems or used to control the operation of FDDs ~~on~~ using plate type or double/triple tube type heat exchangers in ~~HHST and HTST~~ continuous-flow pasteurization systems with the FDD located downstream of the pasteurized regenerator section(s) and/or the final cooler section.
Test 9.2.2 applies only to HTST pasteurization systems with the FDD located immediately following the holding tube.
Test 9.2.3 applies to the testing of plate type and double tube/triple tube type heat exchangers in continuous-flow pasteurization systems in which the differential pressure controller is used to control the operation of the FDD.

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PROPOSAL 122

PMO, Page 78

This proposal clarifies that to comply with the bacteria standard noted in Item 12p and Appendix J, a sample set shall not have **two (2) or more out of four (4) samples** exceeding the bacterial standard.

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PROPOSAL 122

PMO, Page 78

ITEM 12p. CLEANING AND SANITIZING OF CONTAINERS AND EQUIPMENT
ADMINISTRATIVE PROCEDURES …

Page 78:

6. a. The residual bacteria count of multi-use **containers** ~~and closures~~ shall be conducted… shall not exceed one (1) colony per milliliter (1/mL) of capacity, when the rinse test is used, or fifty (50) colonies per fifty (50) square centimeters (cm^2) (one (1) colony per square centimeter) of product-contact surface, when the swab test is used~~,~~. For the sample set containing four (4) multi-use containers, taken at random on a given day, to be in compliance with the bacterial standards of Appendix J. of this *Ordinance* as cited above the sample set shall not have two (2) or more ~~in three (3)~~ out of the four (4) samples making up the sample set exceeding the bacterial standard ~~taken at random on a given day~~. ~~Coliform organisms shall be undetectable in all multi-use containers~~. All multi-use containers making up the sample set shall be free of coliform organisms.

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PROPOSAL 122

PMO, Page 78

ITEM 12p. CLEANING AND SANITIZING OF CONTAINERS AND EQUIPMENT ADMINISTRATIVE PROCEDURES …

b. The residual bacteria count of single-service containers **and closures**, used for packaging pasteurized milk and/or milk products, shall not exceed fifty (50) colonies per container, or in the case of dry product packaging, shall not exceed one (1) colony per milliliter (1/mL) of capacity when the rinse test is used, except that in containers less than 100 mL the count shall not exceed ten (10) colonies, or fifty (50) colonies per fifty (50) cm^2 (one (1) colony per square centimeter) of product-contact surface, when the swab test is used~~,~~. For the sample set containing four (4) single-service containers and/or closures, taken at random on a given day, to be in compliance with the bacterial standards of Appendix J. of this *Ordinance* as cited above the sample set shall not have two (2) or more ~~in three (3)~~ out of the four (4) samples making up the sample set exceeding the bacterial standard ~~taken at random on a given day~~. ~~Coliform organisms shall be undetectable in all single-service containers and/or closures.~~ All single-service containers and/or closures making up the sample set shall be free of coliform organisms.

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PROPOSAL 122

PMO, Page 337

2. Where a rinse test can be used, the residual microbial count shall not exceed fifty (50) per container, except that in containers less than 100 mL the count shall not exceed ten (10), or when using the swab test, not over fifty (50) colonies per fifty (50) cm^2 (one (1) per square centimeter) of product-contact surface. For the sample set containing four (4) single-service containers and/or closures, taken at random on a given day, to be in compliance with the bacterial standards of Appendix J. of this *Ordinance* as cited above shall not have two (2) or more ~~in three (3)~~ out of the four (4) samples making up the sample set exceeding the bacterial standard ~~taken at random on a given day~~. All single-service containers and closures making up the sample set shall be free of coliform organisms.

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COUNCIL II

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PROPOSAL 203

To modify the requirements of the information required on a shipping statement (BOL) for milk and milk products by **eliminating** the requirement for the need for the "Name of the supervising Regulatory Agency at the point of shipment."

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PROPOSAL 203

PMO, Pages 19 and 147

Section 4 Labeling

8. Date of shipment;
~~9.Name of supervising Regulatory Agency at the point of origin of shipment;~~
~~10~~.9. Whether the contents are raw, pasteurized, or in the case of cream, lowfat or skim milk, whether it has been heat-treated;…….

Renumber remaining bullets

2017 PMO, Appendix B, Section IV, 7. 147

h. Date of shipment;
~~i. Name of supervising Regulatory Agency at the point of origin of shipment;~~
~~j.~~i. Whether the contents are raw, pasteurized, or in the case of cream, lowfat or skim milk, whether it has been heat-treated;……

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PROPOSAL 205

The 2017 Procedures Manual requires **Sampling Surveillance Personnel** (SSOs and dSSOs) to be recertified once every three years. This proposal would allow for recertification period to **include the remaining days of the month** similar to what is allowed in the "Industry Plant Sampler" and "Dairy Plant Sampler" definitions found in the 2017 PMO.

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PROPOSAL 205

PMO, Pages 27

6. Recertification: A certified SSO shall continue to 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. The SSO shall be recertified once each three (3) years which includes the remaining days of the month in which the certification expires, by PHS/FDA personnel in an independent side-by-side comparison of sampling procedure observations using the items listed on the appropriate inspection or evaluation report form.

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PROPOSAL 205

PMO, Pages 29

- c. Recertification: A certified dSSO shall be recertified once each three (3) years which includes the remaining days of the month in which the certification expires, by a PHS/FDA certified SSO in an independent side-by-side comparison of sampling procedure observations using the items listed on the appropriate inspection or evaluation report form. The dSSO and SSO shall be in agreement at least eighty percent (80%) of the time on each listed item.

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PROPOSAL 206

To clarify primacy of the FDA/NCIMS 2400 forms over *SMEDP* and *OMA* in the PMO.

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PROPOSAL 206

PMO, Pages 28

Samples shall be analyzed at an appropriate official or officially designated laboratory. All sampling procedures, including the use of approved in-line samplers and approved aseptic samplers for milk tank trucks or for farm bulk milk tanks and/or silos, and required laboratory examinations shall be in substantial compliance with the **FDA/NCIMS 2400 Forms. The** most current edition of *Standard Methods for the Examination of Dairy Products* (*SMEDP*) of the American Public Health Association, and the most current edition of *Official Methods of Analysis of Association of Official Analytical Chemists* (*AOAC) INTERNATIONAL* (*OMA*) **may also be referenced when the FDA/NCIMS 2400 Forms are unclear, however, the FDA/NCIMS 2400 Forms shall have primacy when conflicting information is present**. Such procedures, including the certification of sample collectors and examinations shall be evaluated in accordance with the *Procedures*.

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PROPOSAL 206

PMO, Pages 30

LABORATORY TECHNIQUES: Procedures for the collection, including the use of approved in-line samplers and approved aseptic samplers for milk tank trucks or for farm bulk milk tanks and/or silos, and the holding of samples; the selection and preparation of apparatus, media and reagents; and the analytical procedures, incubation, reading and reporting of results, shall be in substantial compliance with the FDA/NCIMS 2400 Forms~~, *SMEDP* and *OMA*~~. *SMEDP* and *OMA* may also be referenced when the FDA/NCIMS 2400 Forms are unclear, however, the FDA/NCIMS 2400 Forms shall have primacy when conflicting information is present. The procedures shall be those specified therein for

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PROPOSAL 206

PMO, Pages 35 *(footnote)*

*** Results of the analysis of milk and/or milk products which are weighed in order to be analyzed shall be reported in # per gm. (Refer to **FDA/NCIMS 2400 Forms, or if unclear,** the current edition of the *SMEDP.*)

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PROPOSAL 206

PMO, Pages 337

Procedures for obtaining samples and for the laboratory examination of these products are contained in the **FDA/NCIMS 2400 Forms, or, if unclear,** latest edition of *SMEDP* and shall be in substantial compliance with these methods. Such procedures and examinations shall be evaluated in accordance with the current revision of the *EML*. A list of approved laboratories may be found in the current *IMS List*, which is published by FDA and available on the Internet at:

RESULTS OF THE 2019 NCIMS

PROPOSAL 207

This proposal ensures that the milk tests listed under Section 6 of the PMO are kept current by referring to the latest version of M-a-98.

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PROPOSAL 207

Page 30:

LABORATORY TECHNIQUES: Procedures for the collection,… for:
1. Bacterial count at 32ºC ~~(Standard Plate Count (SPC), 3M™ Petrifilm™ Aerobic Count (PAC) or 3M™ Petrifilm™ Rapid Aerobic Count (RAC) methods).~~ (Refer to M-a-98, latest revision, for the list of approved tests for specific milk and/or milk products ~~for which these tests are approved~~.)
2. Alternate methods, for bacterial counts at 32°C ~~(Plate Loop Count (PLC), Spiral Plate Count (SPLC), Foss BactoScan FC (BSC), bioMerieux TEMPO® Aerobic Count (TAC), Charm® Peel Plate® Aerobic Count (PPAC) and Bentley BactoCount IBC (BCC) and Bentley BactoCount IBCm (BCMC) methods).~~ (Refer to M-a-98, latest revision, for the list of approved tests for specific milk and/or milk products ~~for which these tests are approved~~.)
3. Coliform count at 32ºC ~~(Coliform Plate Count (CPC), 3M™Petrifilm™ Coliform Count (PCC) and/or 3M™Petrifilm™High Sensitivity Coliform Count (HSCC), bioMerieux TEMPO CC-Coliform Count (TCC), Charm® Peel Plate Total Coliform Count (PPCC), Charm® Peel Plate® E. coli and Total Coliform (PPEC), Charm® Peel Plate® Total Coliform High Volume Sensitivity (PPCCHV) and/or Charm® Peel Plate E. coli and Total Coliform High Volume Sensitivity (PPECHV) methods).~~ (Refer to M-a-98, latest revision, for the list of approved tests for specific milk and/or milk products ~~for which these tests are approved~~.)
4. A viable bacterial count of nonfat dry milk shall be made in accordance with the procedures in *SMEDP* for the SPC, PPAC or PAC of DryMilk, except agar plates shall be incubated for 72 hours.

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PROPOSAL 208

This proposal eliminates the PCQI review requirement for "qualified facilities" as well as the 7-day time frame for the review to take place for the following:

- vitamin volume control records
- cleaning charts/records
- pasteurization charts
- temperature records/charts
- pH records charts for the cleaning of evaporators and dryers

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PROPOSAL 208

PMO, Page 30

SECTION 6. THE EXAMINATION OF MILK AND/OR MILK PRODUCTS

In addition, all milk plants fortifying milk and/or milk products with vitamins shall keep volume control records. …. .

- 2. Reviewed, dated and signed or initialed ~~by or under the oversight of a preventive controls qualified individual (PCQI) within seven (7) working days after the records were created;~~

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PROPOSAL 208

PMO, Page 74

ITEM 12p. CLEANING AND SANITIZING OF CONTAINERS AND EQUIPMENT

Otherwise, storage tanks shall be cleaned when emptied and shall be emptied at least every seventy-two (72) hours. Records shall be available to verify that milk storage in these tanks does not exceed seventy-two (72) hours. These records shall be:

- b. Reviewed, dated and signed or initialed ~~by or under the oversight of a PCQI within seven (7) working days after the records were created;~~

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PROPOSAL 208

PMO, Page 76

ITEM 12p. CLEANING AND SANITIZING OF CONTAINERS AND EQUIPMENT

c. Cleaning charts and electronically stored records required by this Section shall be:

(ii)Reviewed, dated and signed or initialed ~~by or under the oversight of a PCQI within seven (7) working days after the records were created;~~

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PROPOSAL 208

PMO, Page 107

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

1. PASTEURIZATION RECORDS:

All temperature and flow rate pasteurization recording charts or alternative records, acceptable to FDA in place of charts, shall be:

a. Reviewed, dated and signed or initialed ~~by or under the oversight of a PCQI within seven (7) working days after the records were created;~~

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PROPOSAL 208

PMO, Page 116

ITEM 17p. COOLING OF MILK AND/OR MILK PRODUCTS

7. Each refrigerated room in which milk and/or milk products are stored, is equipped with .... ~~If a temperature- measuring device or temperature-recording device is being utilized, the cooling records shall be:~~

- ~~a. Identified with the name and location of the milk plant or their milk plant code, dated and the signature or initials of the person performing the activity;~~
- ~~b. Reviewed, dated and signed or initialed by or under the **oversight of a PCQI within seven (7) working days after the records were created;**~~
- ~~c. Onsite and shall be reviewed by the Regulatory Agency during each regulatory inspection for at least the previous three (3) months or from the last regulatory inspection, whichever is longer. Electronic records are considered to be onsite if they are accessible from an onsite location; and~~
- ~~d. Retained for at least two (2) years after the date they were created. Offsite storage of these cooling records is permitted if such records can be retrieved and provided onsite within twenty-four (24) hours of a request for official review.~~

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PROPOSAL 208

PMO, Page 213

APPENDIX F. CLEANING AND SANITIZING

III. EVAPORATING, DRYING AND DRY PRODUCT EQUIPMENT CLEANING

CLEANING

1. **Cleaning of Evaporators and Condensers:** Some evaporators are designed so that the milk or milk product is exposed to large surface areas for a long period of time at temperatures conducive to the growth of microorganisms.

Pipelines and/or equipment designed for automated mechanical cleaning of evaporators should meet the following requirements:

(1) Identified with the name and location of the milk plant or their milk plant code, dated and the signature or initials of the person performing the activity;

(2) Reviewed, dated and signed or initialed ~~by a PCQI within seven (7) working days after the records were created;~~

RESULTS OF THE 2019 NCIMS

PROPOSAL 210

This proposal added the criteria to Appendix B for a truck-mounted samplers for obtaining representative, official milk samples as required by the PMO.

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PROPOSAL 210

PMO, page 143/144

- V. REQUIREMENTS FOR USING AN APPROVED **ON-TANKER** FARM BULK MILK TANK ASEPTIC SAMPLER FOR MULTIPLE AND/OR SINGLE FARM PICKUPS
- 1. A protocol specific to the use of an on-tanker farm bulk milk tank aseptic sampler which may be used for the acquisition of official milk samples from multiple and/or single farm pickups shall be approved by the Regulatory Agency in cooperation with the sampling equipment manufacturer and FDA. At a minimum, the protocol (SOP) shall include the following:

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PROPOSAL 210

PMO, page 143/144

a. A description of how the milk sample is to be collected, identified, handled and stored.

b. A description of the means used to maintain the sample at the required temperature (between 0.0 (32F) to 4.5 (40F) degrees Celsius, as per this Appendix) during the sample collection period.

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PROPOSAL 210

PMO, page 143/144

c. A description of the process used to obtain the temperature of milk being loaded from the farm bulk milk tank.

d. A description of how and when the sampler is to be cleaned and sanitized if not of a single use design.

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PROPOSAL 210

PMO, page 143/144

e. A description of the method and the means used to ensure the representative nature of and integrity of milk sample acquired from every farm bulk milk tank.

f. A description of the method and means that will be used to determine weight of the milk in the farm bulk milk tank.

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PROPOSAL 210

PMO, page 143/144

2. The on-tanker farm bulk milk tank sampler shall be installed in consultation with the Regulatory Agency, according to the manufacturer's recommendations and in a manner that is compatible with its' intended use.

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PROPOSAL 210

PMO, page 143/144

3. The State Regulatory Agency shall be provided a list of the licensed bulk milk hauler/samplers who have been trained to maintain, operate the aseptic sampler as well as to collect, identify, handle and store the milk sample.

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PROPOSAL 210

PMO, page 143/144

4. A copy of the approved on-tanker farm bulk milk tank aseptic sampler SOP shall be on file on the tanker.

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PROPOSAL 211

A proposal from the 2017 conference directed the NCIMS Hauling Procedures Committee to conduct a comprehensive review of Appendix B and FDA Form 2399a and report back to the 2019 Conference.

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PROPOSAL 211

PMO, Appendix B, page 139

TRAINING:

Regularly scheduled refresher short courses by the regulatory agents and officials administering weights and measures ~~would~~ should be held annually to assist in maintaining and increasing the efficiency of the bulk milk hauler/sampler. Appropriate training should also be provided to industry plant samplers with regularly scheduled refresher short courses.

RESULTS OF THE 2019 NCIMS

PROPOSAL 211

PMO, Appendix B, page 140

EVALUATION OF BULK MILK HAULER/SAMPLER PROCEDURES:

2. **Equipment Requirements:** a. Sample rack and ~~compartment~~ sample storage case to hold all samples collected.
b. ~~Refrigerant~~ A means to hold temperature of milk samples (e.g. ice and water mixture) between 0ºC- 4.5ºC (32ºF- 40°F).
c. Sample dipper or other approved aseptic sampling devices of sanitary design and material approved by the Regulatory Agency; clean and in good repair.
d. Single use sample containers; properly stored.
e. Calibrated pocket thermometer; certified for accuracy every six (6) months; accuracy ±1°C (2°F).
f. Approved chemical sanitizing agent (Refer to Sanitation Definition YY, Item 11r and Appendix F.) and properly constructed sample dipper container in accordance with Item 9r.
g. An accurate device for timing milk agitation.
h. Applicable sanitizer test kit for the type of sanitizer being used for sanitizing the bulk tank outlet valve and sampling instrument.

RESULTS OF THE 2019 NCIMS

PROPOSAL 211

PMO, Appendix B, page 140

EVALUATION OF BULK MILK HAULER/SAMPLER PROCEDURES:

3. **Milk Quality Checks:**

c. Record milk temperature, collection time (optionally, in military time (24 hour clock)), date of pick-up and bulk milk hauler/sampler's name and license or permit number on the farm weight ticket; monthly the hauler/sampler shall check the accuracy of the thermometer on each bulk tank and record results when used as a test thermometer. Accuracy of required recording thermometers shall be checked monthly against a standardized thermometer and recorded. Pocket thermometer shall be sanitized ~~before use~~ for the appropriate time specified for type of sanitizer being used or a minimum of one minute before use.

RESULTS OF THE 2019 NCIMS

PROPOSAL 211

PMO, Appendix B, page 141

EVALUATION OF BULK MILK HAULER/SAMPLER

Universal Sampling System:

b. The milk shall be agitated a sufficient time to obtain a homogeneous blend. Follow the Regulatory Agency's and/or manufacturer's guidelines or when using an approved aseptic sampling device, follow the specified protocol and Standard Operating Procedure (SOP) (for information purposes only; refer to the FDA issued M-I) for that device.

RESULTS OF THE 2019 NCIMS

PROPOSAL 211

PMO, Appendix B, page 141

EVALUATION OF BULK MILK HAULER/SAMPLER PROCEDURES:

Universal Sampling System:

c. ~~d.~~ While the farm bulk milk tank and/or silo is being agitated, bring the sample container, dipper, dipper container and sanitizing agent for the outlet valve, or single-service sampling tubes into the milkhouse aseptically. Remove the cap from the farm bulk milk tank and/ or silo outlet valve and examine the valve outlet for milk deposits or foreign matter and then rinse, sanitize and re-examine the valve for milk deposits. If ~~necessary~~ milk deposits or foreign matter are present, or the bulk tank cap is not present, then rinse and sanitize. Protect the hose cap from contamination when removing it from the transfer hose and during storage.

RESULTS OF THE 2019 NCIMS

PROPOSAL 211

PMO, Appendix B, page 141

EVALUATION OF BULK MILK HAULER/SAMPLER PROCEDURES:

Universal Sampling System:

e. After washing hands with soap and drying, ~~C~~ **c**ollect a representative sample or samples from the farm bulk milk tank and/or silo by using a sample dipper or other approved aseptic sampling device. (For information purposes only: Refer ~~to Section IV. Requirements for Using an Approved Aseptic Sampler for Farm Bulk Milk Tanks and Silos of Appendix B. of this *Ordinance* for the specific protocol for the use of approved aseptic sampling devices.)~~ to the M-I that is appropriate for the aseptic or inline sampler being used.)

RESULTS OF THE 2019 NCIMS

PROPOSAL 211

PMO, Appendix B, page 141

EVALUATION OF BULK MILK HAULER/SAMPLER PROCEDURES:

Universal Sampling System:

~~g.~~ f. The sample dipper shall be rinsed free of milk and placed in its carrying container~~.~~**, if provided.**

RESULTS OF THE 2019 NCIMS

PROPOSAL 211

PMO, Appendix B, page 141

EVALUATION OF BULK MILK HAULER/SAMPLER PROCEDURES:

Universal Sampling System:

h. The producer sample shall be identified with the producer's ~~number~~ identification, temperature date, and time at the point of collection.

RESULTS OF THE 2019 NCIMS

PROPOSAL 211

PMO, Appendix B, page 142

EVALUATION OF BULK MILK HAULER/SAMPLER PROCEDURES:

5. **Pump Out Procedures:**

a. Once the measurement and sampling procedures are completed, with the agitator still running, open the outlet valve and start the pump. Turn off the agitator when the level of milk ~~is below the level that will cause over-agitation~~ has reached the agitator blade (s).

RESULTS OF THE 2019 NCIMS

PROPOSAL 211

PMO, Appendix B, page 142

EVALUATION OF BULK MILK HAULER/SAMPLER PROCEDURES:

6. **Sampling Responsibilities:**

c. Racks/floaters shall be provided so that the samples are properly cooled ~~in an ice bath~~ and protected in the sample storage case.
d. Adequate insulation of the sample ~~container box~~ storage case or ice chest shall be provided to maintain the proper temperature of the samples throughout the year.

RESULTS OF THE 2019 NCIMS

PROPOSAL 211

PMO, Appendix B, page 142

II. REQUIREMENTS FOR USING AN APPROVED ASEPTIC IN-LINE SAMPLER- (For information purposes only Refer to M-I-06-6)

~~A protocol specific to each milk producer who direct loads milk tank trucks (through by-passing the use of farm bulk milk tanks or silos) while utilizing an approved in-line sampler shall be developed by the Regulatory Agency in cooperation with the sampling equipment manufacturer, the milk buyer, the milk producer and FDA. As a minimum, the protocol should include the following:~~ A protocol for utilizing an in-line sampler system shall be approved by the Regulatory Agency in co-operation with the sampling equipment manufacturer, the milk producer and FDA. A copy of the approved aseptic in-line sampling system's SOP shall be on file and posted for use at the location where the sampling system is utilized.
As a minimum, the protocol (SOP) shall include the following:

RESULTS OF THE 2019 NCIMS

PROPOSAL 211

PMO, Appendix B, page 143

III. REQUIREMENTS FOR USING AN APPROVED ASEPTIC SAMPLER FOR MILK TANK TRUCKS (For informational purposes only Refer to M-I-06-12, M-I-16-17)

A protocol (SOP) specific to each milk plant and milk tank truck(s) in which industry plant samplers utilize an approved aseptic sampler shall be developed by the Regulatory Agency in cooperation with the sampling equipment manufacturer, the milk plant and FDA. As a minimum, the protocol (SOP) ~~should~~ shall include the following:

RESULTS OF THE 2019 NCIMS

PROPOSAL 211

PMO, Appendix B, page 143

3. A listing of the industry plant samplers who have been trained to maintain, operate, clean and sanitize the aseptic sampler as well as to collect, identify, handle and store the milk sample.
A copy of the approved aseptic sampler's SOP shall be on file at the location where the aseptic sampler or sampling system is utilized.

RESULTS OF THE 2019 NCIMS

PROPOSAL 211

PMO, Appendix B, page 143

IV. REQUIREMENTS FOR USING AN APPROVED ASEPTIC SAMPLER FOR FARM BULK MILK TANKS AND/OR SILOS (For informational purposes only Refer to Refer to M-I-06, M-I-06-12 or M-I-12-4)

~~A protocol specific to each milk producer in which the milk producer, who transports milk only from his/her own dairy farm, or bulk milk hauler/samplers utilize an approved aseptic sampler sampling system shall be developed approved by the Regulatory Agency in cooperation with the sampling equipment manufacturer, the milk producer and FDA.~~

A protocol specific to obtaining a sample directly from a farm bulk milk tank / silo prior to loading the milk for transport utilizing an aseptic sampler shall be approved by the Regulatory Agency in cooperation with the sampling equipment manufacturer, the milk producer and FDA. As a minimum, the protocol ~~should~~ shall include the following:

RESULTS OF THE 2019 NCIMS

PROPOSAL 211

PMO, Appendix B, page 143

3. A listing of the milk producer, who transports milk only from his/her own dairy farm, and/or licensed bulk milk hauler/samplers who have been trained to maintain, operate, clean and sanitize the aseptic sampling device as well as collect, identify, handle and store the milk sample.

4. A copy of the approved aseptic sampler SOP shall be on file and posted for use at the location where the sampler is utilized.

RESULTS OF THE 2019 NCIMS

PROPOSAL 211

PMO, Appendix B, page 144

VI. REQUIREMENTS FOR SANITIZING SAMPLING COCKS AND IN-LINE SAMPLE POINTS

1. Sampling cocks: prepare a sanitizing solution containing 200 mg/L (200ppm) of available chlorine such as hypochlorite or another equivalent strength sanitizer. Submerge the sampling cock by fitting a bag of the sanitizer solution around it. While holding the tip of the bag of sanitizing solution tightly around the body of the sampling valve, flush the sanitizer in and out of the sampling cock for at least one minute. Then purge the sampling cock valve with at least 2 liters (about ½ gallon) of milk before collecting the regulatory sample.
2. In-line sample points: (refer to the M-I that is appropriate for the aseptic or in-line sampler being used).

RESULTS OF THE 2019 NCIMS

PROPOSAL 211

PMO, Appendix B, page 144

~~VI~~- VII. MILK TANK TRUCK PERMITTING AND INSPECTION

Milk tank trucks shall be evaluated every twenty-four (24)…

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

RESULTS OF THE 2019 NCIMS

PROPOSAL 211

PMO, Appendix B, page 145

d. The properly constructed sample transfer instrument container (refer to item 9r) is provided and adequate means for maintaining sanitizer solutions is on hand.

RESULTS OF THE 2019 NCIMS

PROPOSAL 211

PMO, Appendix B, page 146

NOTE: First use shall be defined as when milk is first transferred into the milk tank truck and the time is documented.

(3) It is allowable to pickup multiple loads continuously within a twenty-four (24) hour period, provided the milk tank truck is washed after each ~~day's used~~ twenty-four hour period. If a tanker has been exposed to an antibiotic or other contaminant, it shall be immediately cleaned and sanitized prior to its next use.

RESULTS OF THE 2019 NCIMS

PROPOSAL 211

PMO, Appendix B, page 148

9. **Previous Inspection Sheet or Affixed Label Available:** When a milk tank truck transports milk and milk products from one (1) regulatory jurisdiction to another it is not necessary to inspect each milk tank truck upon each arrival. Milk tank truck owners and operators shall carry proof of ~~annual~~ required inspection from a recognized Regulatory Agency.

RESULTS OF THE 2019 NCIMS

PROPOSAL 212

A proposal from the 2017 conference directed the NCIMS Hauling Procedures Committee to conduct a comprehensive review of Appendix B and FDA Form 2399a and report back to the 2019 Conference.

RESULTS OF THE 2019 NCIMS

PROPOSAL 212

FDA Form 2399a (Hauler/Sampler Evaluation)

Proposal 212 of the 2019 NCIMS Conference direct the NCIMS Hauling Procedures Committee to conduct a comprehensive review of FDA Form 2399a and report back to the 2021 Conference.

RESULTS OF THE 2019 NCIMS

PROPOSAL 215

This proposal added clarity to the Appendix N for Farm Trace back and Reinstatement of Producers for to be positive and shipments discontinued for the period until found to be no longer positive for drug residues.

RESULTS OF THE 2019 NCIMS

PROPOSAL 215

PMO Pg. 359-364

APPENDIX N. DRUG RESIDUE TESTING AND FARM SURVEILLANCE

I. INDUSTRY RESPONSIBILITIES

MONITORING AND SURVEILLANCE:

~~Bulk milk pickup tanker samples confirmed positive for drug residues using approved test methods and/or verified screening positive using test methods not evaluated by FDA and accepted by the NCIMS without additional confirmation required shall be retained as determined necessary by the Regulatory Agency.~~

RESULTS OF THE 2019 NCIMS

PROPOSAL 215

PMO Pg. 359-364

APPENDIX N. DRUG RESIDUE TESTING AND FARM SURVEILLANCE

I. INDUSTRY RESPONSIBILITIES

MONITORING AND SURVEILLANCE:

Bulk milk pickup tanker samples shall be confirmed positive for drug residues using approved test methods, as cited in M-a-85, latest version, unless there are two (2) approved test methods for detecting a particular drug or drug family. In this case, verified screening positive results using test methods not evaluated by FDA and accepted by the NCIMS** without additional confirmation required are acceptable. These samples shall be retained as determined necessary by the Regulatory Agency.

RESULTS OF THE 2019 NCIMS

PROPOSAL 215

PMO Pg. 359-364

APPENDIX N. DRUG RESIDUE TESTING AND FARM SURVEILLANCE

REPORTING AND FARM TRACE BACK:

Upon official notification to the Regulatory Agency and milk producer of a violative individual producer's milk, further farm pickups by bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers and/or farm use of the violative individual producer's milk shall be immediately discontinued, until such time, that subsequent tests, using the same or equivalent (M-I-96-10, latest revision) test method as used when the producer was initially found to be violative and are no longer positive for drug residues.

RESULTS OF THE 2019 NCIMS

PROPOSAL 215

PMO Pg. 359-364

APPENDIX N. DRUG RESIDUE TESTING AND FARM SURVEILLANCE

RECORD REQUIREMENTS:

**** One (1) year after two (2) test methods are found acceptable by FDA and the NCIMS for detecting a particular drug or drug family, other than Beta lactams, as cited in M-a-85, latest revision, Option one (1) or two (2) in Section VI of this Appendix shall be used for confirmation.**

RESULTS OF THE 2019 NCIMS

PROPOSAL 215

PMO Pg. 359-364

APPENDIX N. DRUG RESIDUE TESTING AND FARM SURVEILLANCE

II. REGULATORY AGENCY RESPONSIBILITIES

5. Is the dairy farm pickup and/or use of the violative individual producer's milk suspended until subsequent testing, using the same or equivalent (M-I-96-10, latest revision) test method as used when the producer was initially found to be violative, establishes the milk is no longer positive for drug residues?

RESULTS OF THE 2019 NCIMS

PROPOSAL 215

PMO Pg. 359-364
APPENDIX N. DRUG RESIDUE TESTING AND FARM SURVEILLANCE

II. REGULATORY AGENCY RESPONSIBILITIES

(2) Establish that milk is not picked up or used from the drug residue positive producer until the Regulatory Agency has fulfilled their obligations under Section II. of this Appendix, as applicable, based on ~~the test method utilized~~ using the same or equivalent (M-I-96-10, latest revision) test method as used when the producer was initially found to be violative and has cleared the milk for pick up and/or use.
Sufficient records shall be reviewed to assure that all bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers are sampled before additional commingling at the milk receiving facility and the results were made available to the appropriate BTU(s).

RESULTS OF THE 2019 NCIMS

PROPOSAL 215

PMO Pg. 359-364

APPENDIX N. DRUG RESIDUE TESTING AND FARM SURVEILLANCE

ENFORCEMENT:

Permit Suspension and the Prevention of the Sale of Milk: Any time milk is found to test as a confirmed positive using an approved test method, the Regulatory Agency shall immediately suspend the producer's Grade "A" permit or equally effective measures shall be taken to prevent the sale of milk containing drug residues. Upon official notification to the Regulatory Agency and milk producer of a confirmed positive, future farm pickups by bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers and/or farm use of the violative individual producer's milk are prohibited until subsequent testing, using the same or equivalent (M-I-96-10, latest revision) test method as used when the producer was initially found to be violative, reveals the milk is free of drug residue….

RESULTS OF THE 2019 NCIMS

PROPOSAL 215

PMO Pg. 359-364
APPENDIX N. DRUG RESIDUE TESTING AND FARM SURVEILLANCE

Reinstatement: When the permit has been suspended as required, the Grade "A" producer's permit may be reinstated, or other action taken, to allow the sale of milk for human food, when a representative sample taken from the producer's milk, prior to commingling with any other milk, is no longer positive for drug residue, using the same or equivalent (M-I-96-10, latest revision) test method as used when the producer was initially found to be violative.

RESULTS OF THE 2019 NCIMS

PROPOSAL 215

PMO Pg. 359-364
APPENDIX N. DRUG RESIDUE TESTING AND FARM SURVEILLANCE

REGULATORY AGENCY RECORDS:

In regards to the industry reporting a confirmed positive using an approved test method or verified screening positive using test methods not evaluated by FDA and accepted by the NCIMS** tanker and/or a raw milk supply that has not been transported in bulk milk pickup tankers result, the Regulatory Agency's records shall indicate the following:

7. Record of negative test results, using the same or equivalent (M-I-96-10, latest revision) test method as used when the producer was initially found to be violative prior to subsequent milk pickup from the violative producer(s).

RESULTS OF THE 2019 NCIMS

PROPOSAL 215

PMO Pg. 359-364

APPENDIX N. DRUG RESIDUE TESTING AND FARM SURVEILLANCE

REGULATORY AGENCY RECORDS:

**** One (1) year after two (2) test methods are found acceptable by FDA and the NCIMS for detecting a particular drug or drug family, other than Beta lactams, as cited in M-a-85, latest revision, Option one (1) or two (2) in Section VI of this Appendix shall be used for confirmation.**

RESULTS OF THE 2019 NCIMS

PROPOSAL 215

2017 MMSR - *Page 7*

c. Reinstatement

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

RESULTS OF THE 2019 NCIMS

PROPOSAL 216

This proposal eliminates the Appendix N reference to M-I-06-5 for the disposal of adulterated milk and updates the referenced FDA Compliance Policy Guide to the current CPG.

RESULTS OF THE 2019 NCIMS

PROPOSAL 216

Appendix N, page 363

ENFORCEMENT:

If testing reveals milk positive for drug residues, the milk shall be disposed of in a manner that removes it from the human or animal food chain, except where acceptably reconditioned under FDA Compliance Policy Guide (CPG ~~7126.20~~ 675.200) "Diversion of Adulterated Food to Acceptable Animal Feed Use" current revision. The Regulatory Agency shall determine the producer(s) responsible for the violation.

RESULTS OF THE 2019 NCIMS

PROPOSAL 223

- Allow on-site laboratory surveys to be done up to 60 days early yet maintain the previous date for determining the new biennial or triennial expiration dates.
- Require LEO attendance at FDA Milk Seminars comparable to the requirements for SROs and SSOs.
- Remove and replace references to “Region” or “Regional” where specified in the 2017 EML.

RESULTS OF THE 2019 NCIMS

PROPOSAL 223

EML, page 6

SECTION 2: LABORATORY EVALUATION PROGRAMS

Reports of on-site surveys of Official Milk Laboratories and CIS facilities shall be sent within sixty (60) days of the initial, biennial/triennial anniversary or supplemental date of the laboratory ~~evaluation~~ survey to the Official Milk Laboratory/CIS facility, the appropriate FDA ~~Regional Office~~ milk specialist responsible for the state in which the laboratory/facility resides and the FDA/LPET. Reports to the Official Milk Laboratories/CIS facilities shall include the narrative report and may include copies of the completed FDA/NCIMS 2400 Forms. Reports to the appropriate FDA ~~Regional Office~~ milk specialist shall be sent electronically…

RESULTS OF THE 2019 NCIMS

PROPOSAL 223

EML, Pages 6&7

CERTIFICATION/APPROVAL OF MILK LABORATORY ANALYSTS

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

1.Evaluations of State Central Milk Laboratories shall be scheduled and performed by their triennial expiration date. The on-site survey may be conducted up to 60 days prior to the triennial expiration date. State central milk laboratories shall submit requests, ...

2. Evaluations of other milk laboratories within a state shall be scheduled and performed by their biennial expiration date. The on-site survey may be conducted up to 60 days prior to the biennial expiration date. Milk laboratories within a state shall submit requests, ...

RESULTS OF THE 2019 NCIMS

PROPOSAL 223

EML Page 8

Copies of notices of changes of certification or revocation of certification shall be sent to the laboratory or facility involved, the Regulatory Agency, the Rating Agency, the appropriate FDA ~~Regional Office~~ milk specialist responsible for the state in which the laboratory/facility resides and the FDA/LPET. For FDA/LPET notification, changes in certification shall be indicated on the completed FDA summary template and shall be submitted electronically.

RESULTS OF THE 2019 NCIMS

PROPOSAL 223

EML - Page 22:

7. The individual shall not fail, without cause, to attend an FDA ~~Regional~~ Milk Seminar once within their three (3) year certification period. ~~If a region holds an FDA Regional Milk Seminar, then LEOs in that region are obligated to attend. If another region holds their milk seminar in the same year, the LEO may opt to attend that regional milk seminar in lieu of attending the seminar held in their region and still meet the requirement.~~

RESULTS OF THE 2019 NCIMS

PROPOSAL 228

This Proposal that passed added Colitag, a Presence/Absence Chromogenic Substrate (ONPG-MUG), included as an approved test method for Coliforms in Potable Water. Colitag is an EPA-approved selective and differential medium to detect total coliforms and E. coli in water samples in 16-48 hours.

RESULTS OF THE 2019 NCIMS

PROPOSAL 228

As listed on M-a-98 Table 4. Modified Colitag should be included under the Presence/Absence methods of Coliform detection. In addition, Modified Colitag should be included in the 2400m Dairy Waters form.

RESULTS OF THE 2019 NCIMS

PROPOSAL 228/229

As listed on M-a-98 Table 4. Modified Colitag should be included under the Presence/Absence methods of Coliform detection. In addition, Modified Colitag should be included in the 2400m Dairy Waters form.

RESULTS OF THE 2019 NCIMS

COUNCIL III

RESULTS OF THE 2019 NCIMS

PROPOSAL 301

This proposal was submitted and accepted in order to reconcile Appendix K. HACCP program language with the Appendix T. Preventive Controls For Human Food Requirements for Grade “A” Milk and Milk Products language.

RESULTS OF THE 2019 NCIMS

PROPOSAL 301

Page 347:
PREREQUISITE AND OTHER PROGRAMS: …

In addition to PPs, other programs may be necessary to assure the HACCP system is operating as intended. ~~Prerequisite and other programs shall at a minimum provide compliance with 21 CFR 117 (Subpart A, B and F).~~

Page 347:
HAZARD ANALYSIS: …
The Hazard Analysis shall at a minimum provide compliance with ~~21 CFR 117 (Subpart C. (117.130 Hazard Analysis))~~ Appendix T. **Hazard Analysis**~~;~~.

Pages 349:
CORRECTIVE ACTIONS: …
3. All corrective actions taken in accordance with this Section shall be fully documented in records that are subject to verification. Corrective actions and corrections shall at a minimum provide compliance with ~~21 CFR 117 (Subpart C. (117.150 Corrective Actions and Corrections))~~ Appendix T. **Corrective Actions;**

RESULTS OF THE 2019 NCIMS

PROPOSAL 301

PMO Page 350:

b. The calibration of CCP process-monitoring instruments, and the performance of any periodic end-product and in-process testing, ~~in accordance with 1.a.(3)ii) and 1.a.(3)iii) of this Section,~~ shall be documented in records that are subject to the record keeping requirements in ~~this~~ Appendix T.

VERIFICATION AND VALIDATION

1. Verification …

Verifications shall at a minimum provide compliance with ~~21 CFR 117 (Subpart C. (117.155 and 117.165 Verification of Implementation and Effectiveness))~~ Appendix T. **Verification:.**

Page 350:

3. Validation of the Hazard Analysis: …

A QI(s) trained in accordance with the training requirements of this Appendix shall perform the validation. Validation shall at a minimum provide compliance with ~~21 CFR 117 (Subpart C. (117.160))~~ Appendix T. **Validation:**. …

RESULTS OF THE 2019 NCIMS

PROPOSAL 301

Section 8 HACCP SYSTEM RECORDS …

G. Requirements in ~~21 CFR 117 Subpart F~~ Appendix T. are addressed…

Section 9 HACCP SYSTEM PREREQUISITE PROGRAMS …

9. Requirements in ~~21 CFR 117 Subpart F~~ Appendix T. are addressed.

RESULTS OF THE 2019 NCIMS

PROPOSAL 303

This proposal clarified the issuance process for Memorandums of Information (M-I) by requiring NCIMS Document Review Committee to review M-I's specific to Q&As prior to issuance.

RESULTS OF THE 2019 NCIMS

PROPOSAL 303

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

1. PHS/FDA develops the draft M-I, with proposed answers to questions that were received from the field (milk seminars, FDA training courses, workshops, etc.).

2. PHS/FDA will provide the draft M-I to the NCIMS Document Review Committee for review.

3. The NCIMS Document Review Committee will provide comments to PHS/FDA within forty-five (45) days of receiving the draft M-I.

RESULTS OF THE 2019 NCIMS

PROPOSAL 303

4. Within forty-five (45) days PHS/FDA will provide responses to all comments received from the NCIMS Documents Review Committee.

5. The NCIMS Documents Review Committee and PHS/FDA will have thirty (30) days to mutually resolve outstanding issues/concerns.

RESULTS OF THE 2019 NCIMS

PROPOSAL 303

6. If an issue/concern is not resolved and the NCIMS Documents Review Committee identifies a specific question and answer that the committee has determined goes beyond providing guidance/information on what FDA's current thinking is on a specific subject/scenario/situation and has been determined to be more interpretive in nature, then the specific question and answer will be removed from the draft M-I.

RESULTS OF THE 2019 NCIMS

PROPOSAL 303

7. PHS/FDA will finalize the mutually agreed upon M-I and distribute the memorandum to FDA Milk Specialist, Regulatory/Rating Agencies, Laboratory Evaluation Officers and Milk Sanitation Rating Officers.

RESULTS OF THE 2019 NCIMS

PROPOSAL 304

This proposal allows States and TPCs the option of having their State Program Evaluations (SPEs) conducted once every five (5) years, made some editorial changes to the Procedures and incorporated M-i-03-12 (Supplement #1)

RESULTS OF THE 2019 NCIMS

PROPOSAL 304

2017 PROCEDURES

ABBREVIATIONS AND ACRONYMS

Page v:

SAP (Strategic Action Plan)

SCC (Somatic Cell Count) …

RESULTS OF THE 2019 NCIMS

PROPOSAL 304

PROCEDURES - SECTION IV. OVERSIGHT AND RESPONSIBILITIES

A. **PHS/FDA RESPONSIBILITIES** …

Page 10:

7) The Minimum State Program Evaluation Requirements and Criteria cited in M-I-03-12 (Supplement 1) shall be used to determine if a Regulatory/Rating Agency Program is "in compliance" or "not in compliance" with the requirements of the *Grade "A" PMO* and *Procedures*.

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

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

RESULTS OF THE 2019 NCIMS

PROPOSAL 304

PROCEDURES - SECTION IV. OVERSIGHT AND RESPONSIBILITIES

A. **PHS/FDA RESPONSIBILITIES** …

Page 10:

1) None of the Minimum State Program Evaluation Requirements and Criteria cited in M-I-03-12 (Supplement 1) that automatically trigger a Strategic Action Plan (SAP) to be jointly developed by FDA and the State or TPC, respectively, if the percent Compliance falls below the identified level are identified; and
2) The identification of other program requirements not meeting the minimum criteria do not indicate the development and implementation of a SAP.

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

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

RESULTS OF THE 2019 NCIMS

PROPOSAL 304

PROCEDURES - SECTION IV. OVERSIGHT AND RESPONSIBILITIES

A. **PHS/FDA RESPONSIBILITIES** …

Page 10:

1) One (1) or more of the Minimum State Program Evaluation Requirements and Criteria cited in M-I-03-12 (Supplement 1) that automatically trigger a Strategic Action Plan (SAP) to be jointly developed by FDA and the State or TPC, respectively, if the percent Compliance falls below the identified level is/are identified; and

a) The identification of other program requirements not meeting the minimum criteria indicate the development and implementation of a SAP.

….

c. If the next triennial written program evaluation meets the criteria cited in b.2.) above, the Regulatory/Rating Agency Program shall be determined "in substantial non-compliance" with the requirements of the *Grade "A" PMO* and *Procedures*.

RESULTS OF THE 2019 NCIMS

PROPOSAL 304

PROCEDURES - SECTION IV. OVERSIGHT AND RESPONSIBILITIES

A. **PHS/FDA RESPONSIBILITIES** …

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

RESULTS OF THE 2019 NCIMS

PROPOSAL 304

PROCEDURES - SECTION IV. OVERSIGHT AND RESPONSIBILITIES

Continued…

- If the State or TPC elects to have this five (5) year option that shall be documented in writing to their appropriate PHS/FDA Milk Specialist or PHS/FDA MST for TPCs.

RESULTS OF THE 2019 NCIMS

PROPOSAL 304

Page 38:

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*. (Refer to Section IV., A., 3.)

B. Any State or TPC in "substantial non-compliance" as determined by PHS/FDA shall be referred to the NCIMS Executive Board for determination of listing on a separate page ~~in~~ on the *IMS List*. The State or TPC upon notification of PHS/FDA and the NCIMS Executive

RESULTS OF THE 2019 NCIMS

PROPOSAL 305

This proposal eliminates the requirement that shipping states and TPCs must immediately notify all known receiving States when there is a significant change in the number of dairy farms within certified interstate milk shippers supply (BTU).

This proposal also clarifies that when notification is required, the shipping state and TPC must notify the receiving State in writing.

RESULTS OF THE 2019 NCIMS

PROPOSAL 305

Procedures, Page 15

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 in writing all known receiving States and/or TPCs and the appropriate PHS/FDA Milk Specialist or PHS/FDA MST for TPCs.

RESULTS OF THE 2019 NCIMS

PROPOSAL 306

This proposal clearly define attendance at the FDA Regional Milk Seminar for LEOs.

RESULTS OF THE 2019 NCIMS

PROPOSAL 306

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 4 of the *EML*)
2. Holds a valid certificate or provisional endorsement of qualification.
3. Shall not fail, without cause, to attend once within their three (3) year period of certification, the PHS/FDA ~~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.

RESULTS OF THE 2019 NCIMS

PROPOSAL 307

This proposal provides for acceptance of the Appendix N Modification Committee from a Study Committee to a Standing Committee.

RESULTS OF THE 2019 NCIMS

PROPOSAL 307

2017 Procedures, page 85, Article II---Duties of the Chair, Section 3

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

RESULTS OF THE 2019 NCIMS

PROPOSAL 308

The proposal allows for the utilization of the **FD378 Preventive Controls** for Grade "A" milk plants coupled with the abbreviated **"4 hour" training course** approved by the HACCP Implementation Committee constitutes sufficient and adequate training for **original and re-certification** of SROs.

RESULTS OF THE 2019 NCIMS

PROPOSAL 308

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E. QUALIFICATIONS AND CERTIFICATIONS …

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 completed ~~attended~~ at least one (1) abbreviated approved training course in the auditing of milk plant HACCP Systems and NCIMS listing for the period of qualification.

RESULTS OF THE 2019 NCIMS

PROPOSAL 308

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

a. Candidate Background

1.) Training and Experience

C.) 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… HACCP Program. The NCIMS HACCP Orientation and training in general auditing requirements for auditing milk plants, receiving stations and transfer stations at a minimum consists of the Appendix T training from the PHS/FDA Milk Specialists and the abbreviated training course approved and supplied by the HACCP Implementation Committee.

RESULTS OF THE 2019 NCIMS

PROPOSAL 308

c. Continuous Certification

During the three (3) year certification period, the SRO, certified to conduct NCIMS HACCP listings, shall complete the minimum training requirements… ~~both a comprehensive multi-day course presented by members of the NCIMS HACCP Implementation Committee and~~ an abbreviated approved training course of individual instruction that may be presented to individuals or small groups by any of the HACCP Certified FDA Milk Specialists.

RESULTS OF THE 2019 NCIMS

PROPOSAL 308

HACCP TRAINING:

2. Regulatory Personnel: Regulatory personnel performing HACCP audits shall have successfully completed appropriate training in the application of HACCP or Food Safety Plan principles for milk and milk product processing at least equivalent to that received under the Dairy HACCP Core Curriculum. Specialized Appendix T training combined with the abbreviated approved training course in the auditing of milk plant HACCP Systems offered by FDA is acceptable in meeting the training requirement

RESULTS OF THE 2019 NCIMS

NEXT NCIMS CONFERENCE - 2021

Indianapolis, IN

Change is good, right?
QUESTIONS?