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5100 Paint Branch Parkway
College Park, MD 20740-3835

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December 13, 2012

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

FROM: Dairy and Egg Branch (HFS-316)

SUBJECT: NCIMS Aseptic Program (AP) Questions and Answers

Following are questions and answers regarding the National Conference on Interstate Milk Shipments (NCIMS) Aseptic Program for milk plants. These answers have been jointly developed by the NCIMS Aseptic Program Committee and FDA. These questions and answers are available on the NCIMS web site at http://www.ncims.org.

An electronic version of this memorandum is available for distribution to Regional Milk Specialists, State Milk Regulatory Agencies, State Laboratory Evaluation Officers and State Milk Rating Officers in your region. The electronic version should be widely distributed to representatives of the dairy industry and other interested parties and will also be available on the FDA Web Site at http://www.fda.gov at a later date.

If you would like an electronic version of this document prior to it being available on the FDA Web Site, please e-mail your request to Robert.Hennes@fda.hhs.gov.

CAPT Robert F. Hennes, RS, MPH
Milk Safety Team

QUESTIONS AND ANSWERS REGARDING THE NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS (NCIMS) ASEPTIC PROGRAM (AP) FOR MILK PLANTS

THE ANSWERS TO THESE QUESTIONS HAVE BEEN JOINTLY DEVELOPED BY THE NCIMS ASEPTIC PROGRAM COMMITTEE (APC) AND FDA

It is intended that this be a living document that is modified, corrected, adjusted and added to. The questions and answers are not in any particular order or priority, but an attempt has been made to organize them by subject matter.

Topics:
A. Background
B. General
C. Training
D. Process Authority
E. Aseptic Critical Listing Elements (ACLEs)

A. Background:

1. **PMO-Section 11 and Appendix S; Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments (Procedures)-Sections III, V and VIII; and Methods of Making Sanitation Ratings of Milk Shippers (MMSR)-Sections A and C**

   Which Grade “A” aseptic milk plants are required to participate in the National Conference on Interstate Milk Shipments (NCIMS) Aseptic Program (AP)?

   All Grade “A” aseptic milk plants are required to participate in the NCIMS AP as soon as State regulatory and rating personnel responsible for the milk plant(s) in their State have completed the mandatory training developed and sponsored by the Aseptic Program Committee (APC).

2. **PMO-Section 11 and Appendix S; Procedures-Sections III, V and VIII; and MMSR-Sections A and C**

   Are Grade "A" aseptic milk plants participating in the voluntary NCIMS International Certification Pilot Program (ICPP) included in the NCIMS AP?

   Yes, provided that the Third Party Certifier’s (TPC’s) regulatory and rating personnel responsible for the regulatory inspection and IMS rating of the Grade "A" aseptic milk plants under the ICPP have successfully completed the mandatory APC training and successfully passed the exam, similar to their State counterparts.

3. **PMO-Section 11 and Appendix S; Procedures -Sections III, V and VIII; and MMSR-Sections A and C**

Are Grade "A" aseptic milk plants operating under the voluntary NCIMS HACCP program required to be regulated under the NCIMS AP also?

Yes. In order for a Grade "A" aseptic milk plant, operating under the voluntary NCIMS HACCP program, to comply with the NCIMS AP requirements, the Aseptic Processing and Packaging System (APPS) shall be excluded from the NCIMS HACCP requirements since this will be the responsibility of the Food and Drug Administration (FDA) Low-Acid Canned Food (LACF) program. All other NCIMS HACCP requirements shall be complied with under the voluntary NCIMS HACCP program. Any conflicts will be addressed jointly by the NCIMS HACCP Implementation Committee (HIC) and APC.

B. General

1. **PMO-Sections 1, 5 and 7, and Appendix S**

What specific areas of a Grade "A" aseptic milk plant participating in the NCIMS AP are to be routinely inspected by properly trained Regulatory Agency personnel?

Regulatory Agency personnel would be responsible for inspecting all areas of the aseptic milk plant, except for those areas associated with the APPS. The APPS is the responsibility of FDA or a Regulatory Agency designated by FDA, under the LACF program.

2. **PMO-Sections 1, 5 and 7, and Appendix S; Procedures-Sections III, V and VIII; and MMSR-Sections A and C**

In the Definition of the APPS within Section 1-Definitions of the PMO it provides for a Process Authority to expand the APPS by providing written documentation that clearly define additional processes or equipment that are considered critical to the commercial sterility of the product. Would you please provide some possible examples of an expanded APPS?

The following definition is included in the PMO:

ASEPTIC PROCESSING AND PACKAGING SYSTEM (APPS): For the purposes of this document, the Aseptic Processing and Packaging System in a milk plant is comprised of the processes and equipment used to process and package aseptic Grade "A" milk or milk products. The APPS shall be regulated in accordance with the applicable requirements of 21 Code of

Federal Regulations (CFR) Parts 108, 110 and 113. The APPS shall begin at the constant level tank and end at the discharge of the packaging machine, provided that the Process Authority may provide written documentation which will clearly define additional processes or equipment that are considered critical to the commercial sterility of the product.

Examples are:

- *Blending and formulation of ingredients prior to heating;*
- *Sterile transfer of Grade "A" milk and/or milk product;*
- *Storing the aseptic processed Grade "A" milk and/or milk product prior to packaging; and/or*
- *Handling the Grade "A" milk and/or milk product after packaging to maintain sterility and package integrity.*

3. **PMO-Sections 1, 5 and 7, and Appendix S; Procedures-Sections III, V and VIII; and MMSR-Sections A and C**

An Example of an Expanded APPS: A chocolate blend tank is used for the blending of chocolate powder and milk prior to heating. Dry chocolate powder lumps could be critical to the aseptic processing of the finished Grade "A" milk and/or milk product because of its viscosity. If a chocolate blend tank is included as part of the expanded APPS, wouldn't the milk plant be required to monitor the blending operation?

The chocolate blend tank in this scenario has been identified as being a part of the APPS; therefore, it is not the inspectional responsibility of the Regulatory Agency inspector, Sanitation Rating Officer (SRO), or FDA Regional Milk Specialist (RMS) under the NCIMS AP. The operation of the chocolate blend tank and the blending of the chocolate power with milk is the responsibility of the FDA Consumer Safety Officer (CSO) or a Regulatory Agency designated by FDA under the FDA LACF program.

4. **PMO-Sections 1, 5 and 7, and Appendix S; Procedures-Sections III and VIII; and MMSR-Sections A and C**

The Grade "A" aseptic milk plant's documents supplied to the Regulatory Agency personnel, or the SRO or RMS are not clear where the APPS begins and ends. How should the Regulatory Agency personnel, or the SRO or RMS proceed?

The default APPS, which begins at the constant-level tank for the aseptic processing unit and ends at the discharge port of the aseptic packaging machine would be used.

NOTE: *In certain situations, the APPS may be expanded beyond the default APPS for reasons directly related to achieving and maintaining the commercial sterility of the Grade "A" aseptic milk and/or milk products. It is the responsibility of the Grade "A" aseptic milk plant to provide appropriate documentation justifying an expansion of the APPS. Acceptable documentation can be found in the filing documents, i.e., FORM FDA 2541c and Supplemental Submission Identifiers (SUP-SIDs) or in written communication from the Process Authority.*

5. **PMO-Sections 1, 5 and 7, and Appendix S; Procedures-Sections III and VIII; and MMSR-Sections A and C**

Is the APPS defined as the aseptic equipment or as the room or facility in which such aseptic equipment is located?

The APPS as defined in the PMO is comprised of the process and equipment used to process and package aseptic Grade "A" milk and/or milk products. The room or facility in which the APPS is located is not included, except for the exemptions noted in Appendix S of the PMO.

6. **PMO-Sections 1, 5 and 7, and Appendix S; Procedures-Sections III and VIII; and MMSR-Sections A and C**

What should be done if Regulatory Agency personnel or SROs learn that the last FDA LACF inspection, which was completed recently, identified "important" Items that needed correction within the APPS? What should the Regulatory Agency personnel or SRO do?

If, by carrying out their specific responsibilities under the NCIMS AP, it is learned by Regulatory Agency personnel or SROs that an Item(s) within the APPS that was addressed on a recent FDA LACF inspection is still not corrected, there would not be any required action by Regulatory Agency personnel or SROs under the NCIMS AP since the responsibility for the APPS lies with the FDA LACF program. However, it would be acceptable for *the Regulatory Agency personnel or SROs to discuss the Item(s) with the milk plant's management.*

7. **PMO-Sections 1, 5 and 7, and Appendix S; Procedures-Sections III and VIII; and MMSR-Sections A and C**

Regulatory Agency personnel are performing the routine inspection of the portion of the Grade "A" aseptic milk plant outside of the APPS and observe a leaky product pipe going from the aseptic sterilizer to the aseptic filler. A milk plant employee states, when asked, that the pipe has been leaking like that for a couple of weeks. What is the responsibility of the Regulatory Agency personnel?

The leaky product pipe in this location between the aseptic sterilizer and the aseptic filler falls within the APPS and under the NCIMS AP it is the responsibility of the FDA LACF program. The Regulatory Agency personnel should contact the milk plant's management. If follow-up is necessary, Regulatory Agency personnel should inform the management of the Regulatory Agency, who may choose to contact their Local or District FDA office.

8. **PMO-Sections 1 and 7-Items 7p and 17p, and Appendix S; Procedures-Sections III, V and VIII; and MMSR-Sections A and C**

If a secondary cooling plate is used exclusively within the APPS and derives its cooling media only from tower water, is the tower water system a part of the APPS and regulated under the FDA LACF program?

Yes. However, if the tower water is also used for pasteurized Grade "A" milk and/or milk product processing and/or cooling, then the answer is "No" and the tower water would be required to comply with all applicable Item 7p-Water Supply and/or Item 17p-Cooling of Milk and Milk Products requirements of the PMO for all applications outside of the APPS, including the required sampling and testing.

9. **PMO-Sections 1 and 7-Items 7p and 17p, and Appendix S; Procedures-Sections III, V and VIII; and MMSR-Sections A and C**

May toxic additives, i.e., gluteraldehyde, etc., be used in tower water used in these secondary cooling plates used exclusively within the APPS?

All additives used in the tower water, which is used exclusively within the APPS for the secondary cooling plates, shall meet FDA regulations. However, if this tower water is also being used for processing purpose outside of the APPS, then all additives shall meet the PMO requirements.

10. **PMO-Sections 1, 5 and 7-Item 16p, and Appendix S; Procedures-Sections III, V and VIII; and MMSR-Sections A and C**

A Grade "A" milk plant produces Grade "A" pasteurized and/or ultra-pasteurized (UP) milk and/or milk products and Grade "A" aseptic milk and/or milk products using the same processing equipment, with only a few adjustments made to switch from Grade "A" pasteurized and/or UP milk and/or milk products to Grade "A" aseptic milk and/or milk products. Should these Grade "A" milk and/or milk products be inspected and rated as pasteurized milk or milk product (traditional PMO) or an aseptic milk or milk product (under the NCIMS AP)?

A Grade "A" milk plant that produces both Grade "A" pasteurized and/or ultra-pasteurized (UP) and Grade "A" aseptic milk and milk products using modifications of the same processing and packaging system shall have two (2) separate Interstate Milk Shippers (IMS) Listings and two (2) FORM FDA 2359i's-Interstate Milk Shipper Reports submitted by a SRO to FDA. One (1) IMS Listing will cover Grade "A" pasteurized milk and milk products and the other IMS Listing will cover the Grade "A" aseptic milk and milk products. Grade "A" pasteurized milk and milk products must comply with all of the applicable requirements of the PMO and the Grade "A" aseptic milk and milk products must comply with all of the applicable requirements of the NCIMS AP. When the processing and packaging system is modified to process Grade "A" pasteurized milk and/or milk products it shall be properly configured and operated in accordance with Item 16p of the PMO.

11. **PMO-Sections 1, 5 and 7-Item 16p, and Appendix S; Procedures-Sections III, IV, V and VIII; and MMSR-Sections A and C**

During a rating of a Grade "A" milk plant, which operates a processing and packaging system that can process both aseptic and conventional Higher-Heat-Shorter-Time (HHST)/UP milk and/or milk products, if the flow rate cut-out for Grade "A" pasteurized milk and/or milk products is ten (10) gallons per minute (gpm) and for Grade "A" aseptic milk and/or milk products is fourteen (14) gpm, how would a Regulatory Agency inspector, SRO or RMS determine that the proper Grade "A" milk and/or milk product is being run at the correct speed to determine the proper holding time?

Under the NCIMS AP, the Regulatory Agency inspector, SRO and RMS are responsible only for evaluating the pasteurization system(s), which includes the construction, design, operation, maintenance, testing and sealing of the pasteurization equipment just as is currently being conducted during a traditional Regulatory Agency inspection, rating or check rating. The APPS is rated according to the four (4) Aseptic Critical Listing Elements (ACLEs), which does not include a determination of product flow rate for the Grade "A" aseptic milk and/or milk products. Areas such as product flow rates in the APPS are covered under the FDA LACF inspection.

12. **PMO-Sections 1, 5 and 7-Item 16p, and Appendix S; Procedures-Sections III, V and VIII; and MMSR-Sections A and C**

Does the FDA LACF program or schedule filed process address adulteration of Grade "A" milk and/or milk product with added water?

The FDA LACF program addresses the proper operation of the heat treatment process (sterilizing equipment) within the APPS, including the adulteration of Grade "A" milk and/or milk product with the addition of water.

13. **PMO-Sections 1, 5 and 7-Item 16p, and Appendix S; Procedures-Sections III, V and VIII; and MMSR-Sections A and C**

Who determines whether a Grade "A" aseptic milk plant has had significant APPS equipment changes that might affect the critical processing factors for the Grade “A” milk and/or milk products and who is required to notified the Process Authority for a further evaluation?

It is the Grade "A" aseptic milk plant's responsibility to notify their Process Authority of any significant APPS equipment changes that may affect their critical processing factors for the Grade “A” milk and/or milk products . This will be evaluated by the FDA CSO or a Regulatory Agency designated by FDA under the FDA LACF program.

14. **PMO-Sections 1, 6 and 7-Items 7p and 17p, and Appendix S; Procedures-Section VI; MMSR-Sections C and D; and the Evaluation of Milk Laboratories (EML)-Section 1**

Are the laboratories used for the analysis of official regulatory samples from Grade "A" aseptic milk plants, operating under the NCIMS AP, required to be certified under the NCIMS laboratory evaluation program?

Yes. Official regulatory samples from Grade "A" aseptic milk plants, include raw commingled milk samples, vitamin assays of finished products fortified with vitamins and required water supply and water system samples. Required water supply and water system samples may also be officially analyzed at an Environmental Protection Agency (EPA) certified laboratory.

15. **PMO-Sections 1 and 7, and Appendix S; Procedures-Section III; and MMSR-Sections A and C**

How is a SRO or RMS supposed to assign points to arrive at a Sanitation Compliance Rating for violations observed during a rating or check rating at a Grade "A" aseptic milk plant?

After the SRO or RMS has completed the evaluation of the ACLEs and all four (4) are determined to be in compliance (“passed”), then the SRO or RMS continues the rating or check rating, respectively, by evaluating the rest of the Grade "A" aseptic milk plant outside of the APPS. Points are assigned to violations under the NCIMS AP using FORM FDA 2359L- Status of Milk Plants. SROs and RMSs are encouraged to also refer to Appendix S of the PMO and training material provided by the APC for additional guidance on the calculation of the Sanitation Compliance Rating for a Grade "A" aseptic milk plant.

16. **PMO-Section 3**

Are separate Regulatory Agency permits or licenses required under the PMO and NCIMS AP for a Grade "A" aseptic milk plant that runs both Grade "A" pasteurized and aseptic milk and milk products?

No. However, the Regulatory Agency's dairy statutes, laws and regulations may require that such a milk plant have more than one (1) permit or license.

17. **PMO-Section 3**

If a Grade "A" milk plant is covered under one (1) Regulatory Agency license or permit, but produces both Grade "A" pasteurized and Grade "A" aseptic milk and/or milk products and a rating of either the milk plant's IMS listings for Grade "A" pasteurized milk and/or milk products or Grade "A" aseptic milk and/or milk products results in a Sanitation Compliance Rating of less than 90, should the Regulatory Agency begin action against the milk plant's license or permit, including all Grade "A" milk and/or milk products or just the Grade "A" milk and/or milk products included in the specific rating with a Sanitation Compliance Rating of less than 90?

The NCIMS program does not specify that Regulatory Agency license or permit actions is required to be taken by the Regulatory Agency when a milk plant's Sanitation Compliance Rating is less than 90 and their IMS listing is withdrawn. Regulatory Agency license or permit action in such a situation would be dictated by the individual State's dairy statutes, laws, regulations and administrative code. The NCIMS program only requires the Rating Agency to notify FDA and all receiving States of the rating results, which would include the withdrawal of the applicable milk plant's IMS listing.

18. **PMO-Sections 3 and 5, and Appendix S, Procedures-Sections III, IV, V and VIII; and MMSR-Sections A and C**

What protocol should be followed for an aseptic milk plant, which wishes to produce Grade "A" milk and/or milk products, to obtain an initial IMS listing under the NCIMS AP?

Aseptic milk plants and Regulatory Agencies shall follow the protocol below to be eligible for a NCIMS listing.

- *The milk plant shall submit plans to the Regulatory Agency.*
- *The milk plant shall obtain a permit or license from the Regulatory Agency. The plant is required to have an inspection prior to obtaining a Grade "A" permit*
- *The milk plant shall register and file a schedule process(es) with FDA LACF for each Grade "A" aseptic milk and/or milk product.*

- *The Regulatory Agency inspector responsible for the Grade "A" aseptic milk plant and the SRO who will be conducting the rating shall participate in the mandatory APC training and shall pass the written test.*
- *After the successful completion of the mandatory training, the Regulatory Agency inspector shall conduct routine inspections according to the NCIMS AP criteria.*
- *The milk plant shall undergo at least one (1) NCIMS Regulatory Agency Grade "A" aseptic milk plant inspection under the NCIMS AP.*
- *After FDA LACF has "accepted" the filing(s), the Grade "A" aseptic milk plant shall submit a written request to the Rating Agency for a rating.*
- *Upon the completion of the rating and submittal of FORM FDA 2359i-Interstate milk Shipper's Report, along with FORM FDA 2359p-NCIMS Aseptic Processing and Packaging Program Critical Listing Elements for Low-Acid (pH greater than 4.6) Aseptic Milk and Milk Products and a signed FORM FDA 2359o-Permission to Publish, by the SRO and acceptance by the RMS, the IMS listing is granted and the shipper (milk plant) is included on the IMS List, and the Grade "A" aseptic milk plant may begin shipment of Grade "A" aseptic milk and/or milk products under the NCIMS AP.*

19. **PMO-Section 4 and Appendix S; and MMSR-Section D**

How would a low-acid aseptic Grade "A" low-acid milk and/or milk product that is labeled "Refrigerate" or "Keep Refrigerated" and not "Refrigerate after Opening" as require within the PMO be regulated under the Grade "A" Milk Safety Program.

It would be considered a refrigerated pasteurized and/or ultra-pasteurized Grade "A" milk and/or milk product and would be regulated under the PMO like any pasteurized and/or ultra-pasteurized Grade "A" milk and/or milk product and would not be considered a low-acid aseptic Grade "A" milk and/or milk product under the NCIMS AP.

20. **PMO-Section 5**

How often is it required for a Grade "A" IMS Listed milk plant, which produces only Grade "A" aseptic milk and/or milk products, to be inspected by Regulatory Agency personnel?

A minimum of once every six (6) months.

21. **PMO-Section 5 and Appendix K**

How often is it required for a Grade "A" IMS Listed milk plant, which produces both Grade "A" pasteurized and Grade "A" aseptic milk and/or milk products, to be inspected by Regulatory Agency personnel?

A minimum of once every three (3) months with the following two (2) exceptions:

1. Grade "A" milk plants operating under the voluntary NCIMS HACCP program shall be inspected a minimum of once every four (4) months with a possible minimum of once every six (6) months, if determined by the Regulatory Agency.
2. Grade "A" milk plants that produce both Grade "A" pasteurized and Grade "A" aseptic milk and/or milk products where the aseptic operation is in a dedicated and separate area of the milk plant, that dedicated and separate area would be inspected a minimum of once every six(6) months. The rest of the milk plant would still be required to be inspected once every three (3) months.

22. **PMO-Section 5 and Appendix M**

If a Grade "A" milk plant produces both Grade "A" pasteurized and Grade "A" aseptic milk and/or milk products and the Regulatory Agency inspection conducted once every three (3) months covers both areas of the milk plant, can the Regulatory Agency use only one (1) inspection report form for both inspections?

No. Two (2) separate inspection report forms must be completed by the Regulatory Agency inspector noting the area (Grade "A" aseptic or Grade "A" pasteurization) on the forms. This is because the Grade "A" aseptic milk and/or milk products are rated and listed separately from the Grade "A" pasteurized milk and/or milk products. Filling out separate inspection report forms will help to define the PMO Items in violation in each area of the milk plant by the Regulatory Agency. This will also be helpful in clarifying the enforcement ratings conducted by the SRO and RMS.

23. **PMO-Section 6; and MMSR-Section C and Appendix A**

If a Grade "A" aseptic milk plant is receiving only Grade "A" pasteurized milk and/or milk products from an IMS listed source as their source of "commingled raw milk" for Grade "A" aseptic milk and/or milk product processing and packaging, what Section 6-The Examination of Milk and Milk Products of the PMO tests are required to be conducted, and what bacterial standards must be met, i.e., raw or pasteurized?

This Grade "A" pasteurized milk and/or milk product would not be considered "commingled raw milk" for pasteurization, ultra-pasteurization or aseptic processing; therefore, this IMS listed Grade "A" pasteurized milk and/or milk product supply would not be required to be sampled and tested upon receipt at the Grade "A" aseptic milk plant, in accordance with Section 6 of the PMO.

24. **PMO-Section 6; and MMSR-Sections C and D, and Appendix A**

Do Vitamin A and/or A & D fortified Grade "A" aseptic milk and milk products require annual vitamin assays in accordance with Section 6-The Examination of Milk and Milk Products of the PMO?

Yes. At the current time only fluid white milk and chocolate flavored milk at all fat levels are required to have annual vitamin assays.

25. **PMO-Sections 6; and MMSR-Sections C and D, and Appendix A**

Separate IMS Listings are required for a Grade “A” milk plant that produces both Grade “A” pasteurized and aseptic milk and milk products, are two (2) separate laboratory reports of the test results required for the same raw commingled milk that is being utilized to produce both Grade “A” pasteurized and aseptic milk and/or milk products?

No. The same raw commingled milk laboratory report for a Grade “A” milk plant can be used to fulfill the official sample collection and testing requirements for a Grade “A” milk plant’s pasteurized and aseptic milk and milk product listing. A copy of these raw commingled milk laboratory reports shall be available to the SRO or RMS during ratings or check ratings, respectively.

26. **PMO-Section 7 and Appendix S**

Regulatory Agency personnel are performing a routine inspection of the Grade "A" aseptic milk plant and observe that in the warehouse there are several pallets containing swollen Grade "A" aseptic milk and/or milk products. Upon further investigation, it is learned that the milk plant was simply sorting and separating spoiled Grade "A" aseptic milk and/or milk products. What should Regulatory Agency personnel do?

No action is necessary. It is appropriate for Grade "A" aseptic milk plants to segregate spoiled Grade "A" aseptic milk and/or milk products in preparation for disposal.

27. **PMO-Section 7-Item 2p and Appendix S**

Why are the ceiling requirements for dry storage areas for aseptically processed and packaged Grade “A” milk and/or milk products within a Grade “A” aseptic milk plants as addressed in Item 2p-Walls and Ceilings of the PMO exemption under the NCIMS AP?

Aseptically processed and packaged Grade “A” milk and/or milk products are typically stored in a dry, unrefrigerated room similar to a room used for the

storage of dry milk and/or milk products. This exemption provides the necessary safety protection for Grade "A" aseptic milk and milk products and provides consistency with the requirements for dry milk and milk products.

28. **PMO-Section 7-Item 2p and Appendix S**

Does the ceiling exemption for Grade "A" milk and/or milk product storage areas in Grade "A" aseptic milk plants mean that Grade "A" milk and/or milk products may be stored outside?

No. This exemption only applies to the ceiling for Grade "A" milk and/or milk product storage areas in Grade "A" aseptic milk plants. A roof is still required for Grade "A" milk and/or milk product storage areas in Grade "A" aseptic milk plants under the NCIMS AP.

29. **PMO-Section 7, Item 7p and Appendix S**

A Grade "A" milk plant has both a High-Heat-Short-Time (HTST) and an aseptic system for processing raw milk. The milk plant has a common water supply for the milk plant and a dedicated boiler for the APPS. Does the Regulatory Agency inspector, SRO or RMS evaluate the dedicated boiler used within the APPS for water cross connections?

No. However, if a boiler is also used for non-APPS applications within the milk plant, then the answer would be "Yes".

30. **PMO-Section 7-Items 7p and 17p, and Appendix S**

Item 7p-Water Supply of the PMO is identified in the Aseptic Processing and Packaging Program CFR/PMO Comparison Summary Reference in Appendix S of the PMO as having joint coverage, i.e. "PMO/CFR". What does that mean for Regulatory Agency personnel, SROs or RMSs conducting routine inspections, ratings or check ratings, respectively, of a Grade "A" aseptic milk plant?

Water supplies and water systems (recirculated, glycol, tower water, etc.), like a number of other milk plant requirements in the PMO that are identified in the Aseptic Processing and Packaging Program CFR/PMO Comparison Summary Reference in Appendix S of the PMO, are cited for enforcement purposes in two (2) separate ways. For all parts of a Grade "A" aseptic milk plant's water supply or water system, which is not dedicated and utilized only within the APPS, Item 7p requirements are applicable at the full point value (4 points) as cited on FORM FDA 2359L. If the water supply or water system is dedicated and utilized only within the APPS, then Regulatory Agency personnel, the SRO or the RMS are not responsible to determine compliance with Item 7p of the PMO within the APPS. Compliance of the water supply or

water system dedicated and utilized only within the APPS is evaluated under the FDA LACF program based on the enforcement of 21 CFR Parts 108, 110 and 113.

31. **PMO-Section 7-Item 11p and Appendix S**

Are single-service packaging materials and containers/closures used for packaging Grade “A” aseptic milk and milk products required to originate from an IMS listed single-service facility for Grade "A" aseptic milk plants operating under the NCIMS AP?

No. This PMO requirement does not apply under the NCIMS AP for Grade "A" aseptic milk and milk products.

32. **PMO-Section 7-Item 12p and Appendix S**

Does the extended run cleaning and sanitizing criteria in Item 12p-Cleaning and Sanitizing of Containers and Equipment of the PMO apply to Grade "A" aseptic milk plants?

The PMO's extended run provisions, as cited under Item 12p, provide specific criteria on the length of time that processing equipment used for Grade "A" pasteurized milk and milk products, may run between the required cleaning and sanitizing. For Grade "A" aseptic milk plants, the extended run criteria does not apply to operations conducted within the APPS, because food safety concerns associated with extended runs are addressed by the Process Authority through the filed scheduled process and associated documents submitted to FDA LACF. Extended run criteria would be applicable in other parts of a Grade "A" aseptic milk plant or for any part of the milk plant outside of the APPS used in the production of Grade "A" pasteurized milk and milk products.

33. **PMO-Section 7-Item 15p and Appendix S**

Is a one (1) valve separation between Grade “A” milk and/or milk products and Clean-In-Place (CIP) solution adequate within the APPS during a "hot clean" of the APPS’s sterilization system?

Yes, if it is determined appropriate and safe by the Process Authority and accepted by FDA LACF.

34. **PMO-Section 7-Item 16p and Appendices H and S**

Do the same PMO equipment and design criteria apply to processing equipment that is used only for Grade “A” aseptic milk and milk products in an IMS listed aseptic milk plant?

No. The design and configuration of aseptic processing equipment within the APPS that is responsible for delivering commercial sterility is reviewed and validated by the milk plant's Process Authority. This review and validation is the basis for the information provided by the Process Authority to the Grade "A" aseptic milk plant for their process filing with FDA. In turn, each system is reviewed independently by FDA LACF personnel. FDA LACF regulations are designed to provide design and process flexibility for a wide variation of systems and products. Each system and each specific product is reviewed individually for safety and reliability.

35. **PMO-Section 7-Item 16p, Section 11 and Appendix S; Procedures-Sections III, IV and VIII; and MMSR-Sections A and C**

During a rating of a Grade "A" milk plant, which operates a processing and packaging system that can process both aseptic and conventional HHST/UP milk and/or milk products, how would the HHST/UP system be evaluated for compliance with Item 16p-Pasteurization and Aseptic Processing and Packaging of the PMO while the processing and packaging system is configured for the aseptic operation?

Such a Grade "A" milk plant running both Grade "A" pasteurized/UP and Grade "A" aseptic milk and milk products using modifications of the same processing and packaging system shall have two (2) separate ratings, one (1) for the Grade "A" pasteurized milk and/or milk products and the other for the Grade "A" aseptic milk and/or milk products. If both ratings are conducted at the same time, it is likely that at different times during the rating, the processing and packaging system may be observed running both types of milk and/or milk products. If this opportunity does not present itself, then it will be up to the SRO to use other sources of information, i.e., records, employee interviews, existing equipment layout, etc. to determine whether the processing and packaging system is configured and operated properly to comply with the requirements for processing pasteurized/UP milk and milk products in accordance to Item 16p of the PMO.

36. **PMO-Section 7-Item 16p and Appendices H and S**

If a Grade "A" milk plant has a processing system designed to process Grade "A" pasteurized, ultra-pasteurized and aseptic milk and milk products, would the APPS be inspected according to the PMO or FDA LACF program?

The APPS would be inspected based on the Grade "A" milk or milk products being produced in accordance to both the PMO and FDA LACF program. When Grade "A" pasteurized and ultra-pasteurized milk and milk products are processed, the APPS shall be required to comply with Item 16p and Appendix H of the PMO. When only Grade "A" aseptic milk and milk

products are processed within the APPS under the NCIMS AP, the APPS is required to meet the requirements of the FDA LACF program.

37. **PMO-Section 7-Item 16p(D) and Appendices I and S; and MMSR-Appendix A**

A FDA LACF CSO reviews the records related to the holding time, temperatures etc. of the APPS. Who, if anyone, would challenge the public health controls that are typically required under the PMO?

The PMO equipment testing of the APPS is exempt under the NCIMS AP and is the responsibility of the FDA LACF program or a Regulatory Agency designated by FDA under the FDA LACF program.

38. **PMO-Section 7-Item 16p(D) and Appendices I and S; and MMSR-Sections C and D and Appendix A**

What are the PMO Regulatory Agency equipment testing frequency requirements for the APPS under the NCIMS AP?

If it is a dual system that processes both Grade "A" pasteurized and aseptic milk and milk products, then such equipment will be required to be tested by the Regulatory Agency at the frequency prescribed in the PMO, which is once every three (3) months. If the processing system is dedicated only to Grade "A" aseptic milk and/or milk products, there is not a requirement under the PMO or NCIMS AP for the Regulatory Agency to conduct any testing of such equipment. Equipment testing for a dedicated APPS falls under the FDA LACF program.

39. **PMO-Section 7-Item 17p and Appendix S**

In a Grade "A" aseptic milk plant that processes both aseptic and ultra-pasteurized (UP) milk and milk products on the same APPS, which uses tower water for the final cooling, would the PMO requirements for the construction and sampling of the tower water system apply?

Yes.

40. **PMO-Section 11; Procedures-Sections II, III, IV and IV; MMSR-Sections C, E and F**

When can a Grade "A" aseptic milk plant that is initially IMS listed begin to ship Grade "A" aseptic milk and milk products in interstate commerce?

An IMS listing will cover any days of production of Grade "A" aseptic milk and/or milk products from the earliest rating date cited on FORM FDA 2359i-Interstate Milk Shipper's Report from an IMS listing that has been accepted by a FDA RMS and has been submitted to FDA's Center for Food Safety and Applied Nutrition (CFSAN) for inclusion on the IMS List.

NOTE: *Any production of Grade "A" milk and/or milk products prior to the earliest rating date of an IMS listed Grade "A" milk plant would be considered to be coming from an unlisted source and may not be shipped in interstate commerce.*

41. **PMO-Section 11 and Appendix S; Procedures-Sections III, IV and VIII; and MMSR-Sections A and C**

How many IMS listings could there be for a Grade "A" aseptic milk plant producing only Grade "A" aseptic milk and/or milk products?

A Grade "A" aseptic milk plant producing only Grade "A" milk and/or milk products shall have either:

- *One (1) IMS listing, which shall include all of the Grade "A" aseptic milk and/or milk products produced at that milk plant, or*
- *Two (2) IMS listings, with one (1) for the Grade "A" raw milk and/or milk products receiving area of the Grade "A" aseptic milk plant and the second (2nd) for the rest of the Grade "A" aseptic milk plant.*

42. **PMO-Section 11 and Appendix S; Procedures-Sections III, IV and VIII; and MMSR-Sections A and C**

How many IMS listings could there be for a Grade "A" aseptic milk plant that produces HTST, HHST, or ultra-pasteurized (UP) milk and/or milk products and Grade "A" aseptic milk and/or milk products?

A Grade "A" aseptic milk plant producing both Grade "A" pasteurized and aseptic milk and/or milk products shall have either:

- *Two (2) IMS listings, one (1) for Grade "A" pasteurized milk and/or milk products and the second (2nd) for Grade "A" aseptic milk and/or milk products, or*
- *Three (3) IMS listings, one (1) for the Grade "A" raw milk and/or milk products receiving area of the Grade "A" milk plant, a second (2nd) for Grade "A" pasteurized milk and/or milk products, and the third (3rd) for Grade "A" aseptic milk and/or milk products.*

43. **PMO-Section 11 and Appendix S; Procedures-Sections III, V and VIII; and MMSR-Sections A and C**

What options does a Regulatory Agency and/or Rating Agency have if there is only one (1) Regulatory Agency inspector and/or one (1) SRO that has received a certificate from the APC for attending and successfully passing the exam and something happens so that either the Regulatory Agency person and/or SRO cannot conduct the required AP inspections or ratings, respectively, at the Grade "A" aseptic milk plant?

One (1) of the following two (2) options shall be implemented by the Regulatory Agency and/or Rating Agency:

- *The utilization of another Regulatory Agency's AP certified regulatory inspector or Rating Agency's SRO may be used; or*
- *The APC should be immediately contacted to determine whether there is a possibility for individual AP training for another Regulatory Agency inspector and/or Rating Agency SRO.*

***NOTE**: Only Regulatory Agency inspectors and/or Rating Agency SROs that have been certified by the APC are authorized to conduct the NCIMS AP required regulatory inspections and ratings, respectively, of Grade "A" aseptic milk plants under the NCIMS AP.*

44. **PMO-Section 11 and Appendix S; Procedures-Sections IV and VIII; and MMSR-Sections A and C**

Is the IMS listing of a Grade "A" aseptic milk plant based on a Sanitation Compliance Rating of 90 or greater, or is it simply "Pass-Fail"?

The IMS listing of a Grade "A" aseptic milk plant is based on both "Pass - Fail" and a Sanitation Compliance Rating of 90 or greater. All four (4) ACLEs identified on FORM FDA 2359p-NCIMS Aseptic Processing and Packaging Program Critical Listing Elements for Low-Acid (pH greater than 4.6) Aseptic Milk and Milk Products must be determined to be in compliance ("pass") when evaluated by the SRO at the beginning of the rating. If one (1) or more of the four (4) ACLEs has been determined to not be in compliance ("Fail") when evaluated by a SRO, the milk plant's IMS listing will be denied or immediately withdrawn. Following the evaluation of the ACLEs by the SROs, if all of the ACLEs are in compliance ("pass"), then the rating proceeds and the aseptic milk plant must receive a Sanitation Compliance Rating of 90 or greater to have its Grade "A" aseptic milk and milk products listed. A Sanitation Compliance Rating below 90 will result in the milk plant's Grade "A" aseptic IMS listing being denied or immediately withdraw.

45. **MMSR-Section D**

If a Grade "A" aseptic milk plant produces only Grade “A” aseptic milk or milk products and wishes to sell surplus cream as raw or heat-treated, does this require a separate IMS listing for the milk plant and three (3) month minimum inspection frequency?

No. Grade “A” raw cream (Product Code #1) and Grade “A heat-treated cream (Product Code #3) may be listed along with Grade “A” aseptic milk and milk products (Product Code #6) because the raw and heat-treated cream being shipped from the milk plant would not require any additional sampling at the shipping milk plant under Section 6 of the PMO.

46. **MMSR-Section D and Appendix A**

When conducting a rating or check rating of a Grade “A” aseptic milk plant conducted under the NCIMS AP, how is the Enforcement Rating calculated?

The Enforcement Rating for a rating or check rating of an aseptic milk plant conducted under the NCIMS AP is calculated in the same manner as a traditional milk plant rating or check rating conducted under the NCIMS Grade “A” Milk Safety Program. The only difference is that PART II-Milk Plants, Item 5-Pasteurization equipment tested at required frequency from FORM FDA 2359j-Section B-Report of Enforcement Methods (Page 2) is not required for aseptic milk plants. Therefore, when calculating PART II-Milk Plants you would divide by 85 to achieve the TOTAL CREDIT for PART II-Milk Plants.

47. **MMSR-Section F**

What Forms are required to be submitted by the SRO to the RMS along with FORM FDA 2359i-Interstate Milk Shipper’s Report for inclusion of the Grade “A” aseptic milk plant in the IMS List, following the completion of a rating?

The same submission procedures as for a traditional pasteurization milk plant listing shall be followed with the exception that FORM FDA 2359p-NCIMS Aseptic Processing and Packaging Program Critical Listing Elements for Low-Acid (pH greater than 4.6) Aseptic Milk and Milk Products is also required to be submitted.

NOTE: *If this Grade “A” aseptic milk plant is IMS listed under the voluntary NCIMS HACCP program they are also required to submit FORM FDA 2359m-Milk Plant, Receiving Station or Transfer Station NCIMS HACCP System Audit Report and FORM FDA 2359n-NCIMS HACCP System Regulatory Agency Review Report.*

48. **NO NCIMS DOCUMENT REFERENCED**

If Regulatory Agency personnel or SROs learn during an inspection or rating of a Grade "A" aseptic milk plant, that according to milk plant personnel, FDA has not conducted a LACF inspection in the milk plant in “over five (5) years", what should be done?

The responsibility for the inspection of the APPS under the NCIMS AP is FDA's or a Regulatory Agency designated by FDA, under the FDA LACF program. Regulatory Agency personnel are not required to conduct regulatory activities within the APPS of a Grade "A" aseptic milk plant operating under the NCIMS AP. The SRO’s responsibility within the APPS is limited to the evaluation of the ACLEs to verify FDA regulatory oversight under the FDA LACF program. It is the responsibility of the FDA LACF program to address this frequency of inspection issue. No other action by Regulatory Agency personnel or SROs is required.

49. **NO NCIMS DOCUMENT REFERENCED**

Under 21 CFR Part 113, is an indirect regenerator considered the same as a product-to-product regenerator?

No. Indirect regenerators consist of a cold or hot raw or processed milk or milk product, which heats a water media, which in turn, is used to indirectly transfer heat to another raw or processed product milk or milk source. In a product-to-product regenerator, raw milk or milk product is used to directly transfer heat to the processed milk or milk product or vice-versa, without a separation between the two milk and/or milk product streams other than the plates themselves. There is not a use of a water media source in product-to-product regeneration systems.

C. Training

1. **PMO-Sections 5 and 11, and Appendix S; Procedures-Sections III, V and VIII; and MMSR-Sections A and D**

Only Regulatory Agency inspectors and Sanitation Rating Officers (SROs) who have successfully completed the mandatory APC training and passed the examination are authorized to inspect and rate a Grade "A" aseptic milk plant. Is there going to be some method to identify these individuals who have successfully completed the mandatory Aseptic Program Committee (APC) training and passed the examination in the Interstate Milk Shippers (IMS) List or on the National Conference on Interstate Milk Shipments (NCIMS) Web Site so that it will be known who is authorized to conduct the routine regulatory inspections and ratings of Grade “A” aseptic milk plants.

At the current time, the Food and Drug Administration (FDA) and the APC are maintaining a list of Regulatory and Rating Agency personnel that have successfully completed the mandatory APC training and passed the examination on the NCIMS website under the APC. The APC has also provided this information to the individual States that currently have Grade "A" aseptic milk plants with IMS Listings; and to the FDA Regional Milk Specialists (RMSs). For the most current information, please contact Robert Hennes, FDA, at (240) 402-2175 or robert.hennes@fda.hhs.gov.

2. **PMO-Section 11 and Appendix S; and Procedures-Sections V and VIII**

Who determines which individuals are selected or authorized to give the NCIMS AP training? Are aseptic trainers certified?

The APC intends to conduct and directly supervise all training under the NCIMS Aseptic Program (AP). In the future, the APC may determine the criteria that aseptic trainers shall meet in order to conduct such training under the NCIMS AP.

3. **PMO-Section 11 and Appendix S; and Procedures-Sections V and VIII**

Must Regulatory Agency personnel and SROs responsible for the Grade "A" aseptic milk plant attend the NCIMS AP training course and obtain a certificate of attendance in order to conduct an inspection or rating of a Grade "A" aseptic milk plant.

Yes.

4. **PMO-Section 11 and Appendix S; and Procedures-Sections V and VIII**

Does an individual attending the NCIMS AP training course have to complete the entire training course, including the satisfactory completion of any written exam, in order to be NCIMS AP certified and receive a certificate?

Yes.

5. **PMO-Section 11 and Appendix S; and Procedures-Sections V and VIII**

Will there be a formal certificate issued for the attendees participating in the NCIMS AP training courses?

Yes.

6. **PMO-Section 11 and Appendix S; and Procedures-Sections V and VIII**

Who will issue the NCIMS AP training course certificate?

The NCIMS APC.

7. **PMO-Section 11 and Appendix S; and Procedures-Sections V and VIII**

Is the NCIMS AP training course certificate a lifetime certificate, i.e., attend once, pass the training course and attendance at additional NCIMS AP training course is not required?

Yes. However, currently the APC is discussing any additional required retraining requirements, along with a frequency, and nothing has been established at this time.

D. Processing Authority:

1. **PMO-Sections 1, 5 and 7, and Appendix S; Procedures-Sections III and VIII; and MMSR-Sections A and D**

Who is considered a "Processing Authority"?

There is not a specific definition for a "Processing Authority" in the Food and Drug Administration's (FDA's) Low-Acid Canned Foods (LACF) regulations within 21 CFR Parts 108 and 113. But the term is referenced and described in the following sections of the FDA regulations (21 CFR 113.83 and 113.89). "A processing authority is a person who has expert knowledge of thermal processing requirements for low-acid foods packaged in hermetically sealed containers. In addition, anyone who is establishing scheduled processes must have adequate facilities for making the appropriate determinations. Anyone who is evaluating process deviations which indicate irregularities or deficiencies in the delivery of the scheduled process must utilize procedures recognized by competent processing authorities as being adequate to detect any potential hazard to public health."

2. **PMO-Sections 1, 5 and 7, and Appendix S; Procedures-Sections III and VIII; and MMSR-Sections A and D**

How does FDA recognize someone who has this "Processing Authority" expert knowledge?

Knowledge can be obtained through education or experience or both. "Expert" implies experience, knowledge and achievement as well as recognition as an authority on a subject, usually by one's peers. In general a "Processing Authority":

- *Understands the science behind the scheduled process.*
- *Evaluates equipment based on sound scientific principles.*

- *Determines the critical factors and good manufacturing practices (GMPs) for operating above minimum conditions.*
- *Interprets FDA's regulations.*

3. **PMO-Sections 1, 5 and 7, and Appendix S; Procedures-Sections III and VIII; and MMSR-Sections A and D**

   Does FDA approve Processing Authorities?

   No. FDA does not maintain a list or formally recognize a "Processing Authority". FDA does not have specific statutory authority to require that processors obtain Agency prior approval before engaging the services of an individual or an organization to act as a "Processing Authority". There are certain groups and individuals, such as governmental bodies, trade associations, equipment manufacturers, food consulting firms, food container manufacturers, academic institutions, professors, and firms with a thermal processing expert on their staff.

4. **PMO-Sections 1, 5 and 7, and Appendix S; Procedures-Sections III and VIII; and MMSR-Sections A and D**

   If FDA does not approve Processing Authorities how can Regulatory Agency personnel, a Sanitation Rating Officer (SRO) or a FDA Regional Milk Specialist (RMS) be assured that a Grade "A" aseptic milk plant's "Processing Authority" is competent?

   The National Conference on Interstate Milk Shipments (NCIMS) Aseptic Program (AP) does not require Regulatory Agency personnel, a SRO or a RMS to evaluate the competency of a Grade "A" aseptic milk plant's "Processing Authority". This is the responsibility of FDA LACF program personnel. If the process filing has been accepted by FDA, then the "Processing Authority" is recognized by FDA and would be acceptable to the NCIMS AP.

5. **PMO-Sections 1, 5 and 7, and Appendix S; Procedures-Sections III and VIII; and MMSR-Sections A and D**

   What are the responsibilities of the "Processing Authority"?

   As stated in 21 CFR 113.83, a "Processing Authority":

   1) Must establish thermal processes;
   2) Must establish equipment operating procedures to ensure that commercially sterile product is produced. For aseptic products, these procedures will be outlined in the scheduled process; and

3) Is responsible for the evaluation of processing deviations (21 CFR 113.89) and to determine whether a specific lot is, or is not, a potential danger to health.

6. **PMO-Sections 1, 5 and 7, and Appendix S; Procedures-Sections III and VIII; and MMSR-Sections A and D**

What does a "Processing Authority" do to evaluate processing deviations?

The "Processing Authority" evaluation is usually based on a careful review of the processing and production records and the scientific evaluation of the actual processing conditions. The "Processing Authority" will provide a written evaluation report to the processor to document that if the process results in a deviation, the aseptic product is commercially sterile, meets the requirements for the minimal thermal process, or is unsafe. In all cases, the report should list the critical factors considered in the evaluation. In addition, if the "Processing Authority" evaluates a process deviation resulting in a product that may be unsafe they should inform the processor of their options (reprocess in accordance with a process established by qualified individuals or destroy the product) and remind them that FDA must be notified if any product has been distributed.

7. **PMO-Sections 1, 5 and 7, and Appendix S; Procedures-Sections III and VIII; and MMSR-Sections A and D**

So what specifically does a "Processing Authority" do to develop a scheduled process for aseptic products?

The answer to this question can vary depending on the complexity of the Aseptic Processing and Packaging System (APPS). Remember, APPSs are comprised of an aseptic processing system and an aseptic packaging system. Listed below are some of the activities that a "Processing Authority" will perform:

- *They review plans, drawings for an APPS to determine monitoring devices and locations, flow patterns, valving, etc.*
- *They review the control system and alarm details to determine critical factors*
- *They conduct microbial challenge tests and analyze data to prove that the APPS can be sterilized and that commercially sterile products are produced.*
- *If a chemical sterilant, such as hydrogen peroxide is used, they develop procedures for monitoring sterilant concentration, data to support that there are not any residues of sterilant on product contact surface and that harmful substances are not formed on the package.*

- *They document that a hermetic seal is formed and maintained on the finished packaged product.*
- *They conduct on-site testing of the entire APPS to determine compliance with applicable portions of 21 CFR 113.*

8. **PMO-Sections 1, 5 and 7, and Appendix S; Procedures-Sections III and VIII; and MMSR-Sections A and D**

   What records must a “Processing Authority” keep?

   As required in 21 CFR 113.83, the “Processing Authority” shall keep complete records covering all aspects of the establishment of a scheduled process, including associated incubation tests (21 CFR 113.83).

9. **PMO-Sections 1, 5 and 7, and Appendix S; Procedures-Sections III and VIII; and MMSR-Sections A and D**

   Since the “Processing Authority” does not inspect or have an "on-site" presence at a Grade "A" aseptic milk plant, who is responsible for the configuration of the APPS?

   The milk plant is responsible to make sure that the APPS is installed and operated consistent with the configuration when the scheduled process was developed by the “Processing Authority.

10. **PMO-Sections 1, 5 and 7, and Appendix S; Procedures-Sections III and VIII; and MMSR-Sections A and D**

    If the “Processing Authority” makes a mistake, what actions can be taken against the “Processing Authority”?

    FDA does not take direct regulatory action against Process Authorities. If a “Processing Authority” makes an error, which results in the production of an unsafe product, the Grade “A” aseptic milk plant is responsible for the correction of the problem, retrieval of the product and any resulting illnesses. However, a “Processing Authority” that demonstrates a lack of professional knowledge and/or sound judgment may no longer be recognized as a competent “Processing Authority” by the FDA. Historically, Processing Authorities recognized by FDA to handle aseptic systems have been highly qualified and have exhibited sound professional judgment.

11. **PMO-Sections 1, 5 and 7, and Appendices L and S; Procedures-Sections III, IV, V and VIII; and MMSR-Sections A and D**

    Does an FDA approved Better Process Control School provide the training necessary to become a “Processing Authority”?

No. The intent of the FDA approved Better Process Control Schools is to train plant supervisors on the required practices outlined in 21 Code of Federal Regulations (CFR) Parts 108, 110, and 113. This training allows them to recognize regulatory requirements and to supervise the thermal processing operation to ensure the parameters established by the "Processing Authority" are met and that appropriate records are completed and maintained.

E. Aseptic Critical Listing Elements (ACLEs):

1. **PMO-Sections 1 and 11, and Appendix S; Procedures-Sections III, IV, V and VIII; and MMSR-Sections A and C**

   What are the specific responsibilities of State regulatory personnel, Sanitation Rating Officers (SROs) and FDA Regional Milk Specialists (RMSs) related to the use and compliance determination of the Grade "A" Aseptic Program's (AP's) Aseptic Critical Listing Elements (ACLEs) cited on FORM FDA 2359p?

   The evaluation of the National Conference on Interstate Milk Shipments (NCIMS) AP ACLEs is the responsibility of the SROs and RMSs. They are evaluated at the beginning of a Grade "A" aseptic milk plant rating/check rating on a "Pass-Fail" basis. If a SRO or RMS determines that at least one (1) of the ACLEs is not in compliance ("Fails"), the rating/check rating is concluded and the Grade "A" aseptic milk plant is either denied an initial Interstate Milk Shippers (IMS) Listing or is immediately removed from the IMS List. There is not any requirement in the NCIMS AP for State regulatory personnel to evaluate ACLEs as a part of their routine Grade "A" aseptic milk plant inspection.

2. **PMO-Sections 1 and 11, and Appendix S; Procedures-Sections III, IV, V and VIII; and MMSR-Sections A and C**

   What resources and guidance are available to SROs and RMSs to evaluate the ACLEs cited on FORM FDA 2359p?

   Training guidance and recommendations on the proper evaluation of the ACLEs during a Grade "A" aseptic milk plant rating/check rating are provided by the NCIMS Aseptic Program Committee (APC). Specific questions can also be directed toward the APC's "Technical Review Team" for determining compliance by contacting Ms. Sue Esser at essers@michigan.gov.

3. **PMO-Sections 1 and 11, and Appendix S; Procedures-Sections III, IV, V and VIII; and MMSR-Sections A and C**

How does the SRO or RMS confirm that the Grade "A" aseptic milk plant is complying with any or all of the ACLEs?

The SRO or RMS shall request information that documents the milk plant's compliance with each of the four (4) ACLEs. If confirmation of any milk plant documentation is required, the SRO or RMS may contact the milk plant's "Process Authority" or the RMS, who in-turn can contact the Food and Drug Administration (FDA) Low-Acid Canned Foods (LACF) office to confirm any milk plant supplied information.

4. **PMO-Sections 1 and 11, and Appendix S; Procedures-Sections III, IV, V and VIII; and MMSR-Sections A and C**

Regarding NCIMS aseptic HACCP milk plants, how shall the NCIMS AP ACLEs be evaluated by SROs and RMSs during an audit or check audit?

A SRO or RMS shall evaluate all four (4) NCIMS AP ACLEs at the beginning of any Grade "A" aseptic milk plant audit or check audit. If the ACLEs are in compliance, then the remainder of the audit or check audit will follow the HACCP program requirements. If one (1) or more of the ACLEs are not in compliance ("Failed"), the rating or check rating would conclude, resulting in the milk plant either being denied an initial IMS Listing or the milk plant being immediately removed from the IMS List.

5. **PMO-Section 11 and Appendix S; Procedures-Section III, V and VIII; and MMSR-Sections A and C**

ACLE #1: Is the milk plant registered with FDA LACF and are all of the milk plant's low-acid aseptic Grade "A" milk and milk products covered by a filing with the FDA LACF using Form FDA 2541c or equivalent electronic filing?

How many FDA LACF filings are required for all of the different Grade "A" aseptic milk and milk products produced by a Grade "A" aseptic milk plant?

There is not any specific number of FDA LACF filings that are required as long as all of the Grade "A" aseptic milk and milk products are appropriately covered by at least one (1) filed scheduled process and its associated documents.

6. **PMO-Sections 1 and 11, and Appendix S; Procedures-Sections III, IV, V and VIII; and MMSR-Sections A and C**

ACLE #1: Is the milk plant registered with FDA LACF and are all of the milk plant's low-acid aseptic Grade "A" milk and milk products covered by a filing with the FDA LACF using Form FDA 2541c or equivalent electronic filing?

If a SRO or RMS requests documentation that the Grade "A" aseptic milk plant is registered with FDA LACF and all of their Grade "A" aseptic milk and milk products are covered by a filing with the FDA LACF using FORM FDA 2541c and the milk plant states they do not have any documentation at their location, but could obtain copies either from their corporate headquarters or their "Process Authority". What should the SRO or RMS do?

It is the responsibility of all Grade "A" aseptic milk plants to maintain FORM FDA 2541c and other related FDA LACF documents onsite because these documents are necessary for the SRO and RMS to review at the beginning of every rating or check rating. Failure to produce these documents in a reasonable amount of time will result in the SRO and RMS determining that ACLE #1 is not in compliance and has "Failed". This is consistent with current FDA LACF interpretation and enforcement of 21 CFR 113. 8.7, which states, that this information must be "readily available". The SRO or RMS shall conclude the rating or check rating and either deny the initial IMS Listing or immediately remove the aseptic milk plant's IMS Listing.

7. **PMO-Sections 1 and 11, and Appendix S; Procedures-Sections III, IV, V and VIII; and MMSR-Sections A and C**

ACLE #1: Is the milk plant registered with FDA LACF and are all of the milk plant's low-acid aseptic Grade "A" milk and milk products covered by a filing with the FDA LACF using Form FDA 2541c or equivalent electronic filing?

Is a scheduled process filed with FDA LACF for Grade "A" aseptic milk or milk product produced in an IMS listed Grade "A" aseptic milk plant required to be formally accepted by FDA in order for a SRO or RMS to give credit for ACLE #1?

No. ACLE #1 requires that a scheduled process be filed (submitted), but there is not a requirement that the filing be reviewed or accepted by FDA LACF prior to production or shipment. However, Grade "A" aseptic milk plants located outside of the U.S. or U.S. territories shall be required to demonstrate proof of FDA LACF acceptance of a filed process in order to comply with ACLE #1.

8. **PMO-Sections 1 and 11, and Appendix S; Procedures-Sections III, IV, V and VIII; and MMSR-Sections A and C**

ACLEs #1: Is the milk plant registered with FDA LACF and are all of the milk plant's low-acid aseptic Grade "A" milk and milk products covered by a filing with the FDA LACF using Form FDA 2541c or equivalent electronic filing?

During a rating, the SRO compares the list of Grade "A" aseptic milk and milk products produced by the milk plant against the documents provided by the milk plant for its LACF filings. All Grade "A" aseptic milk and milk products are covered by a filing; however, when reviewing the SUP-SID(s) attached to the LACF filings, the SRO observes that all aseptic filling equipment, which is being used per specific Grade "A" aseptic milk or milk product, is not being identified for that specific Grade "A" aseptic milk and milk product. Does this result in a determination of non-compliance for ACLE #1?

No. ACLE #1 for Grade "A" aseptic milk and milk products is specific to whether the milk plant is registered with FDA LACF and whether all of its aseptic Grade "A" milk and milk products are covered by an LACF filing. In this case, the SRO has confirmed that all aseptic Grade "A" milk and milk products are covered by a filing. The findings by the SRO related to some aseptic filling equipment not being covered by Supplemental Submission Identifiers (SUP-SID(s)) attached to the various filings are not related to the evaluation of ACLE #1. The SRO should inform the milk plant and may also contact the FDA LACF office via their FDA RMS to inform them of their findings regarding the SUP-SID(s) and filling equipment.

9. **PMO-Section 1 and 11, and Appendices L and S; Procedures-Sections III, IV, V and VIII; and MMSR-Sections A and C**

ACLE #1: Is the milk plant registered with FDA LACF and are all of the milk plant's low-acid aseptic Grade "A" milk and milk products covered by a filing with the FDA LACF using Form FDA 2541c or equivalent electronic filing"?

A Grade "A" aseptic milk plant has several filings for the same milk or milk product with the difference being the filler that is being utilized or different package sizes. Would it be acceptable for the Grade "A" milk plant to have one (1) filing for the same milk or product and cover the different fillers and packaging differences in the SUP-SID's?

It is possible to cover multiple Grade "A" aseptic milk plant filling machines if they are the same make and model on just one (1) FDA LACF milk or milk product filing, if a milk plant uses the "U.S. FDA Electronic Filing Process". This can be achieved at the present, by including the additional aseptic filler SUP-SID's in the "Comments" section provided on the electronic filing form. For different makes and models of aseptic filling machines, they would be

required to have their own separate SUP-SID's. This advice from the FDA LACF program may be subject to change, so please contact your FDA RMS, if needed, for additional information or clarification.

10. **PMO-Sections 1 and 11, and Appendices L and S; Procedures-Sections III, IV, V and VIII; and MMSR-Sections A and C**

ACLE #1: Is the milk plant registered with FDA LACF and are all of the milk plant's low-acid aseptic Grade "A" milk and milk products covered by a filing with the FDA LACF using Form FDA 2541c or equivalent electronic filing"?

A review of FORM FDA 2541c-Food Processing Filing for Low-Acid Aseptic Systems conducted by the SRO or RMS identifies that "milk" is listed on FORM FDA 2541c as one (1) of the covered milk and milk products, but there is not any specific information addressing another Grade "A" aseptic milk product, i.e., "Strawberry skim milk" on FORM FDA 2541c.. What should the SRO or RMS do?

The SRO or RMS would be required to determine if additional documents submitted with FORM FDA 2541c, reference or include "Strawberry skim milk" or if the processor has a letter from the Process Authority, which provides for the "Strawberry skim milk" to be processed using the same requirements as "milk". If the processor is using a letter from the Process Authority, it must be dated before the date of the filing or must clearly indicate that such variations to the category "milk" were contemplated or reviewed by the Process Authority as part of the process, which was filed or amended to include "Strawberry skim milk".

11. **PMO-Sections 1 and 11, and Appendices L and S; Procedures-Sections III, IV, V and VIII; and MMSR-Sections A and C**

ACLE #1: Is the milk plant registered with FDA LACF and are all of the milk plant's low-acid aseptic Grade "A" milk and milk products covered by a filing with the FDA LACF using Form FDA 2541c or equivalent electronic filing"?

A review of FORM FDA 2541c conducted by the SRO or RMS identifies that "flavored milk" is listed on FORM FDA 2541c as one (1) of the covered Grade "A" milk and milk products, but there is not any specific information about the Grade "A" milk product, i.e., "Strawberry skim milk", on FORM FDA 2541c. What should the SRO or RMS do?

The SRO or RMS would be required to determine if additional documents submitted with FORM FDA 2541c, reference or include "Strawberry skim milk" or if the processor has a letter from the Process Authority which provides for the "Strawberry skim milk" to be processed under the same requirements as "flavored milk". This letter from the Process Authority must

*be dated before the date of the filing or must clearly indicate that such variations to the category "flavored milk" were contemplated or reviewed by the Process Authority as part of the process which was filed or amended to include "Strawberry skim milk**".***

12. **PMO-Sections 1 and 11, and Appendices L and S; Procedures-Sections III, IV, V and VIII; and MMSR-Sections A and C**

ACLE #1: Is the milk plant registered with FDA LACF and are all of the milk plant's low-acid aseptic Grade "A" milk and milk products covered by a filing with the FDA LACF using Form FDA 2541c or equivalent electronic filing"?

If a SRO or RMS finds a Grade "A" aseptic milk plant producing eggnog without a filed process, but the milk plant states that the filed process for chocolate milk is being used for eggnog, is this considered a violation of **ACLE #1** on FORM FDA 2359p-NCIMS Aseptic Processing and Packaging Program Critical Listing Elements (Low-Acid (pH greater than 4.6) Aseptic Milk and Milk Products)?

Yes. A process was not filed for eggnog and ACLE #1 would be identified as not being in compliance and the milk plant's Grade "A" aseptic IMS listing would be denied or immediately withdrawn.

13. **PMO-Sections 1 and 11, and Appendices L and S; Procedures-Sections III, IV, V and VIII; and MMSR-Sections A and C**

ACLE #1: Is the milk plant registered with FDA LACF and are all of the milk plant's low-acid aseptic Grade "A" milk and milk products covered by a filing with the FDA LACF using Form FDA 2541c or equivalent electronic filing"?

Who determines if a change in Grade "A" milk or milk product formulation requires a new filing with FDA LACF?

It is the responsibility of the Grade "A" aseptic milk plant to inform their "Process Authority" of any Grade "A" milk or milk product formulation changes. The "Process Authority" will determine whether the existing filing will cover the new Grade "A" milk or milk product formulation. If requested by the Regulatory Agency inspector, SRO or RMS, Grade "A" aseptic milk plant personnel shall be able to provide written documentation of such a Process Authority's determination.

14. **PMO-Sections 1 and 11, and Appendices L and S; Procedures-Sections III, IV, V and VIII; and MMSR-Sections A and C**

ACLE #1: Is the milk plant registered with FDA LACF and are all of the milk plant's low-acid aseptic Grade "A" milk and milk products covered by a filing with the FDA LACF using Form FDA 2541c or equivalent electronic filing"?

Does a change in manufacturer for the same ingredient, i.e., cocoa, starch, etc., which is used in a Grade "A" aseptic milk or milk product, require the milk plant to notify their "Process Authority" of a change in Grade "A" milk or milk product formulation?

Yes.

15. **PMO-Sections 1 and 11, and Appendix S; Procedures-Sections III, IV, V and VIII; and MMSR-Sections A and C**

ACLE #1: Is the milk plant registered with FDA LACF and are all of the milk plant's low-acid aseptic Grade "A" milk and milk products covered by a filing with the FDA LACF using Form FDA 2541c or equivalent electronic filing?

If SROs or RMSs identify a Grade "A" aseptic milk or milk product that is not covered by a filed scheduled process that has been submitted to FDA LACF, but milk plant personnel state the Grade "A" aseptic milk or milk product is being "test marketed", what is the appropriate action?

The FDA LACF program allows for the "test marketing" of aseptic products under certain conditions therefore, the Grade "A" aseptic milk or milk product being "test marketed" must be covered by a scheduled process filed with FDA LACF. With the scenario cited above, ACLE #1 would not be in compliance ("Fail") and would require the denial of an initial IMS Listing or the immediate removal of the aseptic milk plant's IMS Listing.

NOTE: *"Test marketing" involves an aseptic milk plant that is aseptically processing and packaging milk and milk products for R&D use only (analytical testing, shelf-life studies, employee taste testing, processing parameter experimentation, batch formulation testing, etc.). It does not include aseptically processing and packaging milk and milk products used for general consumer consumption (consumption taste panels, in-store demos, trial runs for limited distribution, etc.).*

16. **PMO-Sections 1 and 11, and Appendix S; Procedures-Sections III, IV, V and VIII; and MMSR-Sections A and C**

ACLE #1: Is the milk plant registered with FDA LACF and are all of the milk plant's low-acid aseptic Grade "A" milk and milk products covered by a filing with FDA LACF using Form FDA 2541c or equivalent electronic filing?

Is a scheduled process filed with FDA LACF for Grade "A" aseptic milk or milk product produced in a new or an unlisted aseptic milk plant required to be formally reviewed and accepted by FDA LACF in order for a SRO or RMS to give credit for ACLE #1?

Yes. A scheduled process filing for Grade "A" milk and milk products from a new or an unlisted Grade "A" aseptic milk plant must first be reviewed and accepted by FDA LACF in order for a SRO or RMS to give credit for ACLE #1. Once the IMS listing is granted, production and shipment of Grade "A" aseptic milk and milk products for interstate commerce may occur. For future ratings or check ratings, a SRO or RMS shall give credit for ACLE #1 if any new Grade "A" aseptic milk and milk products are covered by a scheduled process that has been filed with FDA LACF.

17. **PMO-Sections 1 and 11, and Appendix S; Procedures-Sections III, IV, V and VIII; and MMSR-Sections A and C**

ACLEs #1: Is the milk plant registered with FDA LACF and are all of the milk plant's low-acid aseptic Grade "A" milk and milk products covered by a filing with the FDA LACF using Form FDA 2541c or equivalent electronic filing?

ACLE #2: Are the milk plant's filed scheduled processes for all of its low-acid aseptic Grade "A" milk and milk products developed by a recognized Process Authority qualified as having expert knowledge of thermal process requirements?

How does a SRO or RMS determine what is meant by "all products" in ACLEs #1 and #2?

The aseptic milk plant shall supply, upon request, a list of all Grade "A" aseptic milk and milk products they produce and this list shall be used as the basis to evaluate ACLEs #1 and #2. It is also appropriate for the SRO or RMS to make their own determination during the rating or check rating to ensure that all Grade "A" aseptic milk and milk products produced by the milk plant are addressed in both ACLEs #1 and #2.

18. **PMO-Sections 1 and 11, and Appendix S; Procedures-Sections III, IV, V and VIII; and MMSR-Sections A and C**

ACLE #2: Are the milk plant's filed scheduled processes for all of its low-acid aseptic Grade "A" milk and milk products developed by a recognized Process Authority qualified as having expert knowledge of thermal process requirements?

The SRO or RMS requests from the Grade "A" aseptic milk plant, the name and contact information for their "Process Authority", which the milk plant provides. This identified "Process Authority" is different than the name appearing on FORM FDA 2541c and related documents. What should the SRO or RMS do?

ACLE #2 requires that the "Process Authority", whose name appears on FORM FDA 2541c and related documents, is a recognized "Process Authority" qualified as having expert knowledge of thermal processing according to FDA. A filed and accepted FORM FDA 2541c and related documents serve as evidence of this. Some filed processes can be many years old and it would be reasonable for a Grade "A" aseptic milk plant to use a different "Process Authority" than the one on the filed FORM FDA 2541c, based on retirement or other factors. As long as the name on the filed FORM FDA 2541c is acceptable to FDA, the answer to ACLE #2 would be "YES".

19. **PMO-Sections 1 and 11, and Appendix S; Procedures-Sections III, IV, V and VIII; and MMSR-Sections A and C**

ACLE #2: Are the milk plant's filed scheduled processes for all of its low-acid aseptic Grade "A" milk and milk products developed by a recognized Process Authority qualified as having expert knowledge of thermal process requirements?

If the name of the "Process Authority" identified on FORM FDA 2541c is no longer active or employed by the Grade "A" aseptic milk plant, does this result in the SRO or RMS determining that ACLE #2 is not in compliance ("Failed")?

ACLE #2 is very clear that the milk plant's filed schedule processes for all low-acid aseptic Grade "A" milk and milk products must be developed by a recognized Process Authority qualified as having expert knowledge of thermal processing requirements. The SRO or RMS shall confirm that the Process Authority is recognized and accepted by referencing the current FORM FDA 2541c for all Grade "A" aseptic milk and milk products. If this is confirmed by FORM FDA 2541c, then the answer for ACLE #2 would be "YES".

FDA indirectly acknowledges a "Process Authority" by acceptance of FORM FDA 2541c and related LACF documents, since the Process Authority is identified on the Form. However, ACLE #2 does not require continued operational oversight of the Grade "A" aseptic milk plant once the scheduled process has been developed by a "Process Authority" and filed.

20. **PMO-Sections 1 and 11, and Appendices L and S; Procedures-Sections III, IV, V and VIII; and MMSR-Sections A and C**

ACLE #3: Are the operators of the milk plant's aseptic processing and packaging systems under the supervision of a person who has attended a school approved by the FDA (such as Better Process Control School or recognized equivalent)?

Is there a list of acceptable Better Process Control Schools that are approved by the FDA Commissioner that would qualify under ACLE #3 on FORM FDA 2359p-NCIMS Aseptic Processing and Packaging Program Critical Listing Elements (Low-Acid (pH greater than 4.6) Aseptic Milk and Milk Products)? If so, where can this list be found?

There is not an official list; however, by conducting an Internet search, a list of Better Process Control Schools and schedule of classes can be found. FDA determines which Better Process Control Schools meet the intent of 21 CFR Parts 108, 110 and 113. If there are questions about a certificate from a specific Better Process Control Schools, contact that school for confirmation of their approval by FDA. Concern may be addresses to the FDA Office of Food Safety's Food Processing Evaluation Team (FPET) (240) 402-1781.

21. **PMO-Sections 1 and 11, and Appendices L and S; Procedures-Sections III, IV, V and VIII; and MMSR-Sections A and C**

ACLE #3: Are the operators of the milk plant's aseptic processing and packaging systems under the supervision of a person who has attended a school approved by the FDA (such as Better Process Control School or recognized equivalent)?

Are all operators of the APPS required to attend a FDA-approved Better Process Control School?

No. The FDA LACF regulations (21 CFR Parts108, 110 and 113) require that operators of the APPS must be under the operating supervision ("readily available") of a person who has attended a Better Process Control School approved by the FDA Commissioner.

22. **PMO-Sections 1 and 11, and Appendices L and S; Procedures-Sections III, IV, V and VIII; and MMSR-Sections A and C**

ACLE #3: Are the operators of the milk plant's aseptic processing and packaging systems under the supervision of a person who has attended a school approved by the FDA (such as Better Process Control School or recognized equivalent)?

How would SROs or RMSs determine whether a Grade "A" aseptic milk plant supervisor has attended a FDA approved Better Process Control School or equivalent in order to determine whether ACLE #3 is in compliance ("pass") or not in compliance ("Fail")?

The Grade "A" aseptic milk plant is required to have at least one (1) operating supervisor who has attended a Better Process Control School approved by the FDA Commissioner. This supervisor shall have a certificate to verify such attendance. If there is a question regarding a Better Process Control School certificate, contact the school in question to verify attendance by the individual. If there is still a concern, FDA's FPET may be contacted at (240) 436-2069 or e-mail Dan Geffin at dan.geffin@fda.hhs.gov.

23. **PMO-Sections 1 and 11, and Appendices L and S; Procedures-Sections III, IV, V and VIII; and MMSR-Sections A and C**

ACLE #3: Are the operators of the milk plant's aseptic processing and packaging systems under the supervision of a person who has attended a school approved by the FDA (such as Better Process Control School or recognized equivalent)?

Is the "approved by the FDA Commissioner (such as a Better Process Control School or recognized equivalent)" fulfilled by someone having a Better Process Control School certificate at the corporate level, who is at another location away from the Grade "A" aseptic milk plant?

No. FDA has interpreted this requirement of the LACF program as requiring that at least one (1) individual shall be readily available locally per aseptic milk plant that has attended a school approved by the FDA Commissioner (such as a Better Process Control School or recognized equivalent) and can provide a certificate of completion.

24. **PMO-Sections 1 and 11, and Appendix S; Procedures-Sections III, IV, V and VIII; and MMSR-Sections A and C**

ACLE #3: Are the operators of the milk plant's aseptic processing and packaging systems under the supervision of a person who has attended a

school approved by FDA (such as Better Processing Control School or recognized equivalent)?

The SRO or RMS learns from milk plant management that the person responsible for the supervision of the operators of the aseptic processing and packaging systems to satisfy ACLE #3 is their corporate quality control director that visits the milk plant about once every month. The milk plant produces a copy of the corporate quality control director's certificate documenting successful completion of a Better Processing Control School sanctioned by FDA. What should the SRO or RMS do?

It is the intent of ACLE #3 that the operators be under the supervision of a person who has attended a school approved by the FDA (such as Better Process Control School or recognized equivalent) and means that the individual(s) is available locally, not at some remote location. This also is interpreted to mean that the supervisor does not have to be present at all times during aseptic processing and packaging. The answer by the SRO or RMS for ACLE #3 would be "NO" the aseptic milk plant would not be in compliance ("Failed") and the rating or check rating would conclude, resulting in the milk plant either being denied an initial IMS Listing or the milk plant being immediately removed form the IMS List.

25. **PMO-Sections 1 and 11, and Appendix S; Procedures-Sections III, IV, V and VIII; and MMSR-Sections A and C**

ACLE #3: Are the operators of the milk plant's aseptic processing and packaging systems under the supervision of a person who has attended a school approved by FDA (such as Better Processing Control School or recognized equivalent)?

The SRO or RMS learns from milk plant management that the person responsible for the supervision of the operators of the aseptic processing and packaging systems has left the milk plant for other employment about a month ago. The milk plant has designated another individual to serve as the supervisor and this individual is scheduled to attend an FDA recognized Better Process Control School within two (2) months. After further discussion and a check with FDA, the SRO or RMS learns that there is not another Better Process Control School available prior to that time and there has not been any during the previous month after the LACF supervisor left the milk plant. The SRO or RMS also checks with the milk plant's "Process Authority", who is aware of the situation. What should the SRO or RMS do?

ACLE #3 is very clear that at the time of the rating or check rating, the Grade "A" aseptic milk plant must have a person serving as a supervisor with documentation confirming attendance at a FDA recognized Better Process Control School or recognized equivalent. In this scenario, the SRO or RMS's

answer for ACLE #3 would be "NO" and the aseptic milk plant would not be in compliance ("Failed") and the rating or check rating would conclude, resulting in the milk plant either being denied an initial IMS Listing or the milk plant being immediately removed from the IMS List.

26. **PMO-Sections 1 and 11, and Appendix S; Procedures-Sections III, IV, V and VIII; and MMSR-Sections A and C**

ACLE #3: Are the operators of the milk plant's aseptic processing and packaging systems under the supervision of a person who has attended a school approved by FDA (such as Better Processing Control School or recognized equivalent)?

If a supervisor that has attended a Better Process Control School has left and a new school isn't available for two (2) months then the milk plant is automatically removed from the IMS List because of ACLE #3 not being in compliance ("Failed"). This excludes the possibility of a nearby milk plant providing a Better Process Control School trained supervisor or even contracting out for one. Wouldn't these be better options than the milk plant being removed from the IMS List?

ACLE #3 is very clear that at the time of the rating or check rating, the Grade "A" aseptic milk plant shall have a person serving as a supervisor with documentation confirming attendance at a FDA accepted Better Process Control School or recognized equivalent. This means that the individual(s) shall be available locally and not at some remote location. In this scenario, the SRO or RMS's answer for ACLE #3 would be "NO" and the aseptic milk plant would not be in compliance ("Failed") and the rating or check rating would conclude, resulting in the milk plant either being denied an initial IMS Listing or the milk plant being immediately removed from the IMS List.

27. **PMO-Sections 1 and 11, and Appendix S; Procedures-Sections III, IV, V and VIII; and MMSR-Sections A and C**

ACLE #4: Is the milk plant currently under an "Order of Determination of Need" for an Emergency Permit?

Please provide an explanation of how an SRO or an RMS would determine whether a Grade "A" aseptic milk plant is meeting the requirements of ACLE #4 for aseptic milk and milk products.

An "Order of Determination of Need" for an Emergency Permit is issued by FDA to a plant producing food regulated under 21 CFR Parts 108, 110 and 113 when it is determined that the plant cannot consistently produce foods safely and in compliance with these regulations. A SRO or RMS shall request of the Grade "A" aseptic milk plant whether they have received an

"Order of Determination of Need" for an Emergency Permit from FDA. The SRO may verify the milk plant's response by contacting their RMS.

NOTE: *Whenever it is determined that a Grade "A" milk plant is to be issued an FDA "Order of Determination of Need" for an Emergency Permit, FDA LACF shall contact FDA's Dairy and Egg Branch and the appropriate RMS. The RMS shall contact the Dairy Regulatory/Rating Agency and request the immediate withdrawal of the IMS Listings for this Grade "A" aseptic milk plant. The Rating Agency shall immediately inform the Grade "A" aseptic milk plant and all known receiving States that the milk plant's IMS Listing will be immediately withdrawn.*

Following FDA's lifting or removal of an "Order of Determination of Need" for an Emergency Permit and the subsequent issuance of an Emergency Permit, which allows for the production and shipment of product, or the revocation of the need for an Emergency Permit, the Grade "A" aseptic milk plant that desires an IMS Listing shall submit written notification from an authorized milk plant representative to their Rating Agency requesting a new rating for an IMS Listing.

28. **PMO-Sections 1 and 11, and Appendices L and S; Procedures-Sections III, IV, V and VIII; and MMSR-Sections A and C**

ACLE #4: Is the milk plant currently under an "Order of Determination for Need" for an Emergency Permit.

If a Grade "A" aseptic milk plant is also producing non-Grade "A" aseptic products and is under a FDA "Order of Determination for Need" for an Emergency Permit for the non-Grade "A" aseptic products, what impact will this have on the "Pass-Fail" determination by the SRO or RMS for ACLE #4 for the Grade "A" aseptic milk and milk products?
The SRO or RMS would ("Fail") the Grade "A" aseptic milk plant on ACLE #4 if Grade "A" aseptic milk and/or milk products were produced on the production lines and equipment that are specifically addressed in the FDA LACF's "Order of Determination for Need" for an Emergency Permit and immediately deny a listing or remove the milk plant's Grade "A" aseptic IMS listing.

APPENDIX S. ASEPTIC PROCESSING AND PACKAGING PROGRAM

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

Inspections of a milk plant or portion of a milk plant that is IMS listed to produce aseptically processed and packaged milk or milk products shall be conducted by the Regulatory Agency in accordance with this *Ordinance* and the information provided below at least once every six (6) months. The APPS, as defined by this *Ordinance,* shall be exempt from Items 7p, 10p, 11p, 12p, 13p, 15p, 16p, 17p, 18p, and 19p of this *Ordinance* and shall comply with the applicable portions of 21 CFR Parts 108, 110 and 113. The milk plant's APPS shall be inspected by FDA, or the State Regulatory Agency when designated by FDA, in accordance with the applicable requirements of 21 CFR Parts 108, 110 and 113 at a frequency determined by FDA.

When the APPS, as defined by this *Ordinance*, is utilized to produce aseptically processed and packaged milk or milk products and pasteurized and/or ultra-pasteurized milk and milk products, the APPS shall be inspected and tested by the Regulatory Agency in accordance with the requirements cited in Section 7 of this *Ordinance*.

ASEPTIC PROCESSING AND PACKAGING PROGRAM CFR/PMO COMPARISON SUMMARY REFERENCE

PMO, Section 7 Items	Aseptic Program	Authority
1p. Floors – Construction	Floor drains are not required in storage rooms for aseptic processed and packaged milk or milk products.	PMO
2p. Walls and Ceiling – Construction	Ceiling requirements are exempt in aseptically processed and packaged milk or milk products dry storage rooms. (Same as for dry milk or milk products.)	PMO
3p. Doors and Windows	None	PMO
4p. Lighting and Ventilation	None	PMO
5p. Separate Rooms	Fabrication of containers and closures for aseptic processed and packaged milk and milk products within the APPS is exempt.	PMO
6p. Toilet – Sewage Disposal Facilities	None	PMO

PMO, Section 7 Items	Aseptic Program	Authority
7p. Water Supply*	The APPS 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 is exempt, but shall comply with the CFR.	PMO/CFR
11p. Construction and Repair of Containers and Equipment*	The APPS 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 or milk products that have been aseptically processed and packaged are not required to comply with Appendix J of the PMO; are not required to originate from an IMS Listed Source; and are subject to the requirements of the CFR.	PMO/CFR
12p. Cleaning and Sanitizing of Containers and Equipment*	The APPS is exempt, but shall comply with the CFR.	PMO/CFR
13p. Storage of Cleaned Containers and Equipment*	The APPS is exempt, but shall comply with the CFR.	PMO/CFR
14p. Storage of Single-Service Containers, Utensils and Materials	None	PMO
15p.(A) Protection from Contamination*	The APPS is exempt, but shall comply with the CFR.	PMO/CFR
15p.(B) Protection from Contamination - Cross Connections*	The APPS is exempt, but shall comply with the CFR. APPS equipment is exempt from the separation requirements of the PMO in relationship to instrumented steam blocks between milk and milk products and cleaning and/or chemical sanitizing solutions.	PMO/CFR
16p. Pasteurization and Aseptic Processing and Packaging (A) through (D)*	The APPS is exempt, but shall comply with the CFR. The State Regulatory Agency is not required to conduct the quarterly equipment testing and sealing of aseptic processing equipment. Records and recording charts are not required to be reviewed during	CFR

PMO, Section 7 Items	Aseptic Program	Authority
	routine inspections, State ratings or check ratings.	
17p. Cooling of Milk and Milk Products*	The APPS and aseptic processed and packaged product storage is exempt, but shall comply with the CFR.	PMO/CFR
18p. Bottling, Packaging and Container Filling*	The APPS is exempt, but shall comply with the CFR.	CFR
19p. Capping, Container Closure and Sealing and Dry Milk Product Storage*	The APPS is exempt, but shall comply with the CFR.	CFR
20p. Personnel -Cleanliness	None	PMO
21p. Vehicles	None	PMO
22p. Surroundings	None	PMO

* **NOTE:** In areas of the milk plant where these Items are dedicated only to the APPS, as defined by this *Ordinance*, these Items shall be inspected and regulated in accordance with the applicable FDA regulations (21 CFR Parts 108, 110 and 113).

ACRONYMS:

ACLE - Aseptic Critical Listing Element
AP - Aseptic Program
APC-Aseptic Program Committee
APPIC - Aseptic Pilot Program Implementation Committee
APPS - Aseptic Processing and Packaging System
CCP - Critical Control Point
CFR - Code of Federal Regulations
CLE - Critical Listing Element
DEB - Dairy and Egg Branch
ESL - Extended Shelf Life
FCE - Food Canning Establishment
FDA - Food and Drug Administration
FPET - Food Processing Evaluation Team
HHST - Higher-Heat-Shorter-Time
HTST - High-Temperature-Short-Time
ICPP – International Certification Pilot Program
IMS - Interstate Milk Shipment
LACF - Low Acid Canned Foods
NCIMS – National Conference on Interstate Milk Shipments
PMO - Pasteurized Milk Ordinance
RI – Regulatory Inspector
RMS - Regional Milk Specialist
SRO - Sanitation Rating Officer
SUP-SID - Supplemental Submission Identifier
UHT - Ultra-High Temperature
UP - Ultra-Pasteurized

NCIMS Forms

FORM FDA 2359-Milk Plant Inspection Report (10/11)
FORM FDA 2359h-Interstate Milk Shipper's Check Rating Report (10/11)
FORM FDA 2359i-Interstate Milk Shipper's Report (10/11)
FORM FDA 2359j-Milk Sanitation rating Report (10/11)
FORM FDA 2359L-Status of Milk Plants (10/11)
FORM FDA 2359o-Permission for Publication (10/10)
FORM FDA 2359p-NCIMS Aseptic Processing and Packaging Program Critical Listing Elements (10/11)
FORM FDA 2541-Food Canning Establishment
FORM FDA 2541a-Food Process Filing for All Methods except Low-Acid Aseptic
FORM FDA 2541c-Food Process Filing for Low-Acid Aseptic Systems

APPENDIX

Process Authority and Better Process Control Schools:

Better Process Control Schools are concerned with the requirements and regulations involved in daily aseptic plant operations. After successful completion of the Better Process Control School, plant supervisors are trained to oversee equipment operators, review records to ensure all critical data is being recorded, and ensure that various thermal systems are operating properly. Their training is to ensure that they can properly supervise personnel to ensure minimum standards are met. On the other hand, a Process Authority is concerned with the scientific principles behind scheduled processes. He or she provides scheduled processes, evaluates process deviations, validates equipment, and provides the information necessary to file scheduled processes with the Agency. Unlike the trained supervisor, who ensures that the minimum standards are being met, the Process Authority determines the actual minimum standards to be met. Neither the Better Process Control Schools nor the federal regulations indicate that an individual who completes the Better Process Control School training program is capable of serving as a Process Authority.

Better Process Control Schools are concerned with the day-to-day operations of a registered low-acid or acidified plant. These schools are set up to train plant supervisors on the current Good Manufacturing Practices (cGMPs) prescribed in 21 CFR Parts 108, 113 and 114, which allows them to perform their jobs in an educated and responsible manner. The course is completed in four (4) days and provides a rudimentary base of knowledge in each of the covered areas. The program covers topics which are necessary to work within the framework of the federal regulations, including:

Microbiology
Food Container Handling
Record Keeping
Instrumentation Glass Closures
Still Retorts - Steam
Aseptic Systems
Agitating Cookers - Continuous
Hydrostatic Retorts
Acidified Food
Food Plant Sanitation
Thermal Process Principles
Retortable Flexible Containers
Still Retorts – Water
Metal Closures
Agitating Cookers – Discontinuous

Better Process Control Schools aim to provide the food canning industry with qualified personnel equipped to meet the intent of the FDA and USDA Regulations. The Code of Federal Regulations does not provide a specific definition for Better Process Control Schools, but simply states the scope of its function. The federal regulations require all processors of thermally processed low-acid or acidified foods, which are packaged in hermetically sealed containers, to have certain critical operations under the supervision of personnel who have successfully completed a school of instruction for the appropriate preservation

technology including canned food operations, retorts, processing equipment, aseptic processing & packaging systems, and container closure. This person shall supervise only in those areas which he or she has been identified as having satisfactorily completed.

Process Authorities must understand the scientific principles behind scheduled processes. Process Authorities evaluate process deviations, validate equipment and provide the information necessary to develop and file scheduled processes in accordance with current Good Manufacturing Practices (cGMPs) prescribed in 9 CFR Part 318 and 21 CFR Part 113. The FDA expects a Process Authority to have a certain level of expertise in a variety of scientific disciplines such as microbiology, engineering, mathematics, thermal processing, food technology, chemistry, physics, and product formulation development. In addition, a Process Authority is expected to have experience, knowledge, achievement, and peer recognition as an authority on thermal processing requirements for low-acid and acidified foods packaged in hermetically sealed containers. It should be noted that the federal regulations do not specifically define all of the attributes of a Process Authority, just as they do not distinctly define all of the alarms and monitors, which must be installed on a piece of food processing equipment. Although a precise description of a Process Authority does not exist, a more accurate definition can be established when examining what is expected of a Process Authority. Process Authorities are expected to:

1. Recognize the inadequacies or inexperience of a processor and provide him or her with sufficient information to ensure the processor understands what factors are operationally critical;
2. Determine how to monitor and control the critical factors of a process;
3. Understand what to do if a process failure occurs,
4. Investigate and assess a process failure, determine the cause, and be able to make a recommendation on how to prevent a recurrence;
5. Make a determination on the safety of the product produced when a process failure occurs;
6. Investigate and understand the changes or innovations in processing equipment, product formulations and processing methods and how they affect the critical factors; thus potentially adversely affecting product/package safety; and
7. Understand all pertinent US Food Laws & Regulations, be able to interpret them and know how they affect the product manufacturer’s facility and processing methods