

NCIMS Aseptic Pilot Program (APP) Questions & Answers April 21, 2011

These questions have been assembled from many sources. The answers to these questions have been developed by the NCIMS Aseptic Pilot Program Implementation Committee (APPIC). It is intended that this be a living document that is modified, corrected, adjusted and added to throughout the entire life of the NCIMS Aseptic Pilot Program (APP). The questions and answers are in no 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. What's wrong with the current system? If it's not broken, don't fix it is my philosophy.

Answer: Certainly many people feel this way. However, many of those involved do think the current system was "broken." Essentially, the "problem" is that aseptic Grade "A" milk and milk products are subject to two sets of regulations (i.e., the PMO and CFRs 108, 110 and 113), and this caused confusion, duplication, and some higher costs to industry. Industry certainly had objections to this, and regulators have also experienced confusion and frustration. The NCIMS Aseptic Pilot Program (APP) is intended to evaluate certain ideas and approaches to reduce duplication and utilize the strengths of both the PMO and FDA's LACF programs.

2. As a regulator, I am responsible for the safety of milk products in my State. I'm concerned that I won't have enough control over these milk products just because they are aseptic.

Answer: Many members of the NCIMS APPIC that are State regulators originally felt the same way when developing the APP. However, after understanding in much greater detail the long history of the safety of Grade "A" aseptic milk and milk products and the strong science of food safety associated with the FDA LACF regulations, we came to believe that it is more logical for the CFRs to regulate the aseptic processing and packaging systems and the PMO to regulate the other areas because that is where the strength and expertise of the two regulatory programs reside.

3. But are aseptic milk and milk products safe if they are under the CFRs alone?

Answer: Yes. Aseptic products produced under FDA's LACF program have a 35 - year track record of food safety. Aseptically processed milk and milk products are adequately protected under 21 CFR 108, 110, and 113. Processing under these federal statutes ensures that the product has been subjected to aseptic processing and is packaged into sterile containers, followed by hermetically sealing the sterile container with a sterilized closure in an atmosphere free of microorganisms. These critical areas of aseptic processing and packaging have been reviewed and designed by a designated Process Authority that must evaluate any deviations in the processing and packaging system, assuring the safety of the product.

4. Sounds like a big confusing mess to me...some PMO, some CFR. How do you know this is going to work?

Answer: We understand this point. It is the intent of the APP to determine whether the ideas to reduced duplication and build on the strengths of both the PMO and FDA LACF programs can be effective and practically implemented without compromising the safety of Grade "A" aseptic milk and milk products. There is actually a beautiful simplicity to the APP where everyone benefits from the best of both regulations. CFRs are used when they are most appropriate (i.e., in the Aseptic Processing and Packaging System (APPS)). The PMO is used everywhere else.

5. I understand the main focus of the Proposal (i.e., some parts of the aseptic milk plant are under the CFRs and other parts are under the PMO), but what are the other key elements of the Proposal?

Answer: Other key elements include:

- The role and responsibilities of the FDA LACF investigator, State regulatory personnel, State Rating Officers (SROs) and FDA Regional Milk Specialists (RMSs) are defined and written.
- NCIMS-sponsored training will be provided and is mandatory for all regulatory and rating personnel responsible for the oversight of Grade "A" aseptic milk plants.
- The process for the issuance of a State license/permit to an aseptic milk plant is not affected.
- The testing and sealing of aseptic processing and packaging equipment by the Regulatory Agency is not required.
- A clarification that regulatory sampling and testing of aseptic processed and packaged milk and milk products is not required.

6. Why is there a pilot program?

Answer: One of the goals of the APPIC is to evaluate the effectiveness of this new way of regulating Grade "A" aseptic milk plants to reduce the duplication caused by two strong regulatory programs; the NCIMS and the FDA LACF. For example, the APPIC will evaluate whether or not the regulatory and rating methods used in the APP provide a similar level of oversight, enforcement and compliance with the current system, while reducing duplication and regulatory resources committed to the oversight of Grade "A" aseptic milk plants. This evaluation period provides the APPIC with the opportunity to review and fine-tune its concepts and report back to the 2009 NCIMS Conference.

7. How is the pilot program going to work?

Answer: An APPIC has been formed in accordance with Proposal #303 as passed by the 2007 NCIMS Conference delegates and concurred with by FDA and the NCIMS Executive Board. The APPIC is charged with the oversight of the APP in consultation with FDA. All milk plants producing IMS-listed Grade "A" aseptic milk and milk products will be included in the APP. The APP shall take immediate effect upon each participating State's regulatory and rating personnel being trained in the implementation of the APP. Until this is accomplished, Grade "A" aseptic milk plants will be inspected and rated using the current system.

8. What about Grade "A" aseptic milk plants participating in the International Certification pilot program. Are they included in the NCIMS APP?

Answer: Yes, provided that the Third Party Certifier's regulatory and rating personnel responsible for the regulatory inspection and IMS rating of the Grade "A" aseptic plants under the ICPP have successfully completed the mandatory APPIC training, similar to their State counterparts.

9. How many facilities will this affect?

Answer: Approximately 24 IMS Listed Grade "A" aseptic milk plants in about 16 States/Territories/Countries. All these milk plants have entered the NCIMS APP once State regulatory personnel and SROs have completed the mandatory training sponsored by the NCIMS APPIC.

B. General:

1. Which Grade "A" aseptic milk plants are required to participate in the NCIMS APP?

Answer: All Grade "A" aseptic milk plants are required to participate in the NCIMS APP as soon as State regulatory personnel and SROs responsible for the plant(s) in their State have completed the mandatory training developed and sponsored by the APPIC.

2. 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?

Answer: There is no 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 filed scheduled process and its associated documents.

3. A review of FORM FDA 2541c conducted by the SRO/RMS identifies that "milk" is listed on the 2541c as one of the covered milk and milk products, but there is not any specific information addressing another Grade "A" aseptic milk product, "Strawberry skim milk", on the 2541c. What should the SRO/RMS do?

Answer: The SRO/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" was contemplated or reviewed by the Process Authority as part of the process, which was filed or amended to include "Strawberry skim milk."

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

Answer: The SRO/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" was contemplated or reviewed by the Process Authority as part of the process which was filed or amended to include "Strawberry skim milk."

5. A Grade "A" milk plant produces Grade "A" pasteurized milk and/or milk products and aseptic milk and/or milk products using the same processing line, with only a few adjustments to switch from ESL to aseptic. Should these products be inspected and rated as a pasteurized milk or milk product (traditional PMO) or an aseptic milk or milk product (under the new APP)?

Answer: A Grade "A" milk plant that produces both Grade "A" pasteurized and Grade "A" aseptic milk and milk products will have two separate IMS Listings and two FORM FDA 2359i's submitted by a SRO to FDA, one covering all Grade "A" pasteurized milk and milk products and the other covering only 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 APP.

6. Is the Interstate Milk Shipper's (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"?

Answer: 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 must be determined to be in compliance ("pass") when evaluated by the SRO at the beginning of the rating. If one (1) of the 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 removed. Following the evaluation of the ACLEs by the SROs, if all of the ACLEs are in compliance ("pass"), then the rating proceeds as normal 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. Sanitation Compliance Rating below 90% will result in the immediately removal of the milk plant's Grade "A" aseptic milk and/or milk products from the IMS listing.

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

Answer: 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 milk products produced at that milk plant, or
- Two (2) IMS listings, with one for the Grade "A" receiving portion of the Grade "A" aseptic milk plant and the second for the rest of the Grade "A" aseptic milk plant.

8. How many IMS listings will be required for a Grade "A" aseptic milk plant that produces HTST, HHST, or UP (pasteurized) milk and milk products and aseptic milk and milk products?

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

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

9. What specific areas of a Grade "A" aseptic milk plant participating in the NCIMS APP are to be inspected by properly trained State regulatory personnel?

Answer: State regulatory 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 State Regulatory Agency designated by FDA, under the FDA LACF program.

10. If a Grade "A" aseptic milk plant is also producing non-Grade "A" aseptic products and is under a FDA permit (emergency permit) for the non-Grade "A" aseptic products, what impact will this have on the "pass-fail" determination by the SRO/RMS for ACLE #4 for the Grade "A" aseptic milk and milk products?

Answer: The SRO/RMS would "fail" the Grade "A" aseptic milk plant on ACLE #4 if Grade "A" aseptic milk and milk products were produced on the production lines and equipment that are specifically addressed in the FDA LACF emergency permit and immediately deny a listing or remove the milk plant's Grade "A" aseptic milk and/or milk products from the IMS listing.

11. What is the responsibility of the SRO/RMS if it is learned that the Grade "A" milk or milk product with the "Refrigerate" statement as discussed in #11 above is not covered by a filed process with FDA?

Answer: If any Grade "A" aseptically processed and packaged milk or milk product is not included in at least one filed scheduled process submitted to FDA, this milk or milk product must be inspected and rated as a Grade "A" pasteurized milk or milk product.

12. The Grade "A" milk plant's documents supplied to the State regulatory personnel or SRO/RMS are not clear where the APPS begins and ends. How should State regulatory personnel or the SRO/RMS proceed?

Answer: The default APPS, which begins at the constant-level tank for the aseptic heating 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 aseptic milk and/or milk products. It is the responsibility of the milk plant to provide appropriate documentation justifying this expansion of the APPS. Acceptable documentation can be found in the filing documents (i.e., FORM FDA 2541c, and SUP-SIDs) or in written communication from the Process Authority or equipment manufacturer.

13. If State regulatory 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 plant in "over 5 years," what should be done?

Answer: The responsibility for the inspection of the APPS under the NCIMS APP is FDA's or a State Regulatory Agency designated by FDA, under the FDA LACF program. State regulatory personnel are not required to conduct any regulatory activities within the APPS of a Grade "A" aseptic milk plant operating under the NCIMS APP. The SRO's responsibility within the APPS is limited to the evaluation of the ACLEs to verify 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 State regulatory personnel or SROs is required.

14. What should be done if State regulatory personnel or SROs learns that the last FDA LACF inspection (completed recently) identifies some "important" Items that need correction within the APPS. What should the State regulatory personnel or SRO do?

Answer: If, by carrying out their specific responsibilities under the NCIMS APP, it is learned by a State regulatory personnel or SRO that an Item on a recent FDA LACF inspection within the APPS is still not corrected, there would not be any required action by State regulatory personnel or SROs under the NCIMS APP since the responsibility for the APPS lies with the FDA LACF program. However, it would be acceptable for State regulatory personnel or SROs to discuss the Item with plant management.

15. State regulatory personnel are performing the routine inspection of the portion of the Grade "A" aseptic milk plant outside the APPS and observe a leaky product pipe going from the 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 State regulatory personnel?

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

16. State regulatory 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 or milk product. Upon further investigation, it is learned that the plant was simply sorting and separating spoiled product. What should State regulatory personnel do?

Answer: No action is necessary. It is appropriate for Grade "A" aseptic milk plants to segregate spoiled product in preparation for disposal.

17. 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?

Answer: 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 the APPS. Points are assigned to violations under the NCIMS APP using FORM FDA 2359L (Status of Milk Plants), updated to address the NCIMS APP. SROs and RMSs are encouraged to also refer to training material provided by the NCIMS APPIC for additional guidance on the calculation of the Sanitation Compliance Rating for a Grade "A" aseptic milk plant.

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

Answer: The APPS is defined in the NCIMS APP document (see below) as a system that includes both the equipment and the operations associated with the equipment. The room or facility in which the APPS is located is not included, except for the exemptions noted in the Table below.

ASEPTIC PROCESSING AND PACKAGING SYSTEM: For the purposes of this *Ordinance*, the Aseptic Processing and Packaging System in a milk plant that produces aseptic Grade “A” milk or milk products shall be regulated in accordance with the FDA Low Acid Canned Foods regulations in 21 CFR 108, 110, and 113 and shall be defined by the Scheduled Process filed with FDA (FORM FDA 2541c and reference Supplemental Submission Identifier (SUP-SID) documents, or in written communication from the Process Authority or equipment manufacturer). It would begin and end with any step considered critical to the filed Scheduled Process.

This definition may include some or all of the items below, consistent with the information contained in the answer to question #13 in this Section above:

- Blending and formulation of ingredients prior to heating.
- Rendering the milk or milk product sterile.
- Sterile transfer of product.
- Storing the aseptic product prior to packaging.
- Packaging aseptic product, and/or
- Handling the product after packaging to maintain sterility and package integrity.

PMO - CFR Summary Reference Table

PMO, Section 7 Items	PMO Changes Under the Aseptic Pilot	Points	Authority
1p. Floors - Construction	Floor drains are not required in storage rooms for aseptic processed and packaged milk or milk products.	1	PMO
2p. Walls and Ceiling - Construction	Ceiling requirements are exempt in aseptic processed and packaged milk or milk products storage rooms.	1	PMO
3p. Doors and Windows	None	2	PMO
4p. Lighting and Ventilation	None	2	PMO
5p. Separate Rooms	Fabrication of containers and closures for aseptic processed and packaged milk and milk products is exempt.	3	PMO
6p. Toilet – Sewage Disposal Facilities	None	3	PMO
7p. Water Supply*	The Aseptic Processing and Packaging System is exempt, but shall comply with the CFR.	4	PMO/CFR
8p. Hand washing Facilities	None	2	PMO
9p. Milk Plant Cleanliness	None	3	PMO
10p. Sanitary Piping*	The Aseptic Processing and Packaging System are exempt, but shall comply with the CFR.	3	PMO/CFR
11p. Construction and Repair of Containers and Equipment*	The Aseptic Processing and Packaging System is exempt, but shall comply with the CFR. Paper, plastics, foil, adhesives and other components of containers and closures are not required to comply with Appendix J of the PMO, originate from an IMS Listed Source, and are subject to the requirements of the CFR.	3	PMO/CFR
12p. Cleaning and Sanitizing of Containers and Equipment*	The Aseptic Processing and Packaging System is exempt, but shall comply with the CFR.	10	PMO/CFR
13p. Storage of Cleaned Containers and Equipment*	The Aseptic Processing and Packaging System is exempt, but shall comply with the CFR.	3	PMO/CFR

14p. Storage of Single-Service Containers, Utensils and Materials	None	2	PMO
15p.(A) Protection from Contamination*	The Aseptic Processing and Packaging System is exempt, but shall comply with the CFR.	3	PMO/CFR
15p.(B) Protection from Contamination - Cross Connections*	The Aseptic Processing and Packaging System is exempt, but shall comply with the CFR. Aseptic Processing and Packaging System equipment is not required to comply with the separation requirements of the PMO in relationship to instrumented steam blocks between milk and milk products and cleaning and/or chemical sanitizing solutions.	5	PMO/CFR
16p. Pasteurization and Aseptic Processing ((A) through (E))*	The Aseptic Processing and Packaging system 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 routine inspections, state ratings or check ratings.	36	CFR
17p. Cooling of Milk and Milk Products*	The Aseptic Processing and Packaging System is exempt, but shall comply with the CFR.	5	PMO/CFR
18p. Bottling, Packaging and Container Filling*	The Aseptic Processing and Packaging System is exempt, but shall comply with the CFR.	5	PMO/CFR
19p. Capping, Container Closure and Sealing and Dry Milk Product Storage*	The Aseptic Processing and Packaging System is exempt, but shall comply with the CFR.		
20p. Personnel -Cleanliness	None	1	PMO
21p. Vehicles	None	1	PMO
22p. Surroundings	None	2	PMO

* **NOTE:** In areas of the milk plant where these Items fall under the Aseptic Processing and Packaging System as defined by the PMO, they shall be inspected according to the FDA LACF program (21 CFR 108, 110 & 113).

19. Item 7p in the table above identifies "Water Supply" as having joint coverage, i.e. "PMO/CFR." What does that mean for State regulatory personnel, SROs or RMSs conducting inspections, ratings or check ratings of a Grade "A" aseptic milk plant?

Answer: Water supply, like a number of other milk plant requirements in the PMO, is addressed for enforcement purposes in two (2) separate ways. For all parts of a Grade "A" aseptic milk plant's water system not dedicated only to the APPS, Item 7p requirements are applicable at the full point value (4 points) identified in FORM FDA 2359L. If the water supply is dedicated only to the APPS, then State regulatory personnel, the SRO or the RMS do not have any responsibility to determine compliance with Item 7p of the PMO within the APPS. Compliance of the water supply dedicated only to the APPS is evaluated under the FDA LACF program based on the enforcement of 21 CFR 108, 110 and 113.

20. Will Grade "A" aseptic milk plants currently operating under the NCIMS voluntary HACCP program participate in the NCIMS APP?

Answer: Yes. By adoption of proposal 303 ("All milk plants producing aseptically processed and packaged milk and milk products as defined by the PMO and regulated under the NCIMS

program will participate in the Aseptic Pilot Program."), the 2007 NCIMS delegates clearly intended that NCIMS aseptic milk plants operating under HACCP be included in the NCIMS APP. In order for a Grade "A" milk plant, operating under the NCIMS HACCP program, to comply with the APP requirements, the APPS needs to be excluded from any NCIMS HACCP requirements since this will be the responsibility of the FDA LACF program. All other NCIMS HACCP requirements shall be complied with under the NCIMS HACCP program. Any conflicts will be addressed by the NCIMS HACCP Implementation Committee (HIC) and APPIC.

21. How often should an IMS Listed milk plant producing only aseptic milk and milk products, operating under the NCIMS APP, be inspected by State regulatory personnel?

Answer: A minimum of once every six months.

22. How often should an IMS Listed milk plant producing both Grade "A" pasteurized and aseptic milk and/or milk products, operating under the NCIMS APP, be inspected by State regulatory personnel?

Answer: A minimum of once every three months with the following two exceptions:

1. Those Grade "A" milk plants operating under the NCIMS HACCP program shall be inspected a minimum of once every four months with a possible minimum of once every six months, if determined by the State.
2. For those Grade "A" milk plants that have both pasteurized and aseptic milk or milk products where the aseptic operation is in a dedicated and separate area, that separate area would be inspected a minimum of once every six months. The rest of the plant would still be inspected every three months.

23. Does the extended run criteria found in Item 12p of the PMO apply to Grade "A" aseptic milk plants operating under the APP?

Answer: The PMO's extended run provisions provide specific criteria on the length of time that processing equipment used for Grade "A" pasteurized milk and milk products, may run between required cleaning and sanitizing. For Grade "A" milk plants under the NCIMS APP, 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. Extended run criteria is applicable in other parts of an NCIMS Grade "A" aseptic milk plant or for any part of the plant outside of the APPS used in the production of Grade "A" pasteurized products .

24. If a Grade "A" milk plant is covered under one State license or permit, but produces both Grade "A" pasteurized and aseptic milk or milk products and a rating of either that plant's pasteurized products or the aseptic products results in a Sanitation Compliance Rating of less than 90%, should the State Regulatory Agency begin action against the milk plant's license or permit, including all milk or milk products or just the milk or milk products addressed by the below 90% Sanitation Compliance Rating?

Answer: The NCIMS program does not specify regulatory license or permit actions required to be taken by the State Regulatory Agency when a milk plant's Sanitation Compliance Rating is below 90%. State regulatory license or permit action in such a situation would be dictated by

the individual State's dairy laws, regulations and administrative code. The NCIMS program requires the State Rating Agency to notify FDA and all receiving States of the rating results.

25. During a rating of a Grade "A" milk plant which operates a processing and packaging system which can run either aseptic and conventional HHST/ultra-pasteurized milk and milk products, how do we evaluate the HHST system for compliance with the PMO while the processing and packaging system is configured for aseptic operation?

Answer: Such a Grade "A" dairy plant running both Grade "A" pasteurized and Grade "A" aseptic milk and milk products using modifications of the same processing and packaging system shall have two separate ratings, one for the pasteurized milk and/or products and the other for the 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 product. If this opportunity does not present itself, then it will be up to the rating officer to use other sources of information, records, employee interviews, existing equipment layout, etc. to determine whether the processing and packaging system are configured and operated properly to comply with the requirements for processing pasteurized milk and milk products.

26. If a Grade "A" plant produces both pasteurized and aseptic milk and milk products can one state regulatory inspection conducted once every three months use the same inspection recording document for both inspections?

Answer: No. Two separate inspection forms must be completed by the state regulatory inspector noting the area (aseptic or pasteurization) on the form. This is because the aseptic milk and milk products are rated and listed separately from the pasteurized milk and milk products. Filling out separate inspection forms will help to define the items in violation in each portion of the plant by the state regulatory agency. This will also be helpful in clarifying the enforcement rating conducted by the SRO and RMS.

27. During a rating of a Grade "A" milk plant which operates a processing and packaging system which can run either aseptic and conventional HHST/ultra-pasteurized milk and milk products, if the flow rate cut-out for Grade "A" pasteurized products is 10 gpm and for Grade "A" aseptic products is 14 gpm, how can a state inspector, SRO or RMS be sure that the proper product is being run at the right speed (holding time)?

Answer: Under the APP, the state inspector, SRO and RMS are responsible only for evaluating the pasteurization system, which includes the construction, design, operation, maintenance, testing and sealing of the pasteurization equipment just as is currently being done during a traditional state inspection, state rating or FDA checkrating. The aseptic processing and packaging system is rated according to the four ACLEs, which does not include a determination of product flow rate for the aseptic products. Areas such as product flow rates in aseptic systems are covered under the LACF inspection.

28. What is the procedure that should be followed for an unlisted aseptic milk plant to obtain a new IMS listing under the APP?

Answer: Aseptic milk plants must follow the protocol below to be eligible for a NCIMS listing.

- Submit plans to the State Regulatory Agency, if required by state law or regulation.
- The aseptic milk plant shall obtain a permit or license from the state regulatory authority.

- The plant shall have filed a schedule process(es) with FDA for each Grade "A" aseptic milk or milk product.
- The state regulatory inspector responsible for the Grade "A" aseptic milk plant and the SRO conducting the rating shall have participated in the NCIMS APPIC training and passed the written test.
- After the successful completion of the training, the state regulatory inspector shall conduct routine inspections according to the APP criteria.
- The plant must undergo at least one NCIMS state Grade "A" aseptic plant inspection under the APP.
- After FDA has "accepted" the filing(s), the Grade "A" aseptic milk plant may request an official NCIMS Rating by the State Rating Agency to obtain an IMS listing.
- Upon submittal of the rating by the SRO and acceptance by the FDA RMS, the IMS listing is granted, and the Grade "A" aseptic milk plant may begin shipment of Grade "A" aseptic milk and milk products under the NCIMS APP.

29. When can a newly listed Grade "A" aseptic milk plant begin to distribute Grade "A" aseptic milk and milk products interstate?

Answer: As soon as the conditions identified above are addressed, the newly listed Grade "A" aseptic milk plant may begin to distribute Grade "A" milk and milk products.

30. A FDA LACF inspector reviews the records of holding time, temperatures etc. Who, if anyone, challenges (tests) the controls that are/were typically done under the PMO?

Answer: It is exempt under the pilot and is the responsibility of the FDA LACF program or a State Regulatory Agency designated by FDA, under the FDA LACF program.

31. Do records of these challenges (tests) need to be recorded at any set frequency?

Answer: It is exempt under the pilot and is the responsibility of the FDA LACF program or a State Regulatory Agency designated by FDA, under the FDA LACF program.

32. If a Grade "A" aseptic plant is receiving pasteurized milk or milk product as their only source of "raw" milk for aseptic processing and packaging, what tests have to be done, and what bacterial standards must be met? i.e., Do coliform tests have to be done? Do raw or pasteurized SPC standards have to be met?

Answer: This pasteurized milk or milk product supply would not be required to be sampled and tested upon receipt at the Grade "A" aseptic milk plant, in order to comply with Section 6 (commingled raw milk for pasteurization, ultra-pasteurization or aseptic processing) of the PMO.

33. An example of an Expanded APPS – Chocolate Blend Tank for powder; dry chocolate lumps could be critical to the viscosity of the product. If a blend tank is included as part of the expanded APPS, wouldn't the milk plant be required to monitor the blending operation?

Answer: The chocolate blend tank in this situation has been identified as being a part of the APPS and therefore is not the inspectional responsibility of the state regulatory inspector, SRO, or RMS under the APP. The operation of the blending tank and the blending of the chocolate power is the responsibility of the FDA LACF investigator or a State Regulatory Agency designated by FDA, under the FDA LACF program.

34. Item 16p of the PMO addresses the prevention of adulteration by the addition of water when steam is directly added to a milk product as part of the heat treatment process. What controls are in place in the APP to prevent adulteration from added water? Does the LACF program or schedule filed process address adulteration by added water?

Answer: Item 16p of the PMO is not applicable for IMS Listed Grade "A" aseptic milk plants under the APP, since the FDA LACF program addresses the proper operation of the heat treatment process (sterilizing equipment) within the APPS, including adulteration by the addition of water.

35. Who determines whether a Grade "A" aseptic milk plant has had significant equipment changes that might affect the critical processing factors and has properly notified the Process Authority for a further evaluation?

Answer: It is the Grade "A" aseptic milk plant's responsibility to notify their Process Authority of any significant equipment changes that may affect their critical processing factors. This will be evaluated by the FDA LACF investigator or a State Regulatory Agency designated by FDA, under the FDA LACF program.

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

Answer: Yes. However, if the tower water is also used for pasteurized Grade "A" milk or milk product processing, then the answer is "No" and the tower water must comply with all applicable PMO requirements for all applications outside of the APPS, including sampling and testing.

37. Can toxic (gluteraldehyde, etc) additives be used in tower water used in these secondary cooling plates?

Answer: Additives used exclusively in the tower water within the APPS for the secondary cooling plates shall meet FDA regulations. If this tower water is used for processing purpose outside of the APPS, then the additives must also meet the PMO requirements.

38. SRO paperwork submission: 2359 – Inspection Report: Besides the inspection report form, does FDA want a written comments sheet describing specific violations also submitted?

Answer: Yes, if such comments cannot be completed on the 2359 form itself.

39. PMO 2p – Walls and Ceilings: Why are the ceiling requirements exempt?

Answer: The APP states the following under PMO ITEM 2p. WALLS AND CEILINGS - CONSTRUCTION: "Dry storage rooms used for the storage of packaged dry milk or milk products and aseptically processed and packaged milk or milk products are exempt from the ceiling requirements of this Item." Since aseptically processed and packaged milk and milk products are typically stored in a dry, unrefrigerated room similar to a room used for the storage of dry milk or milk products, this exemption provides the necessary milk safety protection for aseptic products and consistency with dry milk products.

40. PMO-CFR Summary reference table; Item 2p – Does the ceiling exemption in product storage mean they can be stored outside?

Answer: No, this exemption only applies to the ceiling. Roofs are still required under the APP for product storage areas.

41. Is the one valve separation adequate within the APPS to separate product & CIP solution during a "hot clean" of the sterilization system?

Answer: Yes, if determined as appropriate and safe by the Process Authority and accepted by FDA LACF.

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

Answer: No, indirect regenerators consist of a cold or hot raw or processed product, which heats a water media, which in turn, is used to indirectly transfer heat to another raw or processed product source. In a product-to-product regenerator, raw product is used to directly transfer heat to the processed product or vice-versa, with no separation between the two product streams other than the piping itself. There is no use of a water media source in product-to-product regeneration systems.

43. What happens if there is only one state regulatory person or one SRO and something happens so the regulatory person or SRO can no longer conduct the APP inspection/state rating at the Grade "A" aseptic milk plant?

Answer: If acceptable to the state regulatory agency, a couple of alternatives exist.

- Utilization of another state's APP-qualified regulatory inspector or SRO may be used.
- The NCIMS APPIC should be contacted to determine whether there is a possibility for individual APP training for another state regulatory inspector and/or SRO.

44. Are separate state permits required under the PMO and APP for a Grade "A" aseptic milk plant that runs both Grade "A" pasteurized and aseptic milk and milk products?

Answer: No. It is left to the state dairy laws and regulations to determine whether such a plant needs one or more permits or licenses.

45. Does the plant start under the APP after the first inspection? If so, and there is a quarterly equipment test due between the training and the 1st inspection, does the test still need to be done?

Answer: According to Proposal 303 concurred with by FDA and the NCIMS Executive Board at the September 17-18, 2007 NCIMS Executive Board meeting, the APP shall take immediate effect upon each participating State's plant inspection and SRO being trained in the implementation of the APP. Therefore, equipment testing of the Grade "A" aseptic milk plant's product heating equipment would not be required after the State has fulfilled this training requirement.

46. A Grade "A" milk plant has both a 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 aseptic

system. Do you evaluate the boiler used by the aseptic system for cross connections at the water feed line?

Answer: No. However, if the boiler is also used for non-APPS portions of the plant, then the answer would be "Yes".

47. What is the job of the State regulator during the Aseptic Pilot Program?

Answer: A properly trained state regulator inspector is responsible for the inspection, regulatory enforcement and sampling of commingled raw milk and water for any Grade "A" IMS Listed aseptic milk plant within their state. The inspection covers all areas of the aseptic milk plant with the exception of the APPS. The APPS is the responsibility of the FDA LACF program or a State Regulatory Agency designated by FDA, under the FDA LACF program.

48. Do Vitamin A & D fortified Grade "A" aseptic milk and milk products require annual vitamin testing?

Answer: Yes, at the current time only fluid white milk products (whole, reduced fat, low fat and nonfat) are required to have annual vitamin assays.

49. The NCIMS Aseptic Pilot Program Milk Plant Regulatory Agency Review Report is represented as being derived from FORM FDA 2359j-Milk Sanitation Rating Report, Section B. Report of Enforcement Methods, yet the labeling requirements identified in #3 of Part III- Individual Shipper Rating are not included anywhere in the NCIMS Aseptic Pilot Program Milk Plant Regulatory Agency Review Report. How does the APP address the labeling of Grade "A" aseptic milk and milk products?

Answer: Within the current NCIMS Aseptic Pilot Program Milk Plant Regulatory Agency Review Report form, labeling issues are addressed under Item #3 – "PMO requirements interpreted in accordance with the Grade "A" PMO as indicated by past inspections".

50. How often, if ever, is the Grade "A" aseptic milk plant required to test the aseptic portion of the sterilization equipment under the APP?

Answer: 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 State Regulatory Agency at the frequency prescribed in the PMO, which is once every 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 APP for the State Regulatory Agency to conduct any testing of such equipment. Equipment testing for dedicated aseptic processing equipment falls under the FDA LACF program.

51. How often will the FDA LACF or a State Regulatory Agency designated by FDA, under the FDA LACF program, inspect Grade "A" aseptic milk plants?

Answer: On June 27, 2008, FDA's Office of Food Safety issued an assignment to the field committing FDA field resources to inspect all Grade "A" aseptic milk plants under the APP annually from the date of this assignment through the end of FY 2010, (Sept. 30, 2010). The goal is to have two FDA LACF inspections per Grade "A" aseptic milk plant conducted during this time frame.

52. Does the same PMO equipment and design criteria also apply to processing equipment that is used only for aseptic milk and milk products in a Grade "A" aseptic milk plant, i.e., a flow meter design with at least 10 pipe diameters of straight pipe upstream and downstream from the center of the meter, before any elbow or change of direction takes place?

Answer: 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 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 a staff of FDA LACF personnel and engineers. 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.

53. 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 a violation of ACLE #1?

Answer: Yes, a process was not filed for eggnog.

54. May irradiation be used to sterilize packaging material used for packaging Grade "A" aseptic milk and milk products?

Answer: Yes.

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

Answer: No. This PMO requirement is exempt under the APP for Grade "A" aseptic milk and milk products.

56. If a Grade "A" aseptic milk plant is processing homogenized milk, is it required to be labeled Grade "A"?

Answer: Yes, this product is clearly covered under the PMO's definition of "Milk Products" and is included under the NCIMS APP.

57. Who determines if a change in formulation requires a new filing with FDA?

Answer: It is the responsibility of the Grade "A" aseptic milk plant to inform their Process Authority of any formulation changes. The Process Authority will determine whether the existing filing will cover the new formulation. If requested, a Grade "A" aseptic milk plant should be able to provide written documentation of such a Process Authority's determination.

58. Does a change in suppliers for the same ingredient used in a Grade "A" aseptic milk or milk product require notification to the milk plant's Process Authority?

Answer: No, a change in suppliers is not the same as a change in a product formulation.

59. 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 heating or sterilizing equipment be inspected according to the PMO or FDA LACF program?

Answer: The heating or sterilizing equipment would be inspected based on the products being produced. When Grade "A" pasteurized and ultra-pasteurized milk and milk products are processed, the heating or sterilizing system shall be required to comply with Item 16p-Pasteurization of the PMO. When only Grade "A" aseptic milk and milk products are processed under the APP, the heating or sterilizing system and packaging system are required to meet the requirements of the FDA LACF program.

60. In a Grade "A" aseptic milk plant that processes both aseptic and ultra-pasteurized milk and milk products on the same heating equipment, which uses tower water for the final cooling, do the PMO requirements for the construction and sampling of the tower water system apply?

Answer: Yes, since the heating equipment is used to process ultra-pasteurized product.

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

Answer: Yes. Official regulatory samples from Grade "A" aseptic milk plants, include raw commingled milk samples, vitamin assays of finished products and regulatory water samples. Water samples may also be officially analyzed at an EPA certified laboratory.

62. Do any inspection Items identified on FORM FDA 3511-3 (Aseptic Processing and Packaging Report) cover the APPS and would an existing aseptic milk plant already be aware of these Items? Also, how often are these FDA LACF inspections conducted?

Answer: The inspection Items identified on FORM FDA 3511-3 are generic to all aseptic facilities. All of the Items identified on FORM FDA 3511-3 cover the FDA regulations regarding LACF inspections. This form is an exhaustive audit/inspection tool which is designed to cover aseptic LACF operations from beginning to end and identifies public health safety issues as well as gauges administrative compliance. This form is for the use of the FDA investigator only. If FDA identifies a discrepancy which has the potential to impact public health safety, FDA will handle these findings through its regulatory and enforcement process. FORM FDA 3511-3 is available on line at <http://www.fda.gov/opacom/morechoices/fdaforms/efsan.html> (scroll down to 3511-3).

All FDA LACF inspections of aseptic milk plants utilize a risk-based system to establish inspection frequency based on milk plant performance. All of the Grade "A" IMS Listed milk plants are scheduled to be FDA LACF inspected annually through FY 2010. If the agency has concerns about a particular facility, the frequency is increased.

63. Because of the requirement that separate IMS Listings are required for a Grade "A" milk plant that produces both pasteurized and aseptic Grade "A" milk and milk products, are two laboratory reports needed for the same raw commingled milk used for both pasteurized and aseptic milk products?

Answer: No. The same raw commingled milk laboratory report for a Grade "A" milk plant can be used to fulfill the official sample collection requirements for a Grade "A" milk plant's

pasteurized and aseptic milk and milk product listing. A copy of this raw commingled milk laboratory report must be available to the SRO or FDA RMS during a state rating or check rating, respectively.

64. What are requirements for State Regulatory Agencies designated by FDA to conduct LACF inspections in Grade “A” milk plants?

Answer: There is the potential for State Regulatory Agencies to contract with FDA to carry-out FDA LACF inspections, although none have been contracted to do so for Grade “A” milk plants at this time. Any State Regulatory Agency obtaining such a contract will be required to demonstrate that their personnel have received training equivalent to an FDA LACF inspector and have been field standardized by FDA.

65. What are fermented high-acid aseptic Grade “A” milk and milk products?

Answer: Fermented high-acid aseptic Grade “A” milk and milk products are those with a pH of 4.6 or lower, such as yogurt, sour creams and similar products that are fermented (cultured) to achieve their final pH. Shelf stability is achieved through the use of aseptic processing, after the raw milk has been legally pasteurized and fermented (cultured). The aseptically processed fermented high-acid Grade “A” milk or milk product is then aseptically packaged and stored under normal non-refrigerated conditions.

66. Why are fermented high-acid aseptic Grade “A” milk and milk products included under the NCIMS APP?

Answer: The NCIMS APP was designed to include all Grade “A” aseptic milk and milk products. The NCIMS APPIC has been charged with the implementation and assessment of the NCIMS APP and has the expertise and knowledge to address aseptically processed Grade “A” milk and milk products. The NCIMS Executive Board has agreed to assign the responsibility to address these Grade “A” milk and milk products under the APP.

67. Why do fermented high-acid aseptic Grade “A” milk and milk products require a separate set of ACLEs?

Answer: The original NCIMS APP only addressed low-acid aseptically processed Grade “A” milk and milk products that are covered by the FDA Low Acid Canned Food (LACF) program found in 21 CFR 108, 110 and 113. Both the NCIMS program and the FDA LACF program are combined in the original APP and only addressed low-acid aseptically processed Grade “A” milk and milk products. The ACLEs for low-acid aseptic Grade “A” milk and milk products are specific only to this dual regulatory oversight. Fermented high-acid aseptic Grade “A” milk and milk products do not have the same FDA regulatory oversight as low-acid aseptic Grade “A” milk and milk products; therefore, the low-acid aseptic Grade “A” milk and milk product ACLEs are required to be expanded with modifications to ensure that the recommended process for implementation within the Aseptic Processing and Packaging System (APPS) will deliver a safe fermented high-acid aseptic Grade “A” milk or milk product.

68. Where does the Aseptic Processing and Packaging System (APPS) start and end for fermented high-acid aseptic Grade "A" milk and milk products?

Answer: The default APPS starting and ending points for fermented high-acid aseptic Grade “A” milk and milk products begin at the constant-level tank for the aseptic heating unit and end

at the discharge port of the aseptic packaging machine, unless the Process Authority has documented in writing other step(s)/processes considered critical to commercial sterility. In the latter case, the Process Authority's APPS letter shall clearly specify the expanded starting and/or ending steps/processes for these milk and milk products.

69. What key elements should be contained in the documentation from a milk plant producing fermented high-acid aseptic Grade "A" milk and milk products, which is submitted to the State Regulatory Agency in order to obtain State Regulatory Agency's acceptance and concurrence to begin the production of such Grade "A" milk and/or milk products under the NCIMS Aseptic Pilot Program (APP)?

Answer: Key elements should include, but are not limited to:

- Product type and name;
- Milk plant's name and address;
- Process Authority's (PA) process recommendation letter with required information;
- The Process Authority's Aseptic Processing and Packaging System (APPS) letter, which clearly identifies the beginning and end points of the APPS, if the APPS is expanded beyond the start of the constant-level tank for the aseptic heating unit and/or after the end of the discharge port of the aseptic packaging machine,
- FCE #;
- FORM FDA 2541c **or equivalent electronic filing** ; and
- SUP-SID

70. What key elements shall be contained in the letter, email or other documentation of acceptance from the State Regulatory Agency to a milk plant that has requested approval to produce fermented high-acid aseptic Grade "A" milk and milk products under the NCIMS APP?

Answer: Key elements in a letter, email or other documentation from a State Regulatory Agency shall include but are not limited to:

- A statement that the State Regulatory Agency has accepted the process recommendation.
- The name of the milk or milk product(s) and the dates of the milk plant submitted document(s) that the State Regulatory Agency accepted.
- A statement that the milk plant must have the referenced document(s) readily available at the milk plant for review.
- A statement that the milk plant must immediately notify the State Regulatory Agency of any change(s) to critical processing elements prior to implementing the change(s).

Approval date and signature of the State Regulatory Agency official. (NOTE: In the case of an email, the signature of the State Regulatory Agency official must be included).

71. Which Product Code(s) in the IMS List would fermented high-acid aseptic Grade "A" milk and milk products be classified under?

Answer: At this time, these milk and milk products would be classified under Product Code #6 - Aseptic Milk and Milk Products (including flavored).

C. Training:

1. Who determines which individuals are selected or authorized to give the APPIC training? Are aseptic trainers certified?

Answer: The APPIC intends to conduct and directly supervise all training for the APP. In the future, the APPIC may determine the criteria that aseptic trainers under the NCIMS APP must meet in order to conduct such training.

2. Must State regulatory personnel and SROs responsible for the Grade "A" aseptic milk plant attend the APPIC NCIMS APP training course and obtain a certificate of attendance in order to conduct an inspection or rating of a Grade "A" aseptic milk plant participating in the pilot.

Answer: Yes

3. Will there be a formal certificate issued for the attendees participating in the NCIMS APP courses?

Answer: Yes

4. Does an attendee have to complete the training course, including the satisfactory completion of any written exam in order to receive a certificate?

Answer: Yes

5. Who will issue the NCIMS APP training course certificate?

Answer: The NCIMS APPIC.

6. Is the NCIMS APP course certificate a lifetime certificate, (i.e., attend once, pass the training course and no required renewal)?

Answer: No; however, any required retraining frequency has not been established at this time by the APPIC.

7. Is there a list of acceptable Better Process Control Schools that are approved by the FDA Commissioner that would qualify under ACLE #3 (Are the operators of the milk plant's APPS under the supervision of a person who has attended a school approved by the FDA (such as Better Process Control School or recognized equivalent))? Where can this list be found?

Answer: There is not an official list; however, by conducting an Internet search, a list of schools and schedule of classes can be found. FDA determines which Better Process Control Schools meet the intent of 21 CFR 108, 110 and 113. If there are questions about a certificate from a specific school, contact that school for confirmation of their approval by FDA. If there is still a concern, the FDA Office of Food Safety's Food Processing Evaluation Team (FPET) (301) 436-2069 may be contacted.

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

Answer: No. The FDA LACF regulations (21 CFR 108, 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.

9. 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")?

Answer: 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, the FDA Office of Food Safety's Food Processing Evaluation Team (FPET) (301) 436-2069 may be contacted.

10. Is the CFR requirement for a "trained supervisor" who has attended a school on FDA's LACF program approved by FDA Commissioner (such as a Better Process Control School or recognized equivalent) fulfilled by having someone having a Better Process Control School certificate at the corporate level at another location away from the Grade "A" aseptic milk plant?

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

11. As I understand it, only state regulatory inspectors and SROs who have successfully taken this training are authorized to inspect and rate a Grade "A" aseptic milk plant during the Pilot. Are we going to have some method (listing, star by name in IMS list, etc.) to identify the people who have passed this training so we know who is authorized.

Answer: At the current time, FDA and the APPIC are maintaining a list of State Regulatory and Rating personnel that have attended and successfully completed a training course put on by the APPIC. This list will be posted on the NCIMS website under the APPIC; provided to the individual States that currently have Grade "A" aseptic milk plants with IMS Listings; and also be provided to the FDA Regional Milk Specialists. For the most current information, contact Robert Hennes, FDA, at (301) 436-2175 or robert.hennes@fda.hhs.gov.

D. Process Authority:

1. Who is considered a Processing Authority?

Answer: There is no specific definition of a Processing Authority in FDA's regulation for LACF (21 CFR 108 and 113). But the term is referenced and described in the following sections of the regulation (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. How can FDA recognize someone who has this "expert knowledge"?

Answer: Knowledge can be obtained by 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 GMPs for operating above minimum conditions.
- Interprets FDA regulations.

3. Does FDA approve Processing Authorities?

Answer: 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 process expert on their staff.

4. If FDA does not approve processing authorities how can I be assured that a milk plant's Processing Authority is competent?

Answer: The NCIMS APP does not require State regulatory personnel, the SRO or the 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 APP.

5. Does the Better Process Control School provide the training necessary to become a Processing Authority?

Answer: No. The intent of the Better Process Control Schools is to train plant supervisors on the required practices outlined in 21 CFR 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.

6. What are the responsibilities of the Processing Authority?

Answer: First, as stated in 21 CFR 113.83, a Processing Authority must establish thermal processes. Second, a Processing Authority 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. Third, a Processing Authority 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.

7. What does a Processing Authority do to evaluate processing deviations?

Answer: The Processing Authority evaluation is usually based on a careful review of processing and production records and 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 deviant process as 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.

8. So what specifically does a Processing Authority do to develop a process schedule for aseptic products?

Answer: The response to this question can vary depending on the complexity of the system. Remember, aseptic systems 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 for aseptic processing and packaging systems.

- Review plans, drawings for both systems to determine monitoring devices and locations, flow patterns, valving, etc.
- Review the control system and alarm details to determine critical control points (CCPs) and critical limits.
- Conduct microbial challenge tests and analyze data to prove that the system can be sterilized and that commercially sterile products are produced.
- If a chemical sterilant such as hydrogen peroxide is used, 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.
- Document that a hermetic seal is formed and maintained in the finished product.
- Conduct on-site testing of the entire system to determine compliance with applicable portions of 21 CFR 113.

9. What records must a Processing Authority keep?

Answer: As required in 21 CFR 113.83, the Processing Authority must keep complete records covering all aspects of the establishment of a scheduled process, including associated incubation tests (21 CFR 113.83), and all records covering deviation evaluation procedures used and the results (21 CFR 113.89).

10. A milk plant has several filings for the same product with the difference being the filler that is utilized or package size. Can't they have one filing for a product and cover the different fillers and packaging differences in the SUP-SID's?

Answer: Yes, it is possible to cover multiple milk plant filling machines on just one FDA LACF product filing, if a milk plant uses the "US 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. This advice from the FDA LACF program may be subject to change so please contact your FDA Regional Milk Specialist, if needed, for additional information or clarification.

11. What is considered in establishing critical factors for the thermal process?

Answer: According to 21 CFR 113.3 (f), a "critical factor means any property, characteristic, condition, aspect, or other parameter, variation of which may affect the scheduled process and the attainment of commercial sterility". All aspects of the equipment, the process and the product, both in preparation and as a finished product, are considered. For example, the Process Authority takes into account process equipment and flow rate, type of flow (turbulent or

laminar), temperature, product viscosity, ingredients, packaging, etc. in determining critical factors. Information related to critical factors is captured on the filing submitted to FDA. FDA LACF reviews the filing, particularly concentrating on identified critical factors for acceptability.

12. If the Process Authority does not inspect or have an "on-site" presence at a Grade "A" aseptic milk plant, who takes the responsibility for the configuration of the sterilization system?

Answer: For a Grade "A" aseptic milk plant, the configuration of any equipment located in the APPS is first determined by the equipment supplier along with input from the aseptic milk plant. Secondly, the system layout, flow sequence, and system components are reviewed and evaluated by the Process Authority. The Process Authority then determines the critical factors and develops information for a process filing. Then the manufacturer has responsibility to submit it to FDA for review. If only Grade "A" aseptic milk and milk products are produced on this sterilization system under the APP, the regulatory oversight for this equipment is the responsibility of the FDA LACF program.

13. If the Process Authority makes a mistake, what are the actions taken against the Process Authority?

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

E. Aseptic Critical Listing Elements (ACLEs):

1. What are the specific responsibilities of State regulatory personnel, SROs and RMSs related to the use of the Grade "A" APP's ACLEs?

Answer: The evaluation of the NCIMS APP ACLEs are 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 of the ACLEs is not in compliance ("fails"), the rating/check rating is stopped and the Grade "A" aseptic milk plant is either denied an IMS Listing or is immediately removed from the IMS List. There is not any requirement in the NCIMS APP for State regulatory personnel to evaluate ACLEs as a part of their routine Grade "A" aseptic milk plant inspection.

2. What resources and guidance are available to SROs and RMSs to evaluate the ACLEs?

Answer: For SROs and RMSs, 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 APPIC. Specific questions can also be directed toward the APPIC's "Technical Review Team" for determining compliance by contacting Ms. Sue Esser at essers@michigan.gov.

3. ACLE #1: 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?

Answer: It is the responsibility of all Grade "A" aseptic milk plant to maintain FORM FDA 2541c and other related FDA LACF documents onsite because these documents are necessary for the SRO and RMS to use at the very 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 this ACLE is not in compliance and has "failed". This is consistent with current FDA LACF interpretation and enforcement of 21 CFR 113. 87 which states that this information must be "readily available." The SRO or RMS shall stop the rating or check rating and either deny the IMS Listing or immediately remove the IMS Listing.

4. 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 (ACLE #1), but plant personnel state the product is being "test marketed", what is the appropriate action?

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

5. ACLE #2: If the name of the Processing 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")?

Answer: ACLE #2 states: "Are the milk plant's filed scheduled processes for all of its aseptic Grade "A" milk and milk products developed by a recognized Processing Authority qualified as having expert knowledge of thermal processing requirements?" This ACLE is very clear that the milk plant's filed schedule processes for all aseptic Grade "A" milk and milk products must be developed by a recognized Processing Authority qualified as having expert knowledge of thermal processing requirements. The SRO or RMS should confirm that the Processing Authority is recognized and accepted by referencing the current FORM FDA 2541c for all Grade "A" aseptic 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.

6. ACLE #2: 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?

Answer: 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 serves 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."

7. ACLE #3: The SRO or RMS learns from plant management that the person responsible for the supervision of the aseptic processing to satisfy ACLE #3 is their corporate quality control director that stops in at 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?

Answer: ACLE #3 states: "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)?" It is the intent of ACLE #3 that ". . . supervision of a person who has attended a school approved by the FDA (such as Better Process Control School or recognized equivalent)" 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 plant would not be in compliance and the rating or check rating would stop, resulting in the milk plant either being denied an IMS Listing or the milk plant being immediately removed from the IMS List.

8. ACLE #3: The SRO or RMS learns from plant management that the person responsible for the supervision of the aseptic processing to satisfy ACLE #3 left the 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 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 was none during the previous month after the LACF supervisor left the milk plant. The SRO or RMS also checks with the plant's Process Authority, who is aware of the situation. What should the SRO or RMS do?

Answer: 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-accepted Better Process Control School or recognized equivalent. In this scenario, the SRO or RMS's answer for ACLE #3 would be "no," the aseptic plant would not be in compliance and the rating or check rating would stop, resulting in the milk plant either being denied an IMS Listing or the milk plant being immediately removed from the IMS List.

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

Answer: The SRO should request information that documents milk plant compliance with each of the four (4) ACLEs. If confirmation of any plant documentation is needed, the SRO may contact the plant's Process authority or the RMS, who in-turn can contact the FDA LACF office in Washington, DC to confirm any plant-supplied information.

10. Regarding NCIMS aseptic HACCP milk plants, how shall the NCIMS APP ACLEs be evaluated by SROs and RMSs during a rating or check rating?

Answer: A SRO or RMS shall evaluate all four (4) NCIMS APP ACLEs at the beginning of any Grade "A" aseptic milk plant rating or check rating, HACCP-based or otherwise, to determine compliance.

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

Answer: No. ACLE #1 states, "Is the milk plant registered with FDA LACF and are all of the milk plant's aseptic Grade "A" milk and milk products covered by a filing with the FDA LACF using Form FDA 2541c or equivalent electronic filing?" This requires that a scheduled process be filed (submitted), but there is no requirement that the filing be reviewed or accepted by FDA LACF prior to production or shipment. However, Grade "A" aseptic plants located outside of the 50 US states or US territories shall be required to demonstrate proof of FDA LACF acceptance of a filed process in order to comply with ACLE #1.

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

Answer: Yes. A scheduled process filing for Grade "A" milk and milk products from an unlisted Grade "A" aseptic milk plant must first be reviewed and accepted by FDA LACF in order for a SRO to give credit for ACLE #1. Once the IMS listing is granted, then for future ratings, a SRO 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 as stated in the answer to Question #6.

13. If a Grade "A" aseptic milk plant producing only aseptic milk or milk products wants to sell surplus cream as raw or heat-treated, does this require a separate listing for the milk plant and 3 month minimum inspection frequency?

Answer: Raw cream (Product Code #1) may be listed along with aseptic milk and milk products (Product Code #6) because the raw cream being shipped from the milk plant would not require any additional sampling under Section 6 of the PMO at the shipping milk plant. However, the heat-treated cream (Product Code #3) would require a separate IMS Listing and; therefore, such a Grade "A" aseptic milk plant would be required to have an inspection at a minimum frequency of once every 3 months, since heat-treated cream is required to be sampled at the shipping milk plant.

14. On the APP Q & A, it states that if a better process control school supervisor left and a new school isn't available for 2 months – the plant is automatically delisted because of ACLE #3 failure. This excludes the possibility of a nearby plant providing a better process control school-trained supervisor or even contracting out – are these not better options than de-listing?

Answer: 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-accepted Better Process Control School or recognized equivalent. This means that the individual(s) shall be available locally, not at some remote location.

15. How does a SRO or RMS determine what is meant by "all products" in ACLE #2?

Answer: The aseptic milk plant should supply, upon request, a list of all Grade "A" aseptic milk and milk products they produce and this list should be used as the basis to evaluate ACLE's #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 ACLE's #1 and #2.

16. 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 revised ACLE #4 for aseptic milk and milk products (*Is the milk plant currently under an "Order of Determination of Need" for an Emergency Permit?*)

Answer: An "Order of Determination of Need" for an Emergency Permit is issued by FDA to a plant producing food covered under 21 CFR 108 and 113 when it is determined that they cannot consistently produce foods safely and in compliance with the LACF program. 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 answer by contacting their RMS. **NOTE:** Whenever it is determined that a Grade "A" milk plant is to be issued an FDA LACF "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 State Dairy Regulatory/Rating Agency and request the immediate withdrawal of the IMS Listing for this Grade "A" aseptic milk plant. The State Rating Agency shall immediately inform the Grade "A" aseptic milk plant that their IMS Listing will be immediately withdrawn.

Following FDA LACF's lifting or removal of an "Order of Determination of Need" for an Emergency Permit and the subsequent issuance of an Emergency Permit (allows 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 plant representative to their State Regulatory/Rating Agency requesting such an IMS Listing.

17. During a state 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 on 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 notes that for some products, not all aseptic filling equipment is identified for each Grade "A" aseptic milk and milk product. Does this result in a determination of non-compliance with ACLE #1?

Answer: No, ACLE #1 (see below) for 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 finding by the SRO related to some aseptic filling equipment not being covered by Sup-Sid(s) attached to the various filings is 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 finding regarding the Sup-Sid(s) and filling equipment.

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

18. How can a State Regulatory Inspector (SRI), State Rating Officer (SRO) or FDA Regional Milk Specialist (RMS) determine if the milk plant is complying with ACLE #1 - Is the milk plant registered with FDA LACF and are all of the milk plant's fermented high-acid aseptic Grade "A" milk and milk product(s) produced using aseptic processing and packaging equipment

which is under a current FDA LACF FORM FDA 2541c or equivalent electronic filing for a low-acid aseptic Grade “A” milk or milk product?

Answer: ACLE #1 would be in compliance if the SRI, SRO or RMS is able to verify that the milk plant is registered with FDA for producing low-acid aseptic Grade “A” milk or milk products and a current FORM FDA 2541c filing or equivalent electronic filing is available that identifies the aseptic processing and packaging equipment to be used to process the fermented high-acid aseptic Grade “A” milk or milk product(s).

19. How can a State Regulatory Inspector (SRI), State Rating Officer (SRO) or FDA Regional Milk Specialist (RMS) determine if the milk plant is complying with ACLE #2 - Are the milk plant’s process recommendation(s) for all of its fermented high-acid aseptic Grade “A” milk and milk product(s) developed by a recognized Process Authority qualified as having expert knowledge of thermal processing requirements?

Answer: Process recommendations issued by recognized Processing Authorities are expected to be used by a processor of fermented high-acid aseptic Grade “A” milk and milk products to ensure that these products achieve the desired shelf stability. These parameters may include, but are not limited to, product pH, water activity (a_w), temperature, time, and flow rate. These processing parameters are provided in a letter or other documentation by a recognized Process Authority for review and acceptance by the State Regulatory Agency.

20. How can a State Regulatory Inspector (SRI), State Rating Officer (SRO) or FDA Regional Milk Specialist (RMS) determine if the milk plant is complying with ACLE #3 - Have the milk plant’s process recommendation(s) for all of its fermented high-acid aseptic Grade “A” milk and milk product(s) been accepted by the State Regulatory Agency prior to production of these products?

Answer: ACLE #3 requires that the milk plant’s Process Authority's process recommendations for fermented high-acid aseptic Grade “A” milk and milk products must be accepted by the State Regulatory Agency prior to beginning the production of these Grade “A” milk and milk products. A copy of the written State Regulatory Agency acceptance document(s), such as a letter, email or other documentation, shall be readily available at the milk plant.

21. How can a State Regulatory Inspector (SRI), State Rating Officer (SRO) or FDA Regional Milk Specialist (RMS) determine if the milk plant is complying with ACLE #4 - Are the milk plant’s process recommendation(s) that have been accepted by the State Regulatory Agency for all of its fermented high-acid aseptic Grade “A” milk and milk product(s) being implemented by the milk plant?

Answer: The SRI, SRO or RMS shall request and obtain a copy of the document(s) citing the State Regulatory Agency’s acceptance of the Process Authority’s process recommendations from either the milk plant or State Regulatory Agency and then request and obtain from the milk plant, processing records that verify the Process Authority’s process recommendations are being implemented by the milk plant. The Process Authority's process recommendations may include the pH of the product during aseptic processing and packaging as well as the time, temperature and flow rate of the aseptic processing equipment.

22. How can a State Regulatory Inspector (SRI), State Rating Officer (SRO) or FDA Regional Milk Specialist (RMS) determine if the milk plant is complying with ACLE #5 - 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)?

Answer: ACLE #5 is very clear that at the time of the state regulatory inspection, state rating or FDA check rating, the fermented high-acid aseptic Grade "A" milk plant must have a person serving as a supervisor with documentation confirming attendance at a FDA-approved Better Process Control School (BPCS) or recognized equivalent. The SRI and SRO may verify the BPCS certificate by contacting their FDA RMS, who may consult with the FDA LACF group.

23. How can a State Regulatory Inspector (SRI), State Rating Officer (SRO) or FDA Regional Milk Specialist (RMS) determine if the milk plant is complying with ACLE #6 - Is the milk plant currently under an "Order of Determination of Need" for an Emergency Permit?

Answer: An "Order of Determination of Need" for an Emergency Permit is issued by FDA to a plant producing food regulated under 21 CFR 108, 110, 113 and 114 when it is determined that the plant cannot consistently produce foods safely and in compliance with these regulations. A SRI, SRO or RMS shall request of the fermented high-acid aseptic Grade "A" milk plant whether they have received an "Order of Determination of Need" for an Emergency Permit from FDA. The SRI and SRO may verify the plant's response by contacting their FDA RMS.

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

Following FDA LACF's lifting or removal of the "Order of Determination of Need" for an Emergency Permit and the subsequent issuance of an Emergency Permit, or the revocation of the need for an Emergency Permit, the fermented high-acid aseptic Grade "A" milk plant that desires an IMS Listing shall submit written notification from an authorized milk plant representative to their State Rating Agency requesting such an IMS Listing.

24. How does a State Regulatory Inspector (SRI), State Rating Officer (SRO) or FDA Regional Milk Specialist (RMS) determine what is a critical processing element?

Answer: A SRI, SRO or RMS shall obtain a copy of the Process Authority's process recommendations that have been reviewed and accepted by the State Regulatory Agency. The critical processing elements shall be contained in this document(s).

25. What records are acceptable for use by the State Regulatory Inspector (SRI), State Rating Officer (SRO) or FDA Regional Milk Specialist (RMS) to determine compliance with the ACLEs for a non-aseptic Grade "A" milk plant starting up with a new fermented high-acid aseptic Grade "A" milk or milk product?

Answer: The SRI, SRO or RMS should request information that documents the milk plant's compliance with each of the fermented high-acid aseptic Grade "A" milk and milk product ACLEs. Such documentation may reflect start-up or trial run records on new product(s) that are not intended for resale. If verification of any milk plant's documentation is needed, the SRI, SRO or RMS may contact the milk plant's Process Authority.

26. What records are acceptable for use by the State Regulatory Inspector (SRI), State Rating Officer (SRO) or FDA Regional Milk Specialist (RMS) to determine compliance with the ACLEs for an existing aseptic Grade "A" milk plant with a new fermented high-acid aseptic Grade "A" milk or milk product?

Answer: The SRI, SRO or RMS should request information that documents the milk plant's compliance with each of the fermented high-acid aseptic Grade "A" milk and milk product ACLEs. Such documentation may reflect start-up or trial run records on new product(s) not intended for sale or existing aseptic Grade "A" milk or milk products with similar critical factors, as identified by the Process Authority. If verification of any milk plant's documentation is needed, the SRI, SRO or RMS may contact the milk plant's Process Authority.

**Q&As that will need to be updated or deleted in accordance with
2011 NCIMS Proposal 301**

How is the Enforcement Rating of a NCIMS APP rating or check rating calculated?

Answer: The Enforcement Rating of a NCIMS APP rating or check rating is not calculated. The APPIC modeled the Enforcement Rating/Review of a Grade "A" aseptic milk plant after the NCIMS voluntary HACCP program. The NCIMS ASEPTIC PILOT PROGRAM MILK PLANT REGULATORY AGENCY REVIEW REPORT contains eight elements (see below) taken from the traditional FORM FDA 2359j-MILK SANITATION RATING REPORT - Section B. REPORT OF ENFORCEMENT METHODS, Milk Plant, Part II". The eight elements are reviewed and answered by the SRO or RMS and the SRO will submit this Form to the RMS along with all other NCIMS APP Rating documentation.

1. Aseptic milk plant holds a valid permit.
2. Aseptic milk plant operations inspected by the Regulatory Agency at the minimum required frequency.
3. PMO requirements interpreted in accordance with the *Grade "A" PMO* as indicated by past inspections.
4. Water samples tested and reports on file as required.
5. Samples of commingled raw milk collected at the required frequency and all necessary laboratory examinations made.
6. Sampling procedures approved by PHS/FDA evaluation methods.
7. Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required.
8. Regulatory Agency records systematically maintained and current.

How can an Enforcement Rating that is not calculated work to provide information about a State's Grade "A" aseptic milk plant program that may not be in compliance?

Answer: The NCIMS APP requires the SRO to review and provide an answer to all eight elements. The completed NCIMS ASEPTIC PILOT PROGRAM MILK PLANT REGULATORY AGENCY REVIEW REPORT is submitted to the RMS and is used by the RMS to continually assess the capabilities of the State Regulatory Agency to fulfill all of the

NCIMS APP requirements. It will also be used by the RMS when conducting their State Milk Program Evaluations.

Please establish criteria for proving "corrections to substantial operational weaknesses" have been made.

Answer: The evaluation of a state's regulatory and enforcement program under the APP shall be made by the RMS based on check rating observations and information gathered from the NCIMS Aseptic Milk Plant Regulatory Agency Review Report submitted by SROs. Its purpose is to determine whether the Regulatory Agency is providing an acceptable level of oversight required by the APP and if operational weaknesses are identified that raise concern regarding Grade "A" aseptic milk or milk product safety. Included in the RMS evaluation may include, but not be limited to:

- Proper frequency and level of regulatory Grade "A" aseptic plant inspection;
- Proper interpretation of APP and PMO requirements;
- Proper enforcement of APP and PMO;
- Proper follow-up of identified Grade "A" aseptic milk plant deficiencies;
- A combination of many items that could result in an overall deficiency in the state regulatory program and compromise the safety of the Grade "A" aseptic milk or milk product.

The NCIMS Aseptic Pilot Program Milk Plant Regulatory Agency Review Report is represented as being derived from FORM FDA 2359j-Milk Sanitation Rating Report, Section B. Report of Enforcement Methods, yet the labeling requirements identified in #3 of Part III-Individual Shipper Rating are not included anywhere in the NCIMS Aseptic Pilot Program Milk Plant Regulatory Agency Review Report. How does the APP address the labeling of Grade "A" aseptic milk and milk products?

Answer: Within the current NCIMS Aseptic Pilot Program Milk Plant Regulatory Agency Review Report form, labeling issues are addressed under Item #3 – "PMO requirements interpreted in accordance with the Grade "A" PMO as indicated by past inspections".

Acronyms:

ACLE	- Aseptic Critical Listing Element
APP	- Aseptic Pilot Program
APPIC	- Aseptic Pilot Program Implementation Committee
APPS	- Aseptic Processing and Packaging System
CCP	- Critical Control Points
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
IMS	- Interstate Milk Shipment
LACF	- Low Acid Canned Foods
PMO	- Pasteurized Milk Ordinance
RMS	- Regional Milk Specialist
SRO	- State Rating Officer
SUP-SID	- Supplemental Submission Identifier
UHT	- Ultra-High Temperature
UP	- Ultra-Pasteurized

NCIMS Forms

FORM FDA 2359-Milk Plant Inspection Report (Aseptic Pilot) (10/06)

FORM FDA 2359i-Interstate Milk Shipper's Report (Aseptic Pilot) (10/06)

FORM FDA 2359L-Status of Milk Plants

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

NCIMS Aseptic Pilot Program Milk Plant Regulatory Agency Review Report

NCIMS Aseptic Pilot Program Listing Elements

APPENDIX

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

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