TO: All Regional Food and Drug Directors
FROM: Milk and Milk Products Branch (HFS-316)
SUBJECT: Questions And Answers Received From The Field; Regional Milk Seminars; And FDA Training Courses Held During Fiscal Year 2014

Following are questions and answers received from the field; Regional Milk Seminars; and FDA training courses (Special Problems in Milk Protection, Advanced Milk Processing, Milk Plant Sanitation and Inspection, Milk Pasteurization Controls and Tests, and Dairy Farm Sanitation and Inspection) held during fiscal year 2014.

In accordance with procedures established through the National Conference on Interstate Milk Shipments (NCIMS), if an answer to a question results in a new understanding of a long-standing situation or installation, and the condition as it exists does not present an immediate public health hazard, reasonable judgment should be exercised and adequate time provided for modification and correction.

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

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

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1. **PMO-Section 1**

   Do whey cheeses such as ricotta, which do not have a Standard of Identity (SOI) in 21 CFR 133, meet the Definition of Milk Products in the PMO and; therefore, would be considered a Grade “A” milk product?

   No.

2. **PMO-Sections 1 and 4; and Appendix L**

   a) Is UF milk considered a Grade “A” milk product?

      Yes, provided it meets all of the PMO requirements and comes from an IMS listed shipper.

      *The following answers to b) through d) were provided by CFSAN’s ONLDS:*

   b) Would it be acceptable to produce Grade “A” reduced fat milk using UF milk as the total dairy ingredient?

      *No. 21 CFR 131.10 does not allow for the use of UF milk as an ingredient in “milk”, including reduced fat milks.*

   c) Would UF milk be an acceptable ingredient for use in the production of a Grade “A” reduced fat milk?

      *No. 21 CFR 131.10 does not allow for the use of UF milk as an ingredient in “milk”, including reduced fat milks.*

   d) If not allowable as an ingredient in a Grade “A” reduced fat “milk”, if it were used as an ingredient in a Grade “A” defined milk and/or milk product how would this Grade “A” milk and/or milk product be labelled?

      *It could be labelled by the use of a fanciful name; however, it cannot be called “milk”.*

   e) Would this Grade “A” defined milk and/or milk product with a fanciful name identified in d) above be required to be labeled “Grade “A””?

      Yes.

3. **PMO-Sections 1 and 4; and Appendix L**

   Gelatin is not listed in 21 CFR 131.200 as an optional ingredient for yogurt. May gelatin be added to yogurt?
The following answer was provided by CFSAN’s ONLDS:

Yes. Gelatin can function as a stabilizer to minimize/prevent "syneresis" and add body or texture to yogurt. It would be allowed to be added per the "stabilizers" section in the yogurt SOIs. Other stabilizer ingredients that you may see being added to yogurt are "rice starch" and "modified corn starch".

4. **PMO-Sections 1 and 4; and Appendix L**

A milk plant is proposing to recover a water-milk mixture produced during transition phases on a pasteurization system; store this recovered water-milk mixture for twenty-four (24) to seventy-two (72) hours under proper refrigerated conditions; utilize RO on this recovered water-milk mixture to produce a milk product composed of approximately 2.0% milkfat and approximately 18% milk solids non-fat; add non-fat dry milk (NFDM) to the RO water-milk mixture to fortify the total milk solids to approximately 35%; and then inject this milk solids fortified water-milk ingredient back into the raw milk stream of the pasteurization system in order to increase the total milk solids of various fluid milk products. What finished milk or milk products are acceptable for this milk solids fortified water-milk ingredient to be utilized in?

The following answer was provided by CFSAN’s ONLDS:

That would depend on the SOI for a particular milk or milk product. The SOI for “milk” found in 21 CFR 131.110 states “… Milk may have been adjusted by separating part of the milkfat therefrom, or by adding thereto cream, concentrated milk, dry whole milk, skim milk, concentrated skim milk, or nonfat dry milk”. The SOI for “milk” does not provide for the addition of a recovered water-milk mixture. Since the “Other optional ingredients” provisions of yogurt, eggnog and cultured milk were “stayed” in 1982, 47 FR 41519, September 21, 1982, this recovered water-milk mixture may be used to reconstitute dried milk and condensed ingredients for those SOI milk products. It also would be permitted in cottage cheese creaming mixtures and milk products that do not have a SOI (non-standardized). For similar Q&A’s regarding reconstitution and the SOI of milk and milk products, please refer to M-I-85-7 (Question #63), M-I-04-6 (Question #46), and M-I-09-3 (Question #11).

5. **PMO-Sections 1 and 4; and Appendix L**

Are preservatives, i.e., natamax (natamycin) allowed to be added to yogurt?

The following answer was provided by CFSAN’s ONLDS:
Preservatives are allowed in yogurt per the stayed provisions published in Fed. Reg. Vol. 47, No. 183, page 41522 (published in 1982) pending a public hearing on the yogurt SOIs (public hearing has not yet been held). This FR Notice states: “FDA is staying the effective dates of those portions of 131.200(d), 131.203(d), and 131.206(d) insofar as they exclude the addition of preservatives in yogurt, pending the outcome of public hearings. Until such a time as this issue is resolved, the appropriate use of preservatives in these foods will not be the basis for regulatory action.” Since the natamycin (natamycin) will have an effect in the finished yogurt, it would not be considered a processing aid and must be declared on the package ingredient statement with a description (in parenthesis) of its function, e.g., "preservative", "to retard spoilage", "a mold inhibitor", etc.

**NOTE:** Natamycin is listed in 21 CFR 172.155 for use as a food preservative (antimycotic). This CFR reference only cites the use of natamycin for application on cheese in an amount that does not exceed twenty (20) ppm. For any other use, the firm would need to have filed either a GRAS notice or a food additive request with FDA. GRAS Notice No. GRN00517 was filed with FDA on May 7, 2014 by DSM and received a “no questions at this time” letter from FDA dated Nov. 21, 2014. The GRAS notice states use levels not to exceed five (5) ppm in yogurt. A copy of the GRAS notice can be found at: http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm427606.htm.

6. **PMO-Section 4**

If a State’s dairy statues and regulations are determined by FDA to be substantially equivalent to the Grade “A” PMO and a milk plant that is regulated and inspected under those State dairy statues and regulations chooses not to ship in interstate commerce nor be IMS listed, may they label their applicable milk and/or milk products “Grade A” for intrastate commerce?

Yes.

7. **PMO-Section 4**

Is it acceptable for a milk plant to market two (2) gallon containers of milk and/or milk products held together with a neck ring or “dogbone” attachment; and fully label only one (1) of these gallon containers, while partially labeling the other gallon container with only the statement of identity and net quantity of contents?

**NOTE:** The label proofs provided show the statement “This Unit Not Labeled For Individual Sale” printed on each label.
The following answer was provided by CFSAN’s ONLDS:

These milk and/or milk products would not be eligible for the exemption in 21 CFR 1.24(a)(14). Under this exemption, the unit containers in a multiunit or multicomponent retail food package are exempt from regulations of Section 403 (e)(1), (g)(2), (i)(2), (k), and (q) of the Federal Food, Drug and Cosmetic Act (FFDCA) with respect to the requirements for the label declaration of the name and place of business of the manufacturer, packer, or distributor; label declaration of ingredients; and nutrition information when:

(i) The multiunit or multicomponent retail food package labeling meets all the requirements of this part;
(ii) The unit containers are securely enclosed within and not intended to be separated from the retail package under conditions of retail sale; and
(iii) Each unit container is labeled with the statement "This Unit Not Labeled For Retail Sale" in type size not less than one-sixteenth of an inch in height. The word "Individual" may be used in lieu of or immediately preceding the word "Retail" in the statement.

However, in the scenario provided and described, it does not appear that the unit containers would be securely enclosed within a retail package. In that case, both gallon containers would need to be fully labeled with the product identity statement, net quantity of contents, ingredients, name and place of business, and nutrition information.

8. PMO-Section 4

An aseptically processed and packaged Grade “A” milk product is being provided to foodservice establishments to be inserted into a coffee beverage dispensing system. The dispensing system is capable of keeping the milk product refrigerated, but is not capable of bringing the milk product in the opened package down to refrigeration temperatures (41°F) from ambient temperatures within four (4) hours. Would it be appropriate to label this aseptically processed and packaged Grade “A” milk product as “Keep Refrigerated”?

The following response was contained in a letter issued by CFSAN’s ONLDS:

The milk product you are requesting guidance for is considered a Grade “A” milk product which is aseptically processed and packaged and is inserted into a foodservice coffee beverage dispensing system. The dispensing system is capable of keeping the milk refrigerated, but is not capable of bringing the milk product in the opened package down to refrigeration temperatures (41°F) from ambient temperatures within 4 hours. Your
concern is that the milk product needs to be refrigerated just prior to being opened and inserted into the dispensing system, and you want to label it accordingly. In your letter you indicated that the Regulatory Agency had taken the position that it would be inappropriate to use the statement "Keep Refrigerated", on the aseptically processed and packaged and stored milk product. You also mentioned that the FDA’s “Guidance on Labeling of Foods That Need Refrigeration by Consumers” was referred to by the Regulatory Agency as a basis for their objection.

The FDA’s policy as represented in the guidance is that a statement such as “IMPORTANT Must be refrigerated after opening to maintain safety” is an appropriate label statement for aseptically processed and packaged foods because such foods are shelf-stable and may pose a health hazard only after opening. The FDA’s recommended statements also stated the reason why the product should be refrigerated, e.g., for safety or for quality. While the guidance was written for consumer packaging the same general principles and logic used in the development of the guidance would also be applicable to the labeling of foodservice products. The Code of Federal Regulations itself does not address requirements for labeling with regard to refrigeration for aseptically processed and packaged foods.

We are aware of a provision in Section 4-Labeling, Item #2 of the Grade “A” Pasteurized Milk Ordinance (PMO) that specifically requires labeling with the statement “keep refrigerated after opening” for aseptically processed and packaged milk and milk products. The December 13, 2012, Questions and Answers document (M-I-12-16) that was mentioned by the Regulatory Agency is a Memorandum of Information based on the PMO. M-I-12-16 states that an aseptically processed and packaged Grade “A” milk and/or milk product that is labeled “Refrigerate” or Keep Refrigerated” would be considered a refrigerated pasteurized and/or ultra-pasteurized Grade “A” milk and/or milk product and would be regulated under the PMO and would not be considered an aseptically processed and packaged milk product regulated under 21 CFR 113 (Low Acid Canned Foods). Currently, all fifty states and Puerto Rico have adopted the PMO by reference or have codified the PMO in State regulations.

Upon review, we do not believe that either label statement you have suggested, “Keep Refrigerated” or “Place package in refrigerator at least 24 hours before use,” comprehensively conveys the action needed to mitigate the potential food safety risk. Instead, we would like to suggest a statement such as:

“IMPORTANT – Pre-chill product to 41°F or less immediately prior to use and keep refrigerated after opening for safety.”
We hope that we have provided some additional perspectives to assist you in resolving this issue and hope that your client will consider this option as an alternative. Also please note: This communication should not be construed to imply that the use of this product in the manner you described complies with all State and local laws and regulations.

9. **PMO-Section 4; and Appendix N**

   a) May the milk from two (2) bulk milk pickup tankers be commingled into one (1) over-the-road milk transport tanker at a transfer station?

   Yes.

   b) Would the over-the-road milk transport tanker load of milk be required to have separate shipping statements (bills of lading or weight tickets) for the milk from each of the two (2) bulk milk pickup tankers?

   Not, as long as all of the individual dairy producers contained within the two (2) bulk milk pickup tankers are properly identified on a common shipping statement (bill of lading/manifest) which provides all of the required information as cited in Section 4-Labeling of the PMO on the shipping statement (bill of lading/manifest).

   **NOTE:** The individual weigh tickets or load manifests from the two (2) bulk milk pickup tankers may be used in conjunction with a separate shipping statement (bill of lading/manifest) to identify the dairy producers and the IMS BTU Identification Number(s) for the farm groups.

   c) Would the milk contained in each of the two (2) bulk milk pickup tankers be required to be tested in according with Appendix N-Drug Residue Testing and Farm Surveillance of the PMO at the transfer station before they are commingled in the over-the-road milk transport tanker?

   Yes. The results of the Appendix N testing shall be reported on the shipping statement and the individual dairy producer samples shall accompany the over-the-road milk transport tanker or if acceptable to the Regulatory Agency to another location to be held if further testing is warranted.

10. **PMO-Sections 5 and 7**

   Is a distribution center(s) (warehouse) that is at a different location(s) than the milk plant included in a routine milk plant inspection, rating or check rating of an IMS listed milk plant?
That will depend on the function and operations conducted within the distribution center(s) and who has control of the Grade “A” milk and/or milk products at those locations.

Milk plants that have a warehouse(s) or distribution center(s) off site that they transfer milk and/or milk products for cooling and storage, which is still under the control of the milk plant, have been included in a routine milk plant inspection, rating or check rating.

Also, with the incorporation of the cooling temperature exemptions within Item 17p-Cooling of Milk and/or Milk Products of the PMO this has expanded the routine milk plant inspection, rating and check rating to also include off-site warehouses and distribution centers that are utilized to cool the milk and/or milk product(s) to evaluate compliance with the specific milk and/or milk product(s) temperature exemption(s) that a milk plant may have.

Routinely, if a distribution center is used in the traditional sense for only the storage and direct distribution of milk and/or milk products to retailers that are not under the control of the milk plant than they have not been included in a routine milk plant inspection, rating or check rating.

11. **PMO-Section 6**

a) What is the required sampling and testing frequency for Grade “A” condensed milk and/or milk products or dry milk and/or milk products when the condensing or drying milk plant only processes these milk and/or milk products seasonally or intermittently and does not process on a continuous monthly basis throughout the year?

If production occurs during any consecutive six (6) months, then at least four (4) samples shall be collected by the Regulatory Agency in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days from every milk plant.

If production occurs on a basis that any consecutive six (6) months sampling requirement, as cited above, cannot be met then the PMO requires at least five (5) samples shall be taken within a continuous production period.

b) If a condensing or drying milk plant’s continuous production period is only one (1) day and occurs for example on four (4) separate occasions during a year, is the PMO requirement for five (5) samples taken within each of the four (4) continuous production periods satisfied if five (5) samples of that single day’s production are taken per continuous production period?

Yes.
NOTE: For multiple samples of the same condensed milk and/or milk product or dry milk and/or milk product collected from the same processor from the same day’s production, the laboratory results are required to be averaged arithmetically and recorded as the official results for that day.

c) If the continuous production period is spread over several days or months and occurs for example on four (4) separate occasions during a year, is the PMO requirement for five (5) samples taken within each of the four (4) continuous production periods satisfied if five (5) samples of five (5) different day’s production are taken on a single day?

Yes.

NOTE: Section 6-The Examination of Milk and/or Milk Products of the PMO requires that in order for the Regulatory Agency to issue a warning letter and take permit action based on the violative laboratory results for these samples, the samples shall have been collected on separate days. The Regulatory Agency shall send a written notice whenever two (2) of the last four (4) consecutive bacterial counts, coliform determinations or cooling temperatures, as applicable, exceed the standard for the condensed milk and/or milk product or dry milk and/or milk product. This written notice shall be in effect as long as two (2) of the last four (4) consecutive samples exceed the standard. An additional sample shall be taken within twenty-one (21) days of the sending of such written notice, but not before the lapse of three (3) days. Immediate suspension of permit, in accordance with Section 3-Permits of the PMO, and/or court action shall be instituted whenever the standard is violated by three (3) of the last five (5) bacterial counts, coliform determinations or cooling temperatures for the condensed milk and/or milk product or dry milk and/or milk product.

Therefore, in order to be able to comply with the written notification and suspension of permit and/or court action requirements as cited above, it is recommended that samples from different days of production shall be collected on separate days.

12. PMO-Section 6; and Appendix N

a) For testing raw commingled sheep milk, is the Charm® SL Beta lactam test kit the only FDA evaluated and NCIMS accepted test kit for Beta lactams?

Yes.

b) Would this also be the only Beta lactam test kit that can to be used to validate the Standard Plate Count (SPC) for raw commingled sheep milk?
Yes.

13. **PMO-Section 6; and Appendix N**

A direct load dairy producer ships milk in milk tank trucks to a milk plant, and that milk plant has conducted an agitation study per the Standard Methods for the Examination of Dairy Products (SMEDP) for this specific direct load milk producer and the milk tank trucks that are being utilized. The agitation study results on file at the milk plant for that specific direct load dairy producer and the specific milk tank trucks that are being utilized does not indicate any variance between an agitated milk tank truck vs. a non-agitated milk tank truck. Would this receiving milk plant be required to agitate all milk tank trucks that are received from this specific direct load dairy producer for determining compliance with the requirement of obtaining a representative sample addressed in Section 6-The Examination of Milk and/or Milk Products and/or Appendix N of the PMO?

No.

14. **PMO-Section 6; and Appendix N**

If a direct load dairy producer ships milk in milk tank trucks to only one (1) milk plant that utilizes milk tank truck agitation to obtain a representative sample for Section 6 and/or Appendix N sampling and testing, would this eliminate the requirement for an in-line sampler at the direct load dairy farm?

*Sampling of direct load milk tank trucks is at the direction of the Regulatory Agency. If the Regulatory Agency determines that the milk tank trucks can be effectively agitated at the milk plant to collect a representative sample then this would be acceptable.*

**NOTE:** The milk plant would be required to conduct an agitation study that is determined to be acceptable to the Regulatory Agency prior to this practice being allowed to be used for Section 6 and/or Appendix N sampling and testing.

15. **PMO-Section 6; Methods for Making Sanitation Rating of Milk Shippers (MMSR)-Sections B and C ; and Evaluation of Milk Laboratories (EML)**

a) A rating is submitted to FDA on FORM FDA 2359i-Interstate Milk Shipper's Report that indicates an earliest rating date of 4/15/2014; the utilization of an IMS listed laboratory that has expired (3/2014); and the “Yes” box is check for the “Letter of Permission to Publish Transmitted with this Report”. How should a RMS handle the submitted FORM FDA 2359i and the IMS Listed milk shipper?
NOTE: For a milk shipper to be IMS listed it is required that an accredited (approved) IMS laboratory is utilized for the analysis of samples required under Section 6 of the PMO. The PMO states that all samples shall be analyzed at an appropriate Official or Officially Designated laboratory. The MMSR states that ratings and HACCP listed audits shall not be conducted when an approved laboratory has not been utilized by the Regulatory Agency for the necessary tests. Therefore, if an accredited (approved) IMS laboratory actually has an expiration date prior to the earliest rating date as indicated on a submitted FORM FDA 2359i it jeopardizes the validity of the rating and the IMS listing of the milk shipper shall be denied or immediately withdrawn from the IMS List.

The RMS shall not accept a submitted FORM FDA 2359i with an accredited (approved) IMS laboratory that has an expiration date prior to the earliest rating date. The RMS shall reject the submitted FORM FDA 2359i and return it to the SRO who submitted FORM FDA 2359i. The SRO shall contact the State LEO to determine if the laboratory has been re-accredited (re-approved) with the report submitted to FDA’s Laboratory Proficiency and Evaluation Team (LPET) and obtain the new expiration date. If LPET is contacted by the SRO and does not have any information that the laboratory has been re-accredited (re-approved) they can directly contact the State LEO to determine the laboratory’s current status.

- Accredited (approved) laboratories show an expiration date, for example of 3/2014, on the IMS List. This means that the accredited laboratory is approved through the end of the month of the year indicated. For this example 3/31/2014.
- Within the Evaluation of Milk Laboratories (EML) it provides for a LEO to send the evaluation report within sixty (60) days of an on-site evaluation of a milk laboratory to the laboratory and LPET. Therefore, there potentially could be a delay from the date of the re-accreditation evaluation conducted by a LEO and when that information is provided to LPET and subsequently is updated on the IMS List.

b) A rating is submitted to FDA on FORM FDA 2359i-Interstate Milk Shipper’s Report that indicates an earliest rating date of 4/15/2014; the utilization of an IMS listed laboratory that has expired (3/2014); and the “No” box is check for the “Letter of Permission to Publish Transmitted with this Report”. How should the RMS handle the submitted FORM FDA 2359i and the IMS Listed milk shipper?

The RMS shall accept the submitted FORM FDA 2359i and immediately sign off on it so that it can be forwarded to CFSAN where the IMS listing will be denied or the IMS Listed milk shipper will be immediately withdrawn from the IMS List.
c) A rating is submitted to FDA on FORM FDA 2359i-Interstate Milk Shipper’s Report that indicates an earliest rating date of 4/15/2014; the utilization of an IMS listed laboratory that has an expiration date that is later than the expiration date listed on the IMS List (3/2016 and the IMS List indicates 3/2014); and the “Yes” box is check for the “Letter of Permission to Publish Transmitted with this Report”. How should a RMS handle the submitted FORM FDA 2359i and the IMS Listed milk shipper?

Before a RMS accepts and signs off on a submitted FORM FDA 2359i with an accredited (approved) IMS laboratory that has an expiration date that is later than the expiration date listed on the IMS List as cited in c) above, the RMS shall contact FDA’s LPET to determine if the laboratory has been re-accredited (re-approved) by a LEO and obtain the new expiration date. If LPET does not have any information that the laboratory has been re-accredited (re-approved) they can directly contact the State LEO to determine the laboratory’s current status.

If the new expiration date is verified, the RMS shall sign off on the submitted FORM FDA 2359i. If the new expiration date cannot be verified, the RMS shall immediately reject the submitted FORM FDA 2359i and return it to the SRO that submitted FORM FDA 2359i.

16. PMO-Section 6; and MMSR-Sections B and D

A dairy producer has two (2) consecutive months of somatic cell count (SCC) violative results and a two (2) out of four (4) warning letter has been sent to the dairy producer. The Regulatory Agency has identified and already designated the specific date of the next month’s regular producer sample that is to be collected by a licensed bulk milk hauler/sampler as an official regulatory sample for compliance with Section 6 of the PMO. May the Regulatory Agency’s specified next month’s sample be utilized as both the required resampling of the violative dairy producer’s milk within twenty-one (21) days of the sending of the warning letter and that month’s sampling to be in compliance with Section 6 of the PMO?

Sampling History:

- Feb 20 (800,000 SCC)
- March 24 (900,000 SCC)
- March 29 (Two (2) out of four (4) SCC warning letter sent.)
- April 8 (Sample collected and results (good or bad) to be used to satisfy both April’s Section 6 sampling requirement and the two (2) out of four (4) warning letter resampling requirement.
NOTE: This required resampling shall be collected within twenty-one (21) days of the sending of the warning letter but not before the lapse of three (3) days.

Yes.

17. PMO-Section 6; and MMSR-Sections B and D

a) What is the appropriate Product Code for pasteurized flavored cream?


b) What Section 6 tests would be required to be conducted on pasteurized flavored creams?

Temperature, Bacteria (SPC) and Coliform.

NOTE: For these types of new Grade “A” milk and/or milk products the required testing with approved methods for inhibitors and phosphatase will have to be addressed by the NCIMS Lab Committee.

18. PMO-Section 6; and MMSR-Sections C and D

A milk plant only produces non-homogenized white and chocolate flavored milks at different milk fat levels (whole, 2%, 1% and nonfat). Are samples required of all of the white and chocolate flavored milks at the different milk fat levels to be in compliance with Section 6 of the PMO?

Yes.

19. PMO-Sections 6 and 7; and Appendix I; and MMSR-Section D

a) The Regulatory Agency began an inspection of a milk plant on 7/25/2014; however, they did not complete the inspection until 8/16/2014. If the previous milk plant inspection was conducted 4/19/2014, would the Regulatory Agency get credit for this inspection under Milk Plant, Part II, Item 2-Milk plant and receiving station(s) inspected once every three (3) months; aseptic and retort milk plant and transfer stations(s) once every six (6) months on FORM FDA 2359j-Milk Sanitation Rating Report, Section B-Report of Enforcement Methods (Page 2)?

No. Inspections for milk plants and receiving stations are to be conducted every three (3) months with the remaining days of the month in which due to complete the inspection to obtain credit. With this example, the inspection shall have been completed by 7/31/2014 to obtain credit for this inspection.
**NOTE:** This would also apply to obtaining credit for dairy farm, transfer station and aseptic and retort milk plant inspections that are required to be conducted every six (6) months. They get the remaining days of the month in which due to complete the inspection to obtain credit.

b) The Regulatory Agency began a pasteurization system equipment test on 7/25/2014; however, they did not complete the equipment test until 8/16/2014. If the previous pasteurization system equipment test was conducted 4/19/2014, would the Regulatory Agency get credit for this equipment test under Milk Plant, Part II, Item 5-Pasteurization equipment tested at required frequency (Not required for aseptic and retort milk plants) on FORM FDA 2359j-Milk Sanitation Rating Report, Section B-Report of Enforcement Methods (Page 2)?

No. Pasteurization system equipment tests are to be conducted every three (3) months (holding time every six (6) months) with the remaining days of the month in which due to complete the equipment test to obtain credit. With this example, the equipment test shall have been completed by 7/31/2014 to obtain credit for this equipment test.

20. **PMO-Section 7, Table 1; and Appendices B and N**

Proposal 228 from the 2013 NCIMS Conference and incorporated into the 2013 PMO provides requirements within Appendix B-Milk Sampling, Hauling and Transportation of the PMO for the sampling of raw sheep milk that has been frozen prior to being tested for Appendix N of the PMO. The sampling protocol within Appendix B requires that raw sheep milk samples are frozen within twenty-four (24) of sample collection and that the testing for drug residue shall be completed within sixty (60) days of the freezing of the raw sheep milk. As long as the raw sheep milk is tested within the sixty (60) days, may a milk plant process the milk beyond the sixty (60) days?

Yes.

21. **PMO-Section 7, Item 5r**

a) Is the upright combination receiver (balance tank)/CIP vessel (vat) required to be located in the milkhouse on a dairy farm?

Yes.

b) With basement style parlors, if this upright combination receiver/CIP vessel (vat) is located in the basement would this area be required to meet all of Item 5r-Milkhouse – Construction and Cleanliness requirements (doors, walls, cleanliness, etc.) of the PMO?
Yes.

22. **PMO-Section 7, Item 8r**

   a) A dairy farm utilizes a raw milk plate heat exchanger (cooler) which is directly connected to the potable water supply to provide cooling. The water pipeline from the exit of the plate heat exchanger (cooler) does not have any submerged water inlets or cross-connections. Is there a requirement for a back flow prevention device either at the entrance or exit of the plate heat exchanger (cooler) to protect the potable water supply and/or the plate heat exchanger (cooler)?

   No.

   b) A dairy farm utilizes a raw milk plate heat exchanger (cooler) which is directly connected to the potable water supply to provide cooling. The water pipeline from the exit of the plate heat exchanger (cooler) has at least one (1) submerged water inlet or cross-connection. Is there a requirement for a back flow prevention device to protect the potable water supply and/or plate heat exchanger (cooler)?

   Yes. An approved back flow prevention device shall be installed downstream of the exit of the plate heat exchanger (cooler) and prior to the submerged water connection to protect the plate heat exchanger (cooler).

   c) A dairy farm utilizes a raw milk plate heat exchanger (cooler) which is directly connected to the potable water supply to provide cooling. The potable water supply line has a by-pass line around the plate heat exchanger (cooler) that is directly connected to the water pipeline downstream from the exit of the plate heat exchanger (cooler). The water pipeline that exits the plate cooler does not have any submerged water inlets or cross-connections. Is there a requirement for a back flow prevention device to protect the potable water supply and/or the plate heat exchanger (cooler)?

   Yes. An approved back flow prevention device shall be installed in the potable water by-pass line prior to its connection to the water pipeline from the exit of the plate heat exchanger (cooler) to protect the potable water supply.

   d) A dairy farm utilizes a raw milk plate heat exchanger (cooler) which is directly connected to the potable water supply to provide cooling. The potable water supply line has a by-pass line around the plate heat exchanger (cooler) that is directly connected to the water pipeline downstream from the exit of the plate heat exchanger (cooler). The water pipeline exiting the plate heat exchanger (cooler) has a least one (1)
submerged water inlet or cross-connection. Is there a requirement for a back flow prevention device to protect the potable water supply and/or plate heat exchanger (cooler)?

Yes. Two (2) approved back flow prevention devices need to be installed. One (1) downstream of the exit of the plate heat exchanger (cooler) and prior to the submerged water connection to protect the plate heat exchanger (cooler) and one (1) in the potable water by-pass line prior to its connection to the water pipeline from the exit of the plate heat exchanger (cooler) to protect the potable water supply.

23. **PMO-Section 7, Item 8r; and Appendix G; and MMSR-Section B**

A dairy farm utilizes an individual water system (private well) for their water supply for the milkhouse and milking operations. Samples for bacteriological examination are required to be taken at least every three (3) years. Would the following sample collection and testing results meet this three (3) year requirement?

<table>
<thead>
<tr>
<th>Collection Date</th>
<th>Testing Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/15/2011</td>
<td>Satisfactory</td>
</tr>
<tr>
<td>1/23/2014</td>
<td>Unsatisfactory (Positive)</td>
</tr>
<tr>
<td>2/3/2014</td>
<td>Satisfactory</td>
</tr>
</tbody>
</table>

Yes, the sample collected 1/23/2014 would meet the three (3) year sampling and examination requirement of Item 8r-Water Supply of the PMO. To determine if water samples have been taken at the frequency established in Item 8r, the interval shall include the designated period plus the remaining days of the month in which the sample is due.

24. **PMO-Section 7, Item 9r**

If a milking system replacement part(s) and/or system component(s) manufacturer holds a valid 3-A Replacement Parts and System Component Qualification Certification (RPSCQC) that was issued following a Third Party Verification (TPV) inspection, including a site visit, conducted by a 3-A Sanitary Standards, Inc. (SSI) Certified Conformance Evaluator (CCE) for specified replacement or repair part(s) or system component(s) of a milking system addressed within 3-A Accepted Practice 606-##, would the milking system replacement part(s) and/or system component(s) manufacturer also be required to have a Regional Dairy Equipment Review Committee perform a design and construction review for approval prior to utilizing and installing the replacement or repair part(s) or system component(s)?

No.
**NOTE:** The Certificate holder shall not mark the replacement part(s) or system component(s) in any manner to indicate participation in this program. The RPSCQC shall convey all such acknowledgment. This Certificate will bear a complete listing of replacement part(s) or system component types, the models/names, and serial numbers (if appropriate) which have been inspected and the specific 3-A Sanitary Standard(s) or 3-A Accepted Practice(s) that were utilized in the TPV inspection. 3-A SSI may make copies of complete Certificates available on-line for public inspection to help maintain the veracity of Certificates that have been issued.

25. **PMO-Section 7, Item 9r; and MMSR-Section D**

Item 9r-Utensils and Equipment – Construction of the PMO requires detailed plans for clean-in-place (CIP) cleaned pipeline systems are to be submitted to the Regulatory Agency for written approval prior to installation. No alteration or addition shall be made to any milk pipeline system without prior written approval of the Regulatory Agency. If plans have not been submitted to the Regulatory Agency for prior written approval does this constitute an automatic debit of Item 9-Utensil and Equipment, Construction (e)-Approved CIP cleaned milk pipeline system on FORM FDA 2359a-Dairy Farm Inspection Report?

No. To debit Item 9(e) on FORM FDA 2359a-Dairy Farm Inspection Report, the CIP cleaned pipeline system would have to be evaluated and determined not to be in compliance with the construction requirements of the PMO.

**NOTE:** If while conducting a rating or check rating it is observed that during the rating period back to the last rating that a new CIP cleaned pipeline system has been installed or an alteration(s) or addition has been made to any milk pipeline system without the submission of plans and prior written approval of the Regulatory Agency being obtained this would trigger a debit against the dairy farm on the Enforcement Rating. On FORM FDA 2359j-Milk Sanitation Report, Section D-Dairy Farms Enforcement Action and Records Evaluations (Page 4), Category IV-Plan Review File under Dairy Farm Records would be debited for this dairy farm.

26. **PMO-Section 7, Items 10r and 11r**

Item 10r- Utensil and Equipment – Cleaning of the PMO states that partial pickups maybe permitted when the milk storage/holding tank is equipped with a seven (7) day recording devices, provided the milk storage/holding tank shall be completely emptied, cleaned and sanitized at least every seventy-two (72) hours. In the absence of a temperature-recording device, partial pickups may be permitted as long as the milk storage/holding tank is completely emptied, cleaned and sanitized prior to the next milking.
If it has been determined that a dairy producer is not in compliance with the partial pickup requirements cited in 10r of the PMO, would this be considered only a 10r violation or both a 10r and 11r-Utensil and Equipment – Sanitization violation of the PMO?

This would be considered both a 10r and 11r violation of the PMO.

27. **PMO-Section 7, Item 13r**

Several dairy farms, not automatic milking installations (AMIs), are proposing to use the following teat prep protocol prior to milking on all of their milking dairy animals. The protocol is as outlined below:

- The dairy producer wants to use cloth towels, washed in a clothes washer.
- They want to add an Environmental Protection Agency (EPA) approved sanitizer during the final rinse cycle and then let the clothes washer finish the rinse process. By adding the sanitizer during the rinse cycle, the sanitizing solution would be on the cloth towels and the cloth towels would come out of the clothes washer damp after the rinse/spin cycle is completed.
- The dairy producer will not dry these damp cloth towels.
- They will take the damp, sanitized cloth towels from the washer to the milking parlor to be used to prep the dairy cows after entering the milking parlor. No other sanitizing solution will be applied to the teats. The teats are wiped with the damp, sanitized cloth towels and allowed to air dry.
- A manual drying step will **NOT** be used on the teats.

Would this proposed teat prep protocol be acceptable?

**NOTE:** The three (3) acceptable teat prep protocols currently addressed in Item 13r-Milking, Flanks, Udders and Teats of the PMO are:

1. **The udders and teats of the individual dairy animals are determined to be clean and dry prior to milking; therefore the use of a sanitizing solution and the drying of the teats (#2 below) or the cleaning (not dry wiped) and manual drying of the teats (#3 below) would not be required; or**
2. **Teats are cleaned (manually (not dry wiped), rain birds, etc.) and manually wiped dried, treated with a sanitized solution and dried (manually wiped dry or air dried) just prior to milking; or**
3. **Sanitizing of teats is not required if the udder is dry and the teats have been thoroughly cleaned (not dry wiped) and dried (manually wiped dry) prior to milking.**

**FDA’s review of the scientific literature on this issue indicated that the actual act of cleaning and manually drying the teat (#3 above) was identified as**
being equally important as the cleaning, manually drying and sanitizing of the teat (#2 above) in the reduction of bacterial load on the teat surface and ultimately in the milk.

The determination of what constitutes a dry udder and cleaned and dried teats shall be made by the Regulatory Agency.

**THIS PROPOSED TEAT PREP PROTOCOL WOULD MEET #2 ABOVE:**

- If the damp, sanitized cloth towels are used on teats that are determined to be clean; and
- It can be tested and verified to the Regulatory Agency that there is a concentration of the EPA approved sanitizer, acceptable to the Regulatory Agency, on the damp cloth towels immediately prior to use.

**THIS PROPOSED TEAT PREP PROTOCOL WOULD NOT MEET #2 OR #3 ABOVE:**

- If the damp cloth towels are used to clean “soiled udders and teats” as there would not be an adequate sanitization step as addressed in #2 above because you cannot clean and sanitize in the same step; or
- If the damp cloth towels are used to clean “soiled udders and teats”, the teats will not be dried (manually wiped dry) prior to milking as addressed in #3 above.

28. **PMO-Section 7, Item 14r**

M-I-07-7 addresses the FDA accepted teat preparation protocol for the Lely Astronaut Robotic Milking System. Step 4 of the teat preparation protocol is the diversion of the fore-milk, where the fore-milk and water (Lely wash) solution is diverted to the cyclone separator. During the diversion process at the end of the milking cycle for an individual dairy animal, the teat cups are flushed with water and the only separation between the receiver jar and the fore-milk and water solution is a rubber sleeve (hose) that is collapsed by air pressure applied to the area, essentially creating a pinched hose. Chemicals are not being used in the water that is being used to flush the teat cups. Is this single collapsed sleeve (pinched hose) acceptable for the required separation between the milking system and the fore-milk and water solution used to flush the teat cups between the individual milking of dairy animals?

No. Pinch valves (hoses) have not been demonstrated as an acceptable means to provide an adequate separation between the milking system and the fore-milk and water solution.
**NOTE:** An appropriate back flow preventer would also be required on the water line used to flush the teat cups.

29. **PMO-Section 7, Item 14r**

For an AMI, would a liquid level sensor, i.e. similar to a milk probe in a receiver jar, be acceptable in a sanitary moisture trap to shut-down the milking system so liquids collected in the sanitary moisture trap cannot get back into the receiver jar as instructed by 3-A® Accepted Practice 606-05, E8.5? The liquid level sensor would replace the traditional float ball used in most milking systems. The liquid level sensor can be tested to prove the milking system shuts down when it comes in contact with liquid as liquid fills the sanitary moisture trap. Upon the milking system being shutdown, any liquid collected in the sanitary moisture trap would drain out through the automatic drain in the bottom of the sanitary moisture trap.

Yes, provided:

- The sanitary moisture trap meets the requirements of E8.5 of 3-A® Accepted Practices for the Design, Fabrication, and Installation of Milking and Milk Handling Equipment, Number 606-05 and is self-draining when the milking system is shut down, and

- The liquid level sensor, when tested, will shut the milking system down and effectively prevent liquid in the sanitary moisture trap from entering the milk receiver, releaser or vacuum milk holding tank.

30. **PMO-Section 7, Item 14r**

Are butterfly valves acceptable for block-bleed-block valve arrangements as cited within Item 14r-Protection from Contamination of the PMO when installed within AMIs to effectively separate pipelines and equipment used to contain or conduct milk from tanks/silos and/or circuits containing cleaning and/or sanitizing solutions, or from abnormal milk?

No. To comply with Item 14r these block-bleed-block valve arrangements shall consist of at least two (2) automatically controlled valves with a drainable opening to the atmosphere between the valves; be position detectable; and designed to be CIP cleaned. Butterfly valves are not designed for CIP cleaning as they require disassembly for effective Cleaned-out-of-Place (COP) manual cleaning.

31. **PMO-Section 7, Item 15r**

An animal health product “Gold Spike™ For Healthy Cows” highly concentrated capsules containing three (3) branded strains of *Bacillus subtilis* and one (1) branded strain of *Lactobacillus brevis* is making drug
claims for treating mastitis and high somatic cell count (SCC) conditions in dairy cattle in their literature (labeling). They also make the statement that it contains no antibiotics and has no milk and meat withhold times. This product is being found on Amish dairy farms and is being sold as an alternative for use on organic dairy farms for mastitis and high SCC issues. Would this animal health product, as currently labeled, be considered a violation of Item 15r-Drug and Chemical Control of the PMO?

Yes. Their literature (labeling) is making drug claims and; therefore, it would be considered an unapproved new animal drug. If found on a dairy farm and determined to be significant, it would be considered a violation of Item 15r of the PMO and would be debited under 15(d) (five (5) point debit) on FORM FDA 2359a-Dairy Farm Inspection Report.

32. **PMO-Section 7, Item 15r**

Would a footbath solution of formaldehyde and copper sulfate that also contains a drug, i.e. “oxytetracycline”, and makes a label claim to “maintain hoof health” be considered a topical antiseptic or wound dressing and be exempt from the labeling and storage requirements of Item 15r of the PMO?

No. FDA’s Center for Veterinary Medicine (CVM) considers the label claim of “maintain hoof health” to be a structure/function claim and would consider this footbath solution that contains a drug and applied topically to be an unapproved new animal drug. Therefore, if this footbath solution is encountered on a dairy farm during a regulatory inspection, rating or check rating it would be considered a violation of Item 15r of the PMO and would be debited under 15(d) (five (5) point debit) on FORM FDA 2359a-Dairy Farm Inspection Report.

**NOTE:** The use of antibiotics in foot baths constitutes extra-label use. If any antibiotic is being used in a foot bath solution it must be properly extra-labeled by the prescribing veterinarian in accordance with the requirements of Item 15r of the PMO.

33. **PMO-Section 7, Items 18r and 17p**

If a milk plant or dairy farm operator only has a letter from the National Sanitation Foundation (NSF) stating that the glycol that they are using in their recirculated cooling water system is NSF approved and does not make any reference in that letter or on the barrel or container’s label that the glycol is United States Pharmacopeia (USP) grade, food grade, or the glycol and all of its ingredients (components) are Generally Recognized as Safe (GRAS), would this NSF letter alone be acceptable under the PMO?
No. Any letter from the NSF, the manufacturer or distributor of the glycol shall state that the glycol is either USP grade, food grade, or the glycol and all of its ingredients (components) are GRAS. That information may also be on the label attached to the barrel or container for the glycol to be acceptable under the PMO.

34. **PMO-Section 7, Items 18r and 17p**

Would an EPA registered biocide, which has an EPA Registration Number on the label, that is labeled with directions for use as a disinfectant in municipal and public drinking water systems or for use as a disinfectant in “food processing water” be acceptable to be used in recirculated cooling water systems located on Grade “A” dairy farms and in Grade “A” milk plants when used in accordance with the directions for use for the disinfection of municipal and public drinking water systems or as a disinfectant for food processing water?

Yes.

35. **PMO-Section 7, Item 7p**

In a milk plant, well water is being processed utilizing reverse osmosis (RO) and the RO processed water is being stored in a storage tank/silo. The RO processed water is being used on milk product pump seals or for CIP of milk equipment. It is also being run through the HTST where it is pasteurized and the pasteurized RO process water is used to push milk and/or milk products. The RO processed water is not recirculated or reclaimed. The well water feeding the RO process is tested as required each six (6) months. Does the PMO require any additional testing of this RO processed water?

No.

36. **PMO-Section 7, Item 7p; and Appendix D**

What is the PMO required cleaning frequency for RO systems used to remove minerals and other residues from water reclaimed from Grade “A” milk and/or milk products?

*The PMO is silent regarding the cleaning or the frequency of cleaning of RO systems used to remove minerals and other residues from water reclaimed from Grade “A” milk and/or milk products.*

37. **PMO-Section 7, Item 7p; and Appendix D**

Within Appendix D-Standards for Water Sources, V-Water Reclaimed from Milk and Milk Products and from Heat Exchangers or Compressors in Milk
Plants, Category I-Used for Potable Water Purposes of the PMO, would the acceptable water usage include the final rinsing of product-contact surfaces within CIP systems prior to sanitizing?

Yes.

38. **PMO-Section 7, Items 7p and 16p; and Appendix H**

May a sanitary check valve that is spring operated be used:

1) Within a magnetic flow meter based timing system, which closes to prevent positive pressure in the raw milk or milk product side of a regenerative section whenever a power failure, shut down, or flow-diversion occurs; or
2) In an emergency water feed line located downstream of a FDD and before the inlet of an evaporator (in conjunction with the safe water valve); or
3) When used as the automatic means of preventing negative pressure, in conjunction with a vacuum breaker, to protect the pasteurized section of a regenerator in systems with vacuum equipment located downstream of the FDD?

Yes.

**NOTE:** A sanitary check valve located in the emergency water feed line to the evaporator as cited in 2) above would not be considered appropriate protection against backflow. Therefore, the water feed line to the evaporator shall also have an effective backflow prevention device installed in the water feed line.

39. **PMO-Section 7, Items 10p and 11p**

a) Is the use of “wire” in-line strainers acceptable under Items 10p-Sanitary Piping and 11p-Construction and Repair of Containers and Equipment of the PMO?

Yes. The product commercially known as "wedgewire" is described generically in the 3-A® Sanitary Standard for In-line Strainers for Milk and Milk Products, Number 42-##, and for Mechanical Strainers, Number 87-##. It is described in the "fabrication" sections of both of these 3-A® Sanitary Standards as "solid V-shaped profile wire", which does not overlap like woven wire. Products that use this type of construction have been demonstrated to be COP cleanable in these two (2) applications. Wedgewire when used for in-line and mechanical strainers that hold a 3-A® Symbol meets the sanitary design and construction requirements of Items 10p and 11p of the PMO.
Wedgewire used for in-line and mechanical strainers that does not hold a 3-A® Symbol shall be individually evaluated and determined to comply with Items 10p and 11p of the PMO. To comply with the PMO, these in-line and mechanical strainers shall be constructed to be cleanable under conditions of use. Determination of cleanability shall be based on whether these in-line and mechanical strainers are found to be clean upon inspection.

NOTE: There are commercially available wedgewire in-line and mechanical strainers in which the wedgewire meets the 3-A® requirements for the “solid V-shaped profile wire” as cited within 3-A® Sanitary Standards 42-## and 87-## except that it has a welded solid end cap at both ends of each wedgewire strainer to prevent the breakage of pieces of the V-shaped profile wedgewire. The joint between the profile wedgewire and the end caps have a crevice between the welded cap joint and the end of the V-shaped profile wedgewire. These wedgewire in-line and mechanical strainers normally do not have a 3-A® Symbol authorization because they do not comply with 3-A® Sanitary Standards 42-## and 87-##.

b) Is this product commercially known as "wedgewire" as described above considered woven wire?

No. (Refer to M-I-08-7, (Question #36) for additional information addressing woven wire.)

40. PMO-Section 7, Item 12p

Would it be permissible to allow greater than seventy-two (72) hour storage of milk in a silo(s) if it is included in an extended run proposal?

Yes. The extended run proposal to be submitted, reviewed and accepted by the Regulatory Agency, in consultation with FDA, must address and include the storage of milk in a silo(s) for greater than seventy-two (72) hours.

41. PMO-Section 7, Item 12p; and Appendix J, Sections B and C

If a milk plant is bringing in heavy gauge plastic roll stock and running the roll stock through a packaging machine(s)/filling line(s) where the roll stock is formed into cups, shrink wrap labels are applied, filled with milk or milk product and then sealed with a plastic or metal film:

a) Are these formed cups required to be tested in accordance with Item 12p-Cleaning and Sanitizing of Containers and Equipment and Appendix J-Standards for the Fabrication of Single-Service Containers and Closures for Milk and Milk Products of the PMO?
Yes. The packaging machine(s) would be considered a Form/Fill/Seal packaging machine(s).

Please refer to M-I-05-4 (Question #38) for additional information.

b) What is considered a manufacturing line?

For Form/Fill/Seal containers all similar forming/packaging/sealing machines with similar types of formed containers would be considered a manufacturing line for sampling purposes.

c) Would all forming/packaging/sealing machines that form similar types of plastic cups have to be sampled each month to meet the required four (4) samples in a six (6) month period or would a random forming/packaging/sealing machine selection each time samples are collected suffice to meet this required sampling frequency?

Formed and sealed cups from randomly selected individual forming/packaging/sealing machines each sample collection time would suffice.

With your example of seven (7) individual forming/packaging/sealing machines located in this milk plant, taking one (1) sample set, which involves four (4) containers and lids, from one (1) forming/packaging/sealing machine on a rotation basis of the forming/packaging/sealing machines will satisfy this sampling requirement.

Please refer to M-I-07-3 (Question #37) and M-I-08-7 (Questions #42 and 54) for addition information related to “Sample Sets”.

d) The milk plant is also receiving plastic cups from an outside IMS listed single-service manufacturing facility and applying shrink wrap labels to the cups, nesting them and placing a certain number of labeled cups into a plastic protective sleeve for storage until the cups are used within the milk plant. None of these labeled plastic cups are shipped out of the milk plant. Would these labeled cups be required to be sampled and tested in a similar manner to the form/fill/seal cups addressed in a) through c) above?

No. This activity is taking place within the IMS listed milk plant and would be covered under the milk plant’s routine Regulatory Agency inspections.

e) Would formed plastic film tube or pouch containers be required to be sampled and tested similar to the form/fill/seal plastic cups addressed in a) and c) above?

No.
42. **PMO-Section 7, Item 15p(A)**

Item 15p-Protection from Contamination (A), Administrative Procedures #2 of the PMO states: “Packaged milk and/or milk products, which have physically left the premises or the processing milk plant, are not re-pasteurized for Grade “A” use. The Regulatory Agency may, on a specific individual request, authorize reprocessing of packaged milk and/or milk products, provided all other aspects of this Item, including proper storage temperature and container integrity are complied with. …”

A milk plant in one (1) State ships packaged milk and/or milk product to a sister company milk plant in another State for sale and distribution. As the code date was getting near, the receiving milk plant wanted to reprocess the packaged milk and/or product, so they requested their Regulatory Agency to grant them the authority to reprocess the packaged milk and/or milk product.

a) Is the Regulatory Agency that is referred to in the PMO quote cited in the question above, the Regulatory Agency where the milk and/or milk product is initially processed and packaged?

_No. This statement refers to the Regulatory Agency in which the milk plant is located that makes the request to reprocess and repackage the milk and/or milk product._

b) If a milk and/or milk product has not left the control of the “company” but has been shipped from the milk plant that originally processed and packaged the milk and/or milk product, which is located in one (1) State, to a sister “company” milk plant located in another State, may the “company” request the Regulatory Agency in which the sister “company’s” milk plant is located for the authorization to reprocess and repackaged the milk and/or product?

**NOTE:** All other PMO requirements, including proper storage temperature, container integrity, etc. shall be complied with.

_Yes. The milk plant’s corporate headquarters may make a request to the Regulatory Agency in which the milk and/or milk product has been received for sale and distribution for reprocessing and repackaging of the milk and/or milk product. However, it is entirely within the purview of the Regulatory Agency that has received the request to reprocess and repackage the milk and/or milk product to accept or deny such a request._
43. **PMO-Section 7, Item 15p(A)**

Does the PMO require milk plant personnel to remove the outer protective layer of paper bags, which contain ingredients, just prior to the ingredients being added to their batching process?

*No.*

44. **PMO-Section 7, Item 15p(B)**

Are there any requirements in the PMO regarding how long a storage tank/silo may be used to store pasteurized equivalent water before the storage tank/silo is required to be emptied and cleaned?

*No.*

**NOTE:** Some hazard evaluations and safety assessments for pasteurized equivalent water that have been determined to be acceptable to the Regulatory Agency, in consultation with FDA, within the protocol for the continued monitoring of criteria and procedures have specified limits for the period of time that pasteurized equivalent water can be stored in a tank/silo or has specified a cleaning frequency for the storage tank/silo. If such specifications are included in the hazard evaluations and safety assessments for pasteurized equivalent water that has been determined to be acceptable to the Regulatory Agency, in consultation with FDA, then they shall be complied with. If not, they would be considered a violation of Item 15-Protection from Contamination (B) of the PMO.

45. **PMO-Section 7, Item 15p(B)**

Within Item 15p(B), Administrative Procedures #2.(d) it addresses pasteurized water or equivalent and refers to Footnote #10 for an exception to using pasteurized water or equivalent for the rinsing of cottage cheese curd. Footnote 10 under Footnotes of the PMO requires that Regulatory Agencies desiring to regulate cottage cheese, dry curd cottage cheese and reduced fat or low fat cottage cheese under the terms of this Ordinance should add the following:

Provided that the rinsing of cottage cheese curd with sanitized and/or acidified potable water may be accepted by the Regulatory Agency.

The following outlines a milk plant’s cottage cheese water rinse protocol:

1. The first rinse is charcoal treated city water;
2. The second rinse consists of half charcoal treated city water and half chemically treated, sanitizer addition by the milk plant, city water; and
3. The final rinse consists of one hundred percent (100%) chemically treated, sanitizer addition by the milk plant, city water.

Would this outlined milk plant’s cottage cheese water rinse protocol be considered in violation of Item 15p(B) of the PMO?

**Yes. The use of potable water which has not been treated with a sanitizer and/or acidified is not permitted for the rinsing of cottage cheese curd.**

46. **PMO-Section 7, Item 15p(B); and Appendix D**

Does water complying with Appendix D, V-Water Reclaimed from Milk and Milk Products and from Heat Exchangers or Compressors in Milk Plants, Category I-Used for Potable Water Purposes of the PMO meet the requirements of pasteurized equivalent water without further treatment?

**No.**

47. **PMO-Section 7, Item 16p**

A milk plant processes and packages yogurt in bulk containers and transports the yogurt to another milk plant for further packaging, such as repacking with added ingredients. Would the yogurt be required to be repasteurized at this second milk plant prior to repackaging?

**Yes.**

48. **PMO-Section 7, Item 16p**

A milk plant is taking heat-treated cream off the raw milk separator (126°F-160°F), further heating the cream to 166°F or higher in another plate heat exchanger (PHE) and then cooling it to 45°F for storage and later use in the milk plant. Is this permissible under the exception for milk separation as cited in the Preamble of Section 7- Standards for Grade “A” Milk and/or Milk Products of the PMO?

**No. The exception in the Preamble of Section 7 of the PMO for the separation of heat-treated cream is for the heating one (1) time to a temperature less than 166°F in a continuous heating process and immediately cooling the cream to 45°F or less when necessary for enzyme deactivation (such as lipase reduction) for a functional reason. Any heating of the cream to 166°F or higher is required to be conducted in a legal pasteurization system.**
49. **PMO-Section 7, Item 16p**

A pasteurization system is being utilized in which milk and/or milk products are to be either Higher-Heat-Shorter-Time (HHST) pasteurized or UP to a minimum of 138°C (280°F) for at least two (2) seconds in order to be labeled “Ultra-Pasteurized”. This pasteurization system would use operational controls, which are not public health controls, to cause milk and/or milk product, that has not been held for at least 138°C (280°F) for at least two (2) seconds for UP labeling requirements, to be recycled back to the pasteurization system’s constant-level tank until the UP labeling requirements have been met. Is it permissible to seal the legal pasteurization time and temperature controls at less than 138°C (280°F) for two (2) seconds, but greater than one (1) of the minimum time and temperature combinations for HHST pasteurization referenced in Item 16p-Pasteurization, Aseptic Processing and Packaging, and Retort Processed after Packaging of the PMO?

Yes, provided the pasteurization system shall be designed, operated, tested, and sealed as a legal HHST pasteurization system. In addition, if the milk and/or milk products are to be labeled as “Ultra-Pasteurized”, pasteurization records or other documentation acceptable to the Regulatory Agency shall be available that are sufficient to allow the Regulatory Agency to verify whether or not the UP labeling requirements have been met.

50. **PMO-Section 7, Item 16p; and Appendix H**

When a RO or UF system is used to concentrate raw milk prior to pasteurization, the RO or UF system shall comply with Item 16p-Pasteurization, Aseptic Processing and Packaging, and Retort Processed after Packaging, Administrative Procedures #3. b. of the PMO. These requirements specify that the RO or UF system shall be equipped with temperature monitoring and recording devices that comply with the applicable specifications in Appendix H-Pasteurization Equipment and Procedures and Other Equipment, IV-Thermometer Specifications of the PMO. Which of these thermometer specifications would be applicable?

The specifications for the temperature monitoring and recording devices shall be capable of accurately determining and recording the temperatures and times specified within Item 16p, Administrative Procedures #3. b. (2) of the PMO and shall be acceptable to the Regulatory Agency.

51. **PMO-Section 7, Item 16p; and Appendix H**

Are the terminal strips on the input/output blocks, located on the outside of a Programmable Logic Controller (PLC), required to be sealed to prevent the potential re-wiring of public health controls.
No. The rewiring of the terminal connections at the input/output blocks will not change the PLC program or the public health controls within the PLC.

52. **PMO-Section 7, Item 16p(B)**

a) Is an M-b required to be issued for Regulatory Agencies and FDA to accept a variable frequency drive (VFD) that is used to control the speed of booster pumps, timing pumps and/or similar flow promoting devices in continuous flow pasteurization systems?

   No.

b) When is a VFD used to control the speed of booster pumps, timing pumps and/or similar flow promoting devices located in a HTST or HHST pasteurization system, except those located in magnetic flow meter based timing systems, required to be sealed?

   If tested and timed at the maximum speed of the VFD and found to provide a minimum legal pasteurization time at that maximum speed, it would not be required to seal the VFD. However, if the VFD is not tested and timed with the VFD set at the maximum speed, the VFD shall be sealed at a flow rate at which it was tested and timed and found to provide a minimum legal pasteurization time.

   **NOTE:** In all cases any communication port(s) on the VFD controller box shall be sealed or disabled to assure that public health safeguards such as the required interwiring with the FDD’s position detection device, i.e., micro-switches, cannot be over ridden.

c) Are VFDs required to be sealed at the maximum speed when located in a magnetic flow meter based timing system and they utilize a “coast to stop” parameter, which has been tested to ensure that the pump(s) are immediately de-energized when required?

   No.

   **NOTE:** In all cases any communication port(s) on the VFD controller box shall be sealed or disabled to assure that public health safeguards such as the required interwiring with the FDD’s position detection device, i.e., micro-switches, cannot be over ridden.

53. **PMO-Section 7, Item 16p(B)**

May the divert line from the FDD to the constant-level tank in a pasteurization system have a back pressure valve installed, which is drilled
or pinned so that it cannot block the FDD divert line when the back pressure valve is closed?

Yes. The pipeline from the diversion port of the FDD shall be self-draining and shall be free of restrictions or valves; unless such restrictions are noticeable and valves are so designed that stoppage of the diversion line cannot occur.

54. **PMO-Section 7, Item 16p(B)**

Item 16p(B)-High-Temperature-Short-Time (HTST) Continuous-Flow Pasteurization, Administrative Procedures #2.f.-Flow-Promoting Devices: (3) of the PMO specifies that if it is necessary to lengthen the holding time during diverted-flow, an identifiable restriction may be placed in the vertical portion of the diversion pipeline.

A flow-diversion device (FDD) divert line was observed with an identifiable concentric reducer/restriction in the vertical portion of the divert line located between the FDD and the constant-level tank. Before draining back to the constant-level tank, the reduced size piping in the divert line located downstream from the concentric reducer/restriction and upstream of the constant-level tank was observed to include two (2) elbows and a line between them that was determined to be sloped to be self-draining back to the constant-level tank. Would this divert line be considered a violation of the PMO?

No. The concentric reducer/restriction was identifiable and the reduced size piping of the divert line was sloped to be self-draining back to the constant-level tank.

55. **PMO-Section 7, Item 16p(B); and Appendix H**

Is a ½ inch diameter holding tube acceptable for use in an HTST or HHST pasteurization system?

Yes.

56. **PMO-Section 7, Item 16p(B); and Appendix H**

a) In M-b-350 is there a piping diameter size for the magnetic flow meter stipulated in the submitted documentation that was reviewed when used as a component of a magnetic flow meter based timing system?

No.
b) Currently, Rosemont offers a ½ inch diameter magnetic flow meter acceptable for PMO use. Is there a minimum piping diameter size limit?

No.

57. **PMO-Section 7, Item 16p(B); and Appendix I**

Is M-I-09-3 (Question #71), which states that the pasteurization indicating thermometer and the temperature sensor for the safety-thermal-limit-controller (STLR) must always be at the end of the holding tube regardless of the FDD location in conflict with the **NOTE** in Appendix I-Pasteurization Equipment and Controls – Tests, Test 11-Continuous-Flow Pasteurization System Holding Tubes – Pasteurization Holding Time, Tests 11.3-Calculated Pasteurization Holding Time for HHST Pasteurization Systems Using Indirect Heating, 11.4-Calculated Pasteurization Holding Time for HHST Pasteurization Systems Using Direct Heating and 11.5-HHST Pasteurization Systems Holding Time Using Direct Steam Infusion Heating with a Steam Pressure Relief Pop-off Valve and a Vacuum Chamber Orifice in Place of a Timing Pump of the PMO?

The **NOTE** in Appendix I states that the holding tube shall be arranged to have a continuously upward slope in the direction of flow of not less than 2.1 centimeters (0.25 of an inch) per foot. If the indicating temperature sensing element is located at the beginning of the holding tube, the entire length of the holding tube shall be protected against heat loss by a material that is impervious to water.

Yes. The **NOTE** in Appendix I of the PMO applies only to HHST pasteurization systems that have insulated holding tubes with the indicating thermometer located at the beginning of the holding tube and the recording thermometer located at the end of the holding tube.

*The answer to Question #71 from M-I-09-3 failed to consider this exception.*

58. **PMO-Section 7, Item 16p(C)**

How often is the water utilized in a regenerative section of a milk or milk product-to-water-to milk or milk product regenerative section required to be tested?

The **PMO does not require this water to be tested.**

59. **PMO-Section 7, Item 16p(C)**

a) May a line connected to the drain vent/CIP discharge port on a G&H vacuum breaker or other similar style vacuum breakers, which is designed
to be CIP, be positioned and terminate into a secondary drain line or funnel, which is open near the floor, and is used to direct the CIP solution to the floor from an elevated height on a HTST pasteurization system?

Yes. The line connected to the drain vent/CIP discharge port of the vacuum breaker shall terminate and be open to the atmosphere at least twelve (12) inches (30.5 centimeters) above the highest raw milk or milk product level in the HTST pasteurization system.

The required air-gap located at the end of the line connected to the drain vent/CIP discharge port of the vacuum breaker shall be visually evident from the floor or other means, i.e. ladder, stairs, etc. An air gap that cannot be verified will be considered a violation of Item 16p(C)-Pasteurizers Employing Regenerative Heating of the PMO.

b) Would it make a difference if the line connected to the drain vent/CIP discharge port of the vacuum breaker terminates above or below the upper rim of an unobstructed secondary drain line or funnel that provides the required atmospheric break?

No.

60. **PMO-Section 7, Item 16p(C)**

a) May a sampling valve be installed after the final cooler section and before the vacuum breaker on a HTST pasteurization system?

No.

b) May a septum (syringe type) sample port be installed after the final cooler section and before the vacuum breaker on a HTST pasteurization system?

Yes.

61. **PMO-Section 7, Item 16p(C); and Appendix I**

Would it be acceptable if a milk plant utilizes a “lock-out hub” in accordance with State Occupational Safety and Health Administration (OSHA) requirements that is sealed by the Regulatory Agency to prevent access by milk plant personnel to the electric wiring conduit for the booster pump in a HTST system?

Yes.
NOTE: Any broken Regulatory Agency seal on this “lock-out hub” would be required to be reported to the Regulatory Agency.

62. **PMO-Section 7, Item 16p(D)**

   May a milk plant have multiple pasteurization days on a circular vat pasteurization chart?

   No.

   **NOTE:** There would be one (1) exception if the circular vat pasteurization chart has not exceeded the time limit for which the circular chart was designed. For example, a twelve (12) hour circular chart was installed on the afternoon of one (1) day, with a batch of milk or milk product pasteurized that afternoon, and another batch of milk or milk product being pasteurized the next day after midnight and before the twelve (12) hour time limit of the chart was exceeded.

63. **PMO-Section 7, Item 16p(D); and Appendix H**

   A CIPable vacuum breaker is being utilized within a HTST pasteurization system prior to the entrance to an evaporator. Is the CIPable vacuum breaker required to pulse during CIP?

   *The pulsing of this vacuum breaker is not required within the PMO. Within the milk plant’s CIP computer program these vacuum breakers are normally programmed to pulse during CIP. Ultimately the vacuum breaker and associated piping must be clean when inspected.*

64. **PMO-Section 7, Item 16p(D); and Appendix I**

   a) May a measurement of the “draw down”, a level drop in the constant-level tank of a HTST pasteurization system, that has a one (1) inch holding tube be used in lieu of Appendix I-Pasteurization Equipment and Controls - Tests, II-Test Procedures, Test 11-Continuous-Flow Pasteurization System Holding Tubes - Pasteurization Holding Time, 11.1-HTST Pasteurization Systems (Except for magnetic flow meter based timing systems) of the PMO as it is difficult to time these HTST pasteurization systems with testing equipment?

   No.

   b) Is it permissible to use a calculated holding tube length for a HTST pasteurization system with the FDD located at the end of the holding tube in lieu of Appendix I-Pasteurization Equipment and Controls - Tests, II-Test Procedures, Test 11-Continuous-Flow Pasteurization System Holding Tubes - Pasteurization Holding Time, Test 11.1-HTST Pasteurization
Systems (Except for magnetic flow meter based timing systems) of the PMO?

No.

65. **PMO-Section 7, Item 16p(D); and Appendix I**

a) If a HTST pasteurization system has dual (cut-in/cut-out) set points, is the Regulatory Agency required to complete Test #1, 2 and 4 for both (cut-in/cut-out) set points during their quarterly HTST pasteurization equipment tests?

No.

*Test 1-Indicating Thermometers-Temperature Accuracy of Appendix I-Pasteurization Equipment and Controls – Tests of the PMO states that the media bath is to be within 2°C (3°F) of the lowest sealed cut-out pasteurization or ultra-pasteurization temperature.*

*Test 2-Temperature Recording and Recorder-Controller Thermometers - Temperature Accuracy of Appendix I of the PMO states that the media bath is to be heated to a constant temperature at the lowest sealed cut-out pasteurization temperature.*

*Test 4-Temperature Recording and Recorder-Controller Thermometers – Checked Against Indicating Thermometer of Appendix I of the PMO states that the temperature of the Recorder-Controller shall be compared with the Indicating Thermometer at a stabilized temperature at or above the minimum legal pasteurization temperature.*

b) With pasteurization systems that have dual (cut-in/cut-out) set points, is it required that the milk plant's pasteurization system operator utilize Appendix I, II-Test Procedures, Test 10-Milk or Milk Product-Flow Controls and the Milk or Milk Product Temperature at Cut-in and Cut-out, 10.1-HTST Pasteurization Systems of the PMO to confirm daily all of the cut-in/cut-out set points or only those cut-in/cut-out set points for the milk and/or milk products being processed that day?

*Only those cut-in/cut-out set points for the milk and/or milk products being processed that day.*

c) Are dual (cut-in/cut-out) set points required to be tested and confirmed at the beginning of processing each day or can the specific cut-in/cut-out set points be tested and confirmed prior to the processing of any milk and/or milk product to which the cut-in/cut-out set points apply?
All of the FDD dual (cut-in/cut-out) set points may be tested and confirmed by the milk plant's pasteurization system operator at the beginning of processing each day. If they are all not conducted in this manner, then they are required to be tested and confirmed prior to the processing of any milk and/or milk product to which the specific cut-in/cut-out set points apply.

66. **PMO-Section 7, Item 16p(D); and Appendix I**

Is Test #9-Regenerator Pressure Controls within Appendix I of the PMO required for double and triple tubular type pasteurization systems?

Yes. *Double and triple tubular pasteurization systems are required to be equipped with regenerator pressure pasteurization controls so that this test can be appropriately conducted.*

67. **PMO-Section 7, Item 17p**

Some milk plants utilize vat pasteurization which allows milk and/or milk products to cool down in the same vat after pasteurization is completed. This may take thirty (30) minutes to an hour to cool the milk and/or milk products to 45°F or below. Would this be acceptable and fit the requirement of “cool immediately prior to filling or packaging” as cited in Item 17p-Cooling of Milk and/or Milk Products of the PMO?

Yes.

68. **PMO-Section 7, Item 17p**

Following an initial milk plant study and Regulatory Agency approval of a cooling temperature exemption for yogurt as provided for within Item 17p of the PMO, how often should the milk plant check the cooling temperature exemption to verify that they are still complying for their hot pack yogurt?

*The frequency would be determined by the Regulatory Agency.*

69. **PMO-Section 11; and Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments (PROCEDURES)-Section IX**

If a milk plant is IMS listed for yogurt (Product Code #9) and also makes cheese, is it permissible to use the sweet whey from the cheese making process as an ingredient in their Grade “A” drinkable yogurt?

**NOTE:** The raw milk used to make the cheese is from IMS listed sources but the milk plant is not IMS listed for liquid whey (Product Code #11).
Yes. The currently “stayed” dairy ingredient provision for the SOIs for yogurt would allow the sweet whey to be used as an ingredient in yogurt. The sweet whey ingredient would be required to be Grade “A”. “Whey” would be required to be listed in the ingredient statement of their drinkable yogurt.

If the whey process and production were included in the current rating and the milk plant is only utilizing the sweet whey for their own production of Grade “A” drinkable yogurt then they would not have to have an IMS listing that includes Product Code #11 for liquid whey. The important thing to remember for this specific scenario is as long as the current rating included the whey process and production that rating would be sufficient to cover the production of yogurt with their sweet whey being used as an ingredient in their drinkable yogurt.

However, if the whey process and production were not included in the current rating, then a new rating would be required to include the whey process and production before the milk plant could use their sweet whey as an ingredient in their Grade “A” drinkable yogurt. Also, if the milk plant plans to ship out their Grade “A” whey or label it Grade “A”, then the milk plant would have to be re-rated and listed for liquid whey (Product Code #11).

70. PMO-Appendix B, Section V

While conducting the evaluation of bulk milk hauler/samplers it was observed that the milk tank truck had not been used and washed and sanitized in two (2) days as indicated on the attached wash tag. The milk tank truck was not washed and sanitized in the last twenty-four (24) hours and milk was being loaded onto the milk tank truck for the first time since it was last washed and sanitized at the time of the evaluation. Would this be considered a violation of Appendix B of the PMO?

No. The milk tank truck shall be cleaned and sanitized prior to its first use. When the time elapsed after cleaning and sanitizing, and before it first use, exceeds ninety-six (96) hours that tank shall be re-sanitized.

71. PMO-Appendix H, Section IV

Does the self-diagnostic circuitry described in Appendix H, Section IV-Thermometer Specifications, Temperature-Recording Devices for Batch (Vat) Pasteurizers of the PMO require that each temperature sensing probe of a dual temperature probe used with a batch (vat) pasteurizer to be self-diagnostic?
No. The temperature sensing probes for a dual temperature probe used with a batch (vat) pasteurizer are not required to utilize the same technology as the Digital Reference Thermometer (DRT), which makes a continuous comparison of each Resistance Temperature Device (RTD) within the DRT temperature probe. However, the temperature sensing probes in a dual temperature probe sensing device with a batch (vat) pasteurizer shall be able to detect the failure of the recording chart or temperature sensing probe. If a failure has been detected by the recording chart sensor, the pen arm on the recording chart shall go visibly out of range. If the temperature sensing probe detects a failure within the temperature sensing probe the digital display shall blank or become unreadable.

72. **PMO-Appendix I**

When conducting Appendix I-Pasteurization Equipment and Controls - Tests, II-Test Procedures, Test 5 – FDD – Proper Assembly and Function, Test 5.4-Device Assembly - Dual Stem Device of the PMO on a FDD for which an M-b has been issued, is the testing procedure specified in the FDD operator’s manual referenced in the M-b required to be utilized or may the testing procedure outlined in Test 5.4 be used?

*The testing procedures referenced in the specific M-b are required to be utilized and followed. Appendix I, II-Test Procedures of the PMO includes the following: NOTE: For various pieces of equipment approved for pasteurization systems, Testing Procedures which have been reviewed specifically for that equipment are included within the FDA accepted operations manual for the equipment and/or within the Memorandum of Milk Ordinance Equipment Compliance (M-b) issued upon FDA's review and acceptance of the equipment. These Testing Procedures shall be used.*

73. **PMO-Appendix I**

In Appendix I, II-Test Procedures, Test 7-Indicating Thermometers Located Within HTST Pasteurization Systems - Thermometric Response and Test 8- Temperature Recorder-Controller Thermometers - Thermometric Response of the PMO, why is the media bath temperature required to be 4°C (7°F) higher than the pasteurization cut-in temperature?

*Tests 7 and 8 are designed to measure the rate at which the indicating and recorder-controller thermometers, respectively respond to a rising temperature, which is partially dependent on the temperature of the media bath into which the respective thermometer probe is immersed. The criteria required to comply with these Tests, four (4) seconds or less for the indicating thermometer and five (5) seconds or less for the recorder-controller thermometer, were chosen based on the specified media bath.*
temperatures and, therefore, would not be valid for higher or lower media bath temperatures.

**Rationale:** When subjected to a step-change in temperature under controlled conditions, the response time of a thermometer or temperature probe follows a logarithmic curve which is characterized by a time constant known as thermometric lag. The thermometric lag constant is mathematically defined as the time required for a temperature measuring device to reach 63% of a step change in temperature. Tests 7 and 8 are designed to measure this thermometric lag constant. Because the time interval between the presence of under-heated milk and/or milk product at the temperature sensing element and the detection of that temperature is of critical importance, Tests 7 and 8 require that the thermometric lag be measured at the cut-in temperature. Both Tests specify an 11°C (19°F) step change, and measure the time required for the probe to respond to 7°C (12°F) of the 11°C (19°F) span. The span of 7°C (12°F) is approximately 63% of the 11°C (19°F) step change, so that the measured time is a close approximation of the thermometric lag constant.

74. **PMO-Appendix I**

Is the Regulatory Agency required to seal the Anderson AJ-300 Series Vat Pasteurization Combination Electronic Controls and if so, why?

Yes. M-b-364, issued August 5, 2010, addressing this equipment states, in part:

"**Key Public Health Items:**

1. Once testing is completed, a regulatory tamper evident seal shall be placed on the following:

   - **Recorder - Chart plate as per Section 3.2. of the Field Setup Guide.**
   - **Product Sensor - Model CT8V sensor as per Section 3.4. of the Field Setup Guide.**
   - **Airspace Sensor - Model CT8V sensor as per Section 3.4. of the Field Setup Guide.**

These regulatory seals are required to assure that the public health settings have not been changed after the equipment has been correctly configured and properly tested.

75. **PMO-Appendix J, Sections A and D**

a) An IMS listed single-service manufacturing facility is shipping single-service containers and/or closures that they fabricate to another company
that takes the individual single-service containers and/or closures out of their original pillow packs, separates them into smaller packages, and then ships the smaller packages to Grade “A” milk plants for their use. Is this other company’s facility that receives the IMS listed containers and/or closures and repackages them and ships them to Grade “A” milk plants, required to be IMS listed?

Yes. In such facilities during the process of handling the single-service containers and/or closures and repackaging them, the product contact surfaces of the single-service containers and/or closures have the potential to be exposed to contamination from the environment of the facility, the equipment and/or personnel, unless the standards of Appendix J of the PMO are being complied with.

b) If so, are they required to have some identification on their outer packaging that would let a Regulatory Agency know where the single-service containers and/or closures were originally manufactured?

Yes. The identification (name and city or plant code) of the IMS listed single-service manufacturing facility shall appear on the outside of the outer wrapping/packaging of the smaller packages of single-service containers and/or closures. It is recommended that the identification of the repackaging facility also appear on the outside of the outer wrapping/packaging of the smaller packages of single-service containers and/or closures as the repackaging facility.

c) Does Appendix J of the PMO require that sampling also be conducted at the facility that repackages the single-service containers and/or closures?

No.

76. **PMO-Appendix J, Sections A and D**

A manufacturing plant only produces and ships the labels or plastic sleeves (wraps) that are used on the outside of single-service containers to a milk plant where the labels or plastic sleeves (wraps) are applied to containers and filled. The manufacturing plant of the labels or plastic sleeves (wraps) does not apply the labels or plastic sleeves (wraps) to any single-service containers.

a) Are these labels or plastic sleeves (wraps) considered "component parts"?

No.
b) Is this manufacturing plant of the labels or plastic sleeves (wraps) required to be IMS listed?

No.

77. **PMO-Appendix J, Sections B and D**

May an IMS listed single-service containers and/or closures manufacturing plant ship regrind obtained from clean plastic materials in accordance with Appendix J of the PMO to another IMS or non-IMS facility to be pelletized and returned to the original single-service manufacturing plant to be utilized in the production of IMS listed single-service containers and/or closures?

Yes. The IMS listed single-service manufacturing plant receiving and utilizing the pelletized resin for the production of IMS listed single-service containers and/or closures shall have on file from the palletizing facility information indicating that the palletized resin complies with the requirements of 21 CFR Parts 174-178.

78. **PMO-Appendix J, Section D-Item 20**

a) When a single-service containers and/or closures for milk and/or milk products manufacturer is IMS listed as “PARTIAL”, what are the labeling requirements for the outer wrapping or shipping container (cardboard boxes) to indicate that the containers and/or closures are from an approved line(s) or machine(s)?

*Appendix J, Section D-Fabrication Plant Standards, Item 20-Identification and Records of the PMO requires that the outer wrapping, including shipping containers (cardboard boxes), be identified with the name and city of the plant where the contents are fabricated. Where several plants are operated by one (1) firm, the common firm name may be utilized, provided that the location of the plant at which the contents were fabricated is also shown either directly or by the Federal Information Processing Standards (FIPS) numerical code on the outer wrapper.*

*The PMO does allow for the use of a plant code or specific plant identifier assigned by the Regulatory Agency or Single-Service Consultant (SSC) for domestic and foreign manufacturers of single-service containers and/or closures for milk and/or milk products to be utilized in place of the name and city of the manufacturing plant.*

*For single-service containers and/or closures for milk and/or milk products manufacturers that have “PARTIAL” IMS listings, it is recommended that they all should have a specific plant code identifier that is distinct and unique for the IMS listed single-service containers and/or closures that are*
included with a “PARTIAL” IMS listing. This specific plant code identifier shall only be used for IMS listed single-service containers and/or closures for milk and/or milk products to verify to receiving milk plants, Regulatory Agency personnel, SROs and RMSs that the single-service containers and/or closures for milk and/or milk products they are manufacturing and shipping are included under their “PARTIAL” IMS listing.

If a receiving milk plant, Regulatory Agency personnel, SRO or RMS has questions related to the “PARTIAL” IMS listing they should contact the Regulatory Agency for the shipping domestic manufacturer of single-service containers and/or closures for milk and/or milk products or the Third Party Certifier (TPC) or SSC for the shipping foreign manufacturers of single-service containers and/or closures for milk and/or milk products. The Regulatory Agency, TPC or SSC, as applicable, shall have the required information available related to container/closure size(s)/type, equipment line(s), machine(s), etc. that are included on the “PARTIAL” IMS listing. They should also be able to verify that the single-service containers and/or closures for milk and/or milk products that the milk plant is receiving are from the identified “PARTIAL” IMS listing.

b) Would it be acceptable for a single-service containers and/or closures for milk and/or milk products manufacturer that has a “PARTIAL” IMS listing to use the term “IMS APPROVED” to identify their single-service containers and/or closures that are included in their “PARTIAL” IMS listing on the outer wrapping or shipping container (cardboard boxes).

No. There is currently not a provision in the PMO to accept the words “IMS APPROVED” or any similar wording. It would require NCIMS Conference action to allow these words to be used to resolve the issue of what is or is not covered in a “PARTIAL” IMS listing for single-service containers and/or closures for milk and/or milk products. As stated above it is recommended that single-service containers and/or closures for milk and/or milk products manufacturer have a specific plant code identifier that is distinct and unique for the IMS listed single-service containers and/or closures that are included with a “PARTIAL” IMS listing.

79. **PMO-Appendix K; and MMSR-Section VIII**

If a HACCP listed milk plant has lost their HACCP trained personnel, is the milk plant’s current IMS Listing still valid or is the Rating Agency required to conduct a new rating of the milk plant using the traditional rating method?

The Regulatory Agency shall have a discussion with the milk plant to determine if the milk plant wishes to continue under the NCIMS voluntary HACCP Program.
If the milk plant currently has on staff or can provide at least one (1) individual that is trained (formally or by job experience) in accordance with Appendix K-HACCP Program of the PMO as required, their current HACCP listing would be considered valid and the milk plant may continue in the NCIMS voluntary HACCP Program.

However, if the milk plant does not have on staff or cannot provide at least one (1) individual that is trained (formally or by job experience) in accordance with Appendix K of the PMO as required, the milk plant will not be able to fulfill their basic obligations under the NCIMS voluntary HACCP program. This would include such things as the required HACCP Plan records reviews. Therefore, the HACCP listing cannot be sustained and the milk plant’s HACCP listing shall be immediately withdrawn. If the milk plant wishes to maintain a listing on the IMS List, they shall request a new rating. This new rating shall be conducted using the traditional rating methods.

80. **PMO-Appendix N**

a) When a load of milk is confirmed positive in accordance with Appendix N of the PMO for Beta lactams, there is guidance in Appendix N, II-Regulatory Agency Responsibilities, Enforcement of the PMO that provides an exception to the load of milk being disposed of in a manner that removes it from the human or animal food chain. This exception cites that the adulterated milk could be acceptably reconditioned under FDA Compliance Policy Guide (CPG 7126.20). Does FDA maintain a list of calf facilities or other facilities that are operating under a FDA CVM acceptable Beta lactam milk reconditioning program per State?

NOTE: The current reference is CPG 675.200-Diversion of Adulterated Food to Acceptable Animal Feed Use.

No. However, each State that has an FDA CVM acceptable Beta lactam milk reconditioning program should have a list of facilities in their State that are operating under the State/FDA CVM acceptable Beta lactam milk reconditioning program.

b) Is there additional testing that required to be conducted prior to these loads of adulterated milk being reconditioned?

Any and all required testing would be specified in the State/FDA CVM acceptable Beta lactam milk reconditioning program.

c) If a State/FDA CVM acceptable reconditioning program only addresses Beta lactam adulterated milk, are other cases of milk adulteration such as
testing positive for aflatoxin or a drug other than Beta lactams covered under the State FDA CVM acceptable reconditioning program?

No.

81. **PMO-Appendix N**

**Scenario:** A “train”, which consists of two (2) separate milk tankers pulled by a tractor, has one (1) of the milk tankers being unloaded at one (1) milk plant and the second milk tanker is being unloaded at a different milk plant. The first receiving milk plant tests the milk tanker that they receive milk from and the Appendix N result is negative and they receive the milk. The second receiving milk plant tests the milk tanker that they receive milk from and the Appendix N result from the same or a different test is positive. During the dairy producer trace back, the dairy producer that is positive on the second milk tanker is noted to also have milk on the first milk tanker.

Do the Appendix N testing results and dairy produce trace back from the second milk tanker have any effect on the first milk tanker of milk that tested negative and was received at the first plant?

Yes. The first tanker contained milk from a known Appendix N positive dairy producer and the PMO does not provide for the dilution of positive Appendix N milk with unadulterated milk to make the milk acceptable for use. This is similar to how MST has already provided answers to the Appendix N testing of multi-compartment milk tank trucks (M-I-12-9 (Question #72)) and multi-tanks/silos/vessels at an on-farm producer/processor (M-I-15-3, (Question #68)).

**NOTE:** It is strongly recommended that the milk hauling company make provisions to not provide milk to these two (2) separate milk plants that have milk from one (1) or more dairy producers that are contained on both of the milk tankers. If the milk hauling company cannot provide for this, then the first receiving milk plant must be aware of which dairy producer’s milk is on the two (2) milk tankers so that this situation does not occur. If a dairy producer’s milk is on both milk tankers, it is recommended that the first receiving milk plant also test the milk on the second milk tanker to make sure that milk also tests negative. The results/records from the Appendix N testing conducted at the first receiving milk plant should accompany the milk tank truck load to the second receiving milk plant. An agreement may be worked out between the two (2) receiving milk plants to cover the expenses for this Appendix N testing. Any agreement for this required Appendix N testing would also have to be acceptable to the Regulatory Agency.
82. **PMO-Appendix N**

**Scenario:** The milk handler of an organic coop milk supply wishes to partially unload a milk tank truck load of milk at a receiving milk plant. This receiving milk plant conducts an Appendix N test prior to partially unloading the milk tank truck and then they reseal the milk tank truck. The milk that remains on the milk tank truck is then delivered to a different receiving milk plant to finish the unloading of the milk tank truck.

a) Is the second receiving milk plant required to conduct an Appendix N test or may the results/records from the Appendix N testing conducted at the first receiving milk plant accompany the milk tank truck load and be accepted by the second milk plant?

*If the second receiving milk plant chooses to accept the results from the Appendix N testing conducted at the first receiving milk plant that would be considered acceptable for compliance with the required Appendix N testing at the second receiving milk plant. With this acceptance, the results of the Appendix N testing shall accompany the milk tank truck load of milk to the second receiving milk plant and those results shall be recorded and maintained for the individual loads of milk received at the second receiving milk plant. Any such agreement for this required Appendix N testing would also have to be acceptable to the Regulatory Agency.*

b) If the second milk plant decides to conduct their own Appendix N testing using the same test or a different test of the remaining milk on that milk tank truck that they receive prior to unloading and their Appendix N testing is positive, do their results have an effect on the milk that tested negative and was received at the first plant?

Yes. *If the same and or different Appendix N test kit is being used then positive results from one (1) of the milk plants would be considered as positive for the entire load of milk.*

**NOTE:** It is strongly recommended that an agreement be worked out between the two (2) receiving milk plants to cover the Appendix N testing of the milk tank truck loads of milk at one (1) milk plant and that the associated expenses for this Appendix N testing be worked out between the two (2) receiving milk plants. Any agreement for this required Appendix N testing would also have to be acceptable to the Regulatory Agency.

83. **PMO-Appendix N**

**Background:** Appendix N, III-Testing Program for Drug Residues Established, Bulk Milk Pickup Tanker and/or All Raw Milk Supplies that Have Not been Transported in Bulk Milk Pickup Tankers Screening Test, 2-
Initial Drug Testing Procedures, a.(2) of the PMO provides the following option:

The owner of the presumptive positive milk may reject the load and/or raw milk supply that has not been transported in bulk milk pickup tankers without further testing. At that time the milk represented by the presumptive positive test is not available for sale or processing into human food. The milk cannot be re-screened. The Regulatory Agency involved (origin and receipt) shall be notified. Under this option, producer trace backs shall be conducted for the reject load.

a) If the owner of the milk decides to utilize this option and rejects the load of milk based on this presumptive positive test, which was run at an Appendix N screening laboratory only, may the producer trace back from the presumptive positive load be conducted at this Appendix N screening laboratory or is it required to be conducted in an NCIMS accredited lab?

The required producer trace back from the presumptive positive load is required to be conducted in an NCIMS accredited laboratory by a certified analyst.

b) If a producer/processor has an Appendix N screening lab and gets a presumptive positive on their own milk, would they have to confirm the presumptive positive if they have a written agreement with the Regulatory Agency authorizing them to dump the milk based on the results of the presumptive test?

No. The producer/processor is the owner of the milk and they have the right, with or without a written agreement with the Regulatory Agency, to make the decision to dump or confirm the milk based on the results of the presumptive Appendix N test that they have conducted. With a producer/processor that owns the milk, they would not have to conduct a producer trace back as they have already identified the producer as themselves. The Regulatory Agency shall be notified and the producer/processor shall not use any of their milk supply until a clearing negative sample conducted in an NCIMS accredited laboratory by a certified analyst of their milk supply has been obtained and reported to the Regulatory Agency.

84. PROCEDURES-Sections III and IV

If a BTU fails a rating or check rating, may an individual producer transfer to another BTU before the failed BTU achieves a new IMS listing?

No. The definition of an “IMS Listed Shipper” in the Procedures requires a BTU to be certified by a Rating Agency as having attained the Sanitation
Compliance and Enforcement Ratings necessary for inclusion on the IMS List. When the Sanitation Compliance status of a listed BTU changes as a result of a new rating, the most recent Rating, including Enforcement Rating, shall apply. Because of this failed BTU rating or check rating, this individual producer is considered not to be in a milk supply that has been awarded a Milk Sanitation Compliance Rating equal to ninety percent (90%) or higher.

The Sanitation Compliance Rating of a BTU is used for the purpose of evaluating the overall sanitation compliance requirements of all the milk producers within the BTU and not individual milk producers within the BTU to determine the degree of compliance with public health standards as expressed in the PMO. The list of milk producers included in a BTU is provided before the rating or check rating begins. Therefore, the failed rating or check rating affects all of the milk producers equally that are included in the BTU at the time it was rated.

By allowing this individual producer to transfer to another BTU before the failed BTU can achieve a new IMS listing, FDA sees this as a maneuver to circumvent the results of the failed rating or check rating and to allow an individual milk producer to continue to ship milk when the BTU that they were originally rated with and identified to be a part of has failed a rating or check rating. If an individual milk producer wants to transfer to another BTU after a failed rating or check rating and before a new rating can be conducted of the withdrawn BTU, FDA would expect that their request be made in writing to the Regulatory Agency; the Regulatory Agency follow applicable State laws; and the Rating Agency conduct a new rating of the BTU that the individual milk producer is transferring to.

85. PROCEDURES-Section IV

If a FDA certified Sanitation Rating Officer (SRO) holds a valid FDA certification transfers from one (1) State to another State would he/she be required to be re-certified as a SRO because of this transfer before their current valid FDA certification expires?

No.

86. PROCEDURES-Section IV; and MMSR-Section C

May a milk plant choose to be IMS listed if they manufacture yogurt that is used as an ingredient in a frozen yogurt product that is processed and packaged in another milk plant?

Yes.
A dry powder blending facility currently has two (2) IMS listings and two (2) permits issued by the Regulatory Agency. Both IMS listings have a common address; use the same entrance, same staff, same warehouse area, same receiving and shipping, all under the same roof. The only distinctions between them is they have separate and distinct dry powder blending, agglomeration and bagging lines on separate sides of a common wall. Basically they have two (2) dry powder blending production lines in a single milk plant.

The milk plant management thinks of them as two (2) separate facilities because one (1) is set up and authorized to produce Kosher dry powder blend milk and milk products and the other produces non-Kosher dry powder blend milk and milk products.

When the PMO and DMO were combined in 2003, it was required to combine PMO milk and milk products and DMO milk and milk products IMS listings at a single milk plant into one (1) IMS listing. Then at the 2005 NCIMS Conference, a Proposal was passed that allowed for the separate IMS listing of PMO and DMO milk and milk products produced in the same milk plant if the Regulatory Agency issued separate permits for each IMS listing. While there are separate permits issued to this milk plant, they are both issued for DMO related milk and milk products, so does this separate IMS listing provision for PMO and DMO milk and milk products apply?

No. This is one (1) milk plant with two (2) production lines that produce the same dry-blended milk and milk products with the exception that one (1) line may be Kosher at times. The PMO and the IMS Program do not provide for an IMS listing to make the distinction for a milk and/or milk product to be Kosher or not.

NOTE: Even though this milk plant has two (2) permits issued by the State, which was their choice, under the IMS Program this facility would be considered a single milk plant under one (1) roof and should only have one (1) IMS listing and one (1) permit. Being Kosher or not does not have any bearing on the number of IMS listings.

A Rating Agency is required to obtain a hard copy of a signed FORM FDA 2359o-Permission For Publication (Interstate Milk Shipper's Listing) or FORM FDA 2359d-Report of Certification (Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products) prior to a milk shipper or single-service containers and closures manufacturer, respectively, to be listed on the IMS List. Would it be permissible for the
Rating Agency to scan the hard copies of these Forms and save them in an
electronic format, thus eliminating/destroying any paper versions of the
Forms?

Yes. The electronic copies of the Forms shall be readily available in a
format that can be easily read. Remember, if the data is lost, it would be
considered the same as if the original signed Forms were not available.

89. **PROCEDURES-Section V**

May a FDA certified SRO for dairy farms, who is currently in training for FDA
certification for milk plants, get certified for single-service containers and
closures manufacturers before he/she is ready to be FDA certified for milk
plants?

No. The Procedures document identifies within Section V-Qualification and
Certifications, D-Milk Sanitation Rating Personnel the categories that a
candidate can be FDA certified for as a SRO.

In one (1) or any combination of the following categories:

- Milk pasteurization plants, including HACCP and/or aseptic processing
  and packaging, and/or retort processed after packaging, if appropriate;
- Dairy farms; and
- Transfer/receiving stations, including HACCP if appropriate.

The FDA certification for single-service containers and closures
manufacturers is included within the milk pasteurization plant category and
involves five (5) milk plants and one (1) single-service containers and
closures manufacturer independent side-by-side comparisons with a
nationally headquarters’ standardized RMS. A SRO candidate must be
proficient in milk pasteurization plant ratings before they can also be
certified for single-service containers and closures manufacturers within this
milk pasteurization plant category.

90. **MMSR-Section D**

If it is determined that a Regulatory Agency does not have a valid sampling
surveillance training program would the Regulatory Agency get credit for
issuing valid bulk milk/hauler sampler permits under FORM FDA 2359j-Milk
Sanitation Report, Section C-Evaluation of Sampling Procedures, Dairy
Farm Sampling Procedures, 4-All samplers hold a valid permit?

Yes, provided that the individual bulk milk/hauler sampler permits that have
been issued have not expired.
91. **MMSR-Section D**

What action on ratings and check ratings would be taken if the SOI product(s): “Heavy Cream (Heavy Whipping Cream)”, “Light Cream (Coffee Cream or Table Cream)”, or “Light Whipping Cream (Whipping Cream)” is/are being labeled as “Manufacturing Cream” or “Manufacturing Style Cream” on individual containers or on Bills of Laden (shipping statements) for bulk shipments?

*This would be considered a milk product labeling violation for each of the SOI cream products identified above that are improperly labelled and would be debited on FORM FDA 2359j-Milk Sanitation Rating Report, Section B-Report of Enforcement Methods (Page 2) under Part Ill-Individual Shipper Rating, Item 3-All milk and milk products properly labelled. Also, if the Regulatory Agency continues to allow this practice to continue after they have been informed of the labeling violation(s) this would be identified in their next Regulatory/Rating Agency Program Evaluation.*