TO: All Regional Food and Drug Directors  
FROM: Milk and Milk Products Branch (HFS-316)  
SUBJECT: Answers to Extended Run Questions Received From The Field; Regional Milk Seminars; And FDA Training Courses

Following are answers to extended run questions received from the field; Regional Milk Seminars; and FDA training courses (Special Problems in Milk Protection, Advanced Milk Processing, Milk Plant Sanitation and Inspection, and Milk Pasteurization Controls and Tests).

In accordance with procedures established through the National Conference on Interstate Milk Shipments (NCIMS), if an answer to these questions 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, 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 7, Item 12p**

*M-I-04-10 (QUESTIONS AND ANSWERS FROM A FY’04 REGIONAL MILK SEMINAR, AN ADVANCED MILK PROCESSING COURSE AND A SPECIAL PROBLEMS IN MILK PROTECTION COURSE) (QUESTION #34)-12/27/2004*

With extended runs, what is meant by “in consultation with FDA”? Does that mean FDA must be in the loop or does it mean that FDA sees all documentation and has approval or what?

For extended runs, FDA (Regional Milk Specialist(s) and MST, if necessary), must be included in the review and be privy to all appropriate information to provide input to the Regulatory Agency. With the initial approval of an extended run, the Regulatory Agency makes the determination with input (consultation) from FDA. FDA may have additional say in this matter, when conducting a check rating of the facility and it evaluates the extended run protocol. Remember, extended run protocols and approvals are product, process, equipment and milk plant specific.

Additional information that is related to what is meant by “in consultation with FDA” from when this answer was provided and issued in 2004:

The Regulatory Agency consults with FDA and provides the FDA Regional Milk Specialist (RMS) and the Milk Safety Team (MST), if requested, with all the supporting information required in Item 12p-Cleaning and Sanitizing of Containers and Equipment of the PMO and any additional information that may have been requested by the Regulatory Agency in support of the extended run proposal. This may include the findings of any inspections that were conducted by the Regulatory Agency. FDA shall have the opportunity to provide feedback on the information provided and may choose to accompany the Regulatory Agency during an extended run proposal inspection. If the RMS has concerns/comments, these concerns/comments shall be conveyed to the Regulatory Agency in writing in a timely manner. If there are not any concerns identified, the RMS shall provide the Regulatory Authority with written notification that there are not any objections to the extended run proposal.

2. **PMO-Section 7, Item 12p**

a) Is the Regulatory Agency required to provide written documentation of their approval to the milk plant of a milk plant’s extended run proposal?

Yes.
NOTE: If the Regulatory Agency has previously provided only a verbal approval, this now must be reaffirmed in a written document from the Regulatory Agency to the milk plant.

b) Is the Regulatory Agency required to keep on file and make readily available for review upon request by the Rating Agency and/or FDA a copy of the Regulatory Agency’s written documentation of their approval, in consultation with FDA, of a milk plant’s extended run proposal, a copy of the approved extended run proposal and all documentation received from the milk plant and FDA addressing the specific milk plant’s extended run proposal?

Yes.

c) What is the timeframe for the milk plant to receive feedback from the Regulatory Agency concerning a submitted extended run proposal?

The PMO does not cite any specified timeframe for the Regulatory Agency to respond to a submitted extended run proposal. It is within the Regulatory Agency’s purview to establish a reasonable timeframe to conduct their review, including time for FDA’s review and comment.

d) Is a milk plant required to keep on file at the milk plant and make readily available for review upon request by the Regulatory Agency, Rating Agency and/or FDA a copy of the Regulatory Agency’s written documentation of their approval, in consultation with FDA, of the milk plant’s extended run proposal and a copy of the approved extended run proposal with all supporting documentation?

Yes.

NOTE: Until a milk plant receives official written documentation of the Regulatory Agency’s approval of their submitted extended run proposal, in consultation with FDA, they are not authorized to process or package Grade “A” milk and/or milk products beyond the applicable PMO equipment cleaning requirement.

3. PMO-Sections 3 and 7, Item 12p

M-I-15-3 (QUESTIONS AND ANSWERS RECEIVED FROM THE FIELD; REGIONAL MILK SEMINARS; AND FDA TRAINING COURSES HELD DURING FY 2013) (QUESTION #9)-6/29/2015

a) When a milk plant, receiving station and/or transfer station changes legal ownership (not just a cosmetic name change), is the existing IMS listing for
the previous ownership still valid, or is a new rating required to be conducted?

A new rating would be required. Section 3-Permits of the PMO states: "Permits shall not be transferable with respect to persons and/or locations." The new ownership would be required to submit an application for a permit to their Regulatory Agency. The Regulatory Agency shall notify the Rating Agency that such a change of ownership has occurred and the Rating Agency would request the removal of the milk plant from the IMS List. The Regulatory Agency would conduct an inspection of the milk plant, receiving station or transfer station, respectively; and if determined to be in compliance with the PMO, they would issue a new permit. At this time, the new ownership may submit a request to their Rating Agency for a rating if they wish to be on the IMS List.

b) If the previous milk plant ownership had a Regulatory Agency, in consultation with FDA, reviewed and accepted extended run(s) in place, would the new ownership be required to submit a complete new extended run(s) application including a current trial run(s) with samples to continue the operation of this previously accepted extended run(s)?

Regulatory Agency acceptance of an extended run(s) is specific to equipment, process, milk and/or milk product(s), operating procedures and is issued to the ownership of the milk plant that originally submitted the extended run(s) application. If the new ownership wishes to utilize the previous ownership’s previously accepted extended run(s), along with the new ownership’s application for a permit submitted to the Regulatory Agency they shall include or have available for the Regulatory Agency’s review a copy of the extended run(s) application, protocol and acceptance documentation from the previous ownership. They shall inform the Regulatory Agency that they plan to utilize and follow the prior ownership’s previously accepted extended run protocol(s). During the routine Regulatory Agency quarterly inspections, Regulatory Agency personnel shall verify that the accepted extended run(s) protocol is being followed. If the new ownership cannot provide this extended run(s) documentation or they plan to utilize a new extended run(s) protocol, then they would be required to follow the requirements for an extended run(s) as cited within Item 12p-Cleaning and Sanitizing of Containers and Equipment of the PMO.

4. PMO-Section 7, Item 12p

Does the PMO set an upper limit on the length of time for an extended run, for example 72 hours?

No. The PMO does not limit extended runs to 72 hours or provide an upper limit on the length of time for the extended run. However, prior to accepting any period of time for any extended run, the Regulatory Agency must review and accept, in consultation with FDA, supporting information as noted in Item 12p-Cleaning and Sanitizing of Containers and Equipment, Administrative Procedure #1, of the PMO that supports their decision to establish an extended run time period.

5. PMO-Section 7, Item 12p

M-I-05-4 (QUESTIONS AND ANSWERS FROM FY’04 AND FY’05 FD3105-DAIRY FARM SANITATION AND INSPECTION COURSES AND FROM FY’05 REGIONAL MILK SEMINARS AND CHECK RATINGS) (QUESTION #27) - 8/1/2005

May plant management use one extended run protocol to cover an entire Grade “A” milk plant, which produces multiple products and utilizes different processes and equipment?

No. This was never the intent and we do not believe that only one protocol can adequately cover all situations within an individual plant setting. An extended run protocol as described in Item 12p is specific to a product and/or process.

6. PMO-Section 7, Item 12p

If all Grade “A” milk and/or milk products are handled and processed the same, does the PMO require that the milk plant submit separate extended run proposals for each Grade “A” milk and/or milk product to the Regulatory Agency for their review and approval, in consultation with FDA?

No. The extended run proposal shall specify all of the milk and/or milk products to be included under the extended run proposal. A milk plant may group milk and/or products within a similar milk and/or milk product category, i.e., whole white milk, 1% white milk, 2% white milk and nonfat white milk. (Refer to Question 15 for additional examples of similar categories of milk and/or milk products.)

NOTE: If there are different handling and blending operations, holding equipment, processing and/or packaging, etc. for different categories of Grade “A” milk and/or milk products then separate extended run proposals shall be submitted by the milk plant for each category of Grade “A” milk and/or milk products handled differently. Hazard evaluations shall be
conducted and submitted by the milk plant of each different category of Grade “A” milk and/or milk products with the milk plant's extended run proposal(s).

7. **PMO-Section 7, Item 12p**

May scientific data generated only from the processing of non-Grade “A” milk and/or milk products be utilized by the milk plant in their validation of their submitted Grade “A” milk and/or milk products extended run proposal if the processing is identical?

*No. Data submitted in support of an extended run proposal shall be representative of the Grade “A” milk and/or milk products that will be processed during the proposed extended run.*

8. **PMO-Section 7, Items 12p and 17p**

**M-I-13-6 (QUESTIONS AND ANSWERS RECEIVED FROM THE FIELD; REGIONAL MILK SEMINARS; AND FDA TRAINING COURSES HELD DURING FY 2012) (QUESTION #56)-10/31/2013**

Item 12p-Cleaning and Sanitizing of Containers and Equipment, Administrative Procedures #1 of the PMO states: “In the case of pasteurized storage tanks, which are CIP cleaned at intervals of less than seventy-two (72) hours, the CIP cleaning records required under Item 2.b. of this Section shall be considered adequate.”

a) This statement implies that pasteurized milk and/or milk product storage tanks are required to have a CIP record of cleaning, which shows that the storage tanks have been emptied and cleaned at an interval less than seventy-two (72) hours after milk or milk product enters the tank. Is this correct?

*Yes.*

b) May pasteurized milk and/or milk product storage tanks be allowed to store milk and/or milk products longer than twenty-four (24) and up to seventy-two (72) hours before they are required to be emptied and cleaned without an extended run application?

*Yes.*

c) How is the temperature of the pasteurized milk or milk product stored in these tanks monitored to meet the requirements of Item 17p-Cooling of Milk and Milk Products that requires that all pasteurized milk and milk products,
with specified exceptions, shall be stored at a temperature of 45°F (7°C) or less and maintained thereat following filling or until further processed?

_The temperature of the pasteurized milk or milk product stored in these tanks shall be obtained by reading the temperature from the required indicating thermometer on the pasteurized storage tank or by taking the temperature of a sample of the milk or milk product from the pasteurized storage tank._

9. **PMO-Sections 7, Item 12p**

**M-I-16-10 (QUESTIONS AND ANSWERS FROM FY 14 REGIONAL MILK SEMINARS, AND AN ADVANCED MILK PROCESSING COURSE) (QUESTION #40)-7/8/2016**

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._

10. **PMO-Section 7, Item 12p**

**M-I-04-6 (QUESTIONS AND ANSWERS FROM FY’04 REGIONAL MILK SEMINARS, AND AN ADVANCED MILK PROCESSING COURSE) (QUESTION #37)-8/27/2004**

Due to the sanitization and washing requirements for milk storage tanks, may cooled pasteurized cultured products be held in a storage tank or vessel longer than 72 hours?

_The tank or vessel is required to be emptied and cleaned every 72 hours, unless the State Regulatory Agency, in consultation with FDA, has reviewed an extended run protocol and has granted acceptance for this specific tank or vessel._

11. **PMO-Section 7, Item 12p**

May equipment, such as raw transfer lines, valve clusters, blending/batching tanks, and liquefiers that are used to process raw milk and/or milk products that are not in continuous operation during the proposed extended run be included in an extended run proposal?

Yes. _Supporting documentation that is submitted by the milk plant to the Regulatory Agency for their review and approval, in consultation with FDA_,
shall include all equipment, transfer lines, valve clusters, etc. that will be covered in the milk plant’s extended run proposal.

**NOTE:** The PMO does not identify specific supporting documentation that is required to be submitted with extended run proposals. It is the responsibility of the milk plant to provide sufficient information that will be representative of the Grade “A” milk and/or milk products that will be processed and demonstrate that the identified multi-use equipment, containers and utensils included in the extended run proposal can be cleaned at the proposed cleaning frequency without compromising the safety of the finished Grade “A” milk and/or milk products produced during the proposed extended run.

12. **PMO-Section 7, Item 12p**

**M-I-04-6 (QUESTIONS AND ANSWERS FROM FY’04 REGIONAL MILK SEMINARS, AND AN ADVANCED MILK PROCESSING COURSE) (QUESTION #35)-8/27/2004**

Is a Grade “A” RO or UF milk processor that runs for longer than 24 hours required to have an extended run approval?

Yes.

13. **PMO Section 7, Item 12p**

May HTST, HHST, or Ultra-pasteurized (UP) pasteurization systems or vat pasteurizer(s) be included in an extended run proposal?

Yes. The extended run proposal’s documentation and scientific data shall support the inclusion of the pasteurization system or vat pasteurizer(s) in the milk plant’s extended run proposal.

14. **PMO-Section 7, Item 12p**

**M-I-04-6 (QUESTIONS AND ANSWERS FROM FY’04 REGIONAL MILK SEMINARS, AND AN ADVANCED MILK PROCESSING COURSE) (QUESTION #38)-8/27/2004**

An evaporator has a built-in HTST system as part of the evaporator. This evaporator can only be operated if the HTST system runs product through it.

a) May the entire system run for 44 hours prior to clean up?

Yes. The HTST must be an integral part of the evaporator and the product is being fed directly to the evaporator.
b) May all components used to feed the evaporator, such as, pre-heat press units, etc., run for the 44 hours with the evaporator?

Yes.

**NOTE:** The separator(s) in the systems used to verify the safety of operating an evaporator for a continuous period not to exceed 44 hours did not operate continuously during the 44-hour evaluation period. Currently, there is not an exemption for the operation of separators in excess of 24 hours.

c) The heater section, balance tank, etc., of the HTST system is built into the evaporator. Does this proposal only limit the 44-hour run to the evaporator from the FDD downstream?

No.

15. **PMO-Section 7, Item 12p**

a) Please provide some examples of different categories of milk and/or milk products that would be considered as similar milk and/or milk products that could be utilized in an extended run proposal?

*The following is not an all-inclusive list, but provides some examples that would be considered as similar milk and/or milk products:*

- Whole white milk, 1% white milk, 2% white milk and nonfat white milk;
- Flavored whole milk, flavored 1% milk, flavored 2% milk and flavored nonfat milk; and
- Half-and-Half, heavy whipping cream, light cream and light whipping cream.

b) Within the different categories identified in a) above, which would be the recommended milk and/or milk product(s) that the extended run proposal’s documentation and scientific data should address to support the inclusion of a category of milk and/or milk product(s) in the extended run proposal for review and approval by the Regulatory Agency, in consultation with FDA?

- Category White Milks: Whole Milk;
- Category Flavored Milks: Flavored Whole Milk; and
- Creams: Heavy Whipping Cream.
16. **PMO-Section 7, Item 12p**

Eggnog is a seasonal milk product that may not have been included in a milk plant’s extended run proposal that had been previously approved by the Regulatory Agency, in consultation with FDA.

a) May eggnog be added to the current approved extended run proposal by conducting a single run and testing of the eggnog?

*No. The addition of eggnog to an approved extended run proposal would be considered a significant processing change that would be required to be communicated to the Regulatory Agency. The new extended run proposal submitted to the Regulatory Agency to include eggnog shall include supporting documentation then just the test results from a single run.*

b) With the scenario above, may eggnog be processed in the first twenty-four (24) hours of an extended production time period without the submission of a new extended run proposal to the Regulatory Agency?

*No. This would be considered a significant processing change and would be required to be communicated to the Regulatory Agency. Supporting documentation would have to be submitted to the Regulatory Agency for their approval, in consultation with FDA.*

17. **PMO-Section 7, Items 12p and 15p**

**M-I-06-15 (QUESTIONS AND ANSWERS FROM FD-578 ADVANCED MILK PROCESSING COURSES HELD IN FY’05 AND THE REGIONAL MILK SEMINARS HELD IN FY’06) (QUESTION #40)-9/25/2006**

A plant may choose to re-circulate water for two (2) hours before actually starting to run milk or milk product through a pasteurization system or they may run orange juice first, followed by a caustic rinse and clear water flush but not a complete cleaning, before starting to run milk or milk products.

a) When does the twenty-four (24) hour cleaning requirement of the PMO begin for the shut down and cleaning of a pasteurization system? Is it required to be cleaned twenty-four (24) hours from when the cut-in/cut-out is conducted, or when actual milk or milk product processing begins?

*We are basing this response on the premise that the words “day used” in Section 7, Item 12p, of the PMO, means a twenty-four (24) hour day.*

*The twenty-four (24) hour PMO cleaning requirement would begin when product (milk, orange juice, etc.) enters the pasteurization system.*
b) What is the effect of a “caustic rinse and clear water flush” on this twenty-four (24) hour PMO cleaning requirement?

This would not have an effect on the PMO twenty-four (24) hour cleaning requirement. A caustic rinse and clear water flush is not considered an appropriate cleaning and sanitization process to meet this PMO requirement.

18. PMO-Section 7, Items 12p and 15p

M-I-04-6 (QUESTIONS AND ANSWERS FROM FY’04 REGIONAL MILK SEMINARS, AND AN ADVANCED MILK PROCESSING COURSE) (QUESTION #36)-8/27/2004

a) Will a quick wash on an HHST pasteurizer, that is done with the equipment remaining in forward flow, satisfy the requirement that the HHST equipment be cleaned every 24 hours?

No.

b) What if it has been evaluated and accepted for longer operation under the extended run provision?

The Regulatory Agency should have scientific and inspectional data that supports their decision and that the criteria for regulatory evaluation identified in Item 12p, Administrative Procedure #1, of the PMO is followed.

19. PMO-Section 7, Items 12p and 15p

Are short caustic washes, which are conducted above the cut-out temperature set point, acceptable as a means to extend a processing run beyond twenty-four (24) hours before the required full clean-in-place (CIP) cycle is conducted?

No. Short caustic washes cannot be the sole justification for an extended run proposal. They may be approved by the Regulatory Agency, in consultation with FDA, if they are included in the submitted extended run proposal and the submitted scientific documentation supports extending the processing time and cleaning frequencies when utilizing such short caustic washes.

NOTE: Short caustic washes are only acceptable to be utilized within the required twenty-four (24) hour full CIP cycle or within an extended run proposal if an effective means of separation as required in Item 15p- Protection from Contamination (B) of the PMO is provided between the
Grade “A” milk and/or milk product and any cleaning solutions during this short caustic wash procedure.

20. **PMO-Section 7, Items 12p and 15p**

Are there any restrictions on the number of short caustic washes that may be conducted in an extended run proposal?

*Not as long as the supporting documentation submitted to the Regulatory Agency for their review and approval, in consultation with FDA, justifies the extended run, which includes the specified number of short caustic washes that are to be performed in the extended run proposal. (Please refer to Questions #17.b) and #19 for additional information related to short caustic washes.)*

21. **PMO-Section 7, Item 12p; and Appendix F**

A milk plant has submitted to the Regulatory Agency an extended run proposal in which the packaging machines are to be sanitized using hot water. Would this be acceptable and what information would be required to be submitted with the extended run proposal to the Regulatory Agency for their review and approval, in consultation with FDA?

*Hot water sanitizing is provided for and described in Appendix F-Cleaning and Sanitization of the PMO. The water at the outlet end of the assembly being sanitized shall be maintained at a temperature of at least 77°C (170°F) for at least five (5) minutes. A means acceptable to the Regulatory Agency to verify that this minimum required temperature and time are being met shall be provided and all milk and/or milk product contact surfaces shall be adequately sanitized.*

*It is recommended that the milk plant proposing to use this method of sanitization submit a complete drawing and description of their hot water sanitization procedure with their extended run proposal that will be submitted to their Regulatory Agency for review and approval, in consultation with FDA.*

22. **PMO Section 7, Item 12p**

What is meant by “significant equipment or processing change” in relation to an extended run proposal?

*Significant equipment or processing changes may be defined as any change that is made to the process being utilized or the milk and/or milk product(s) that may alter the extended run's characteristics of the milk and/or milk product(s) or affect the overall cleaning of the equipment being*
utilized other than what is defined in the extended run proposal as approved by the Regulatory Agency, in consultation with FDA.

23. **PMO Section 7, Item 12p**

Item 12p-Cleaning and Sanitizing of Containers and Equipment of the PMO requires that any significant equipment or processing changes shall be communicated to the Regulatory Agency, and may result in a re-verification of the extended run proposal, if it is determined that the change could potentially affect the safety of the finished milk and/or milk product(s). Is this information required to be forwarded to FDA by the Regulatory Agency, and who determines if a re-verification of the extended run protocol is required?

All appropriate information regarding significant equipment or processing changes to an approved extended run protocol shall be communicated by the milk plant to the Regulatory Agency for their review. This information shall be forwarded to FDA and the final determination that a re-verification of the extended run proposal will or will not be required shall be conducted in consultation with FDA. FDA shall have the opportunity to provide feedback on the information provided concerning the proposed changes and may choose to accompany the Regulatory Agency during the re-verification of the extended run protocol.

24. **PMO-Section 7, Item 12p**

What action would be required if it is determined during a rating or check rating that a milk plant is not in compliance with their extended run proposal that was reviewed and approved by the Regulatory Agency, in consultation with FDA? For example, dirty equipment, a significant change(s) made without informing the Regulatory Agency, etc.

The milk plant would be debited under Item 12p-Cleaning and Sanitizing of Containers and Equipment (a) and (c). In addition, the Regulatory Agency may require the extended run to be re-verified.

25. **PMO-Section 7, Item 12p**

What action would be required if it is determined during a rating or check rating that a milk plant is utilizing an extended run that has not been reviewed and approved by the Regulatory Agency, in consultation with FDA?

The milk plant would be debited under Item 12p-Cleaning and Sanitizing of Containers and Equipment (a) and (c).