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M-I-14-8
Supplement 2

March 28, 2018

TO: Director, Office of State Cooperative Programs
Attn: All Staff, Division of Milk Safety

FROM: Milk and Milk Products Branch (HFS-316)

SUBJECT: Guidance Related To The Requirements For Automatic Milking Installations (AMIs) As Addressed In Section 7-Standards For Grade "A" Raw Milk For Pasteurization, Ultra-pasteurization, Aseptic Processing And Packaging Or Retort Processed After Packaging And Appendix Q-Operation Of Automatic Milking Installations For The Production Of Grade "A" Raw Milk For Pasteurization, Ultra-pasteurization, Aseptic Processing And Packaging Or Retort Processed After Packaging Of The Grade "A" Pasteurized Milk Ordinance

Automatic Milking Installations (AMIs) utilized on Grade "A" dairy farms are required to comply with all of the requirements cited in Section 7-Standards for Grade "A" Raw Milk for Pasteurization, Ultra-pasteurization, Aseptic Processing and Packaging or Retort Processed after Packaging and Appendix Q-Operation of Automatic Milking Installations for the Production of Grade "A" Raw Milk for Pasteurization, Ultra-pasteurization, Aseptic Processing and Packaging or Retort Processed after Packaging of the Grade "A" Pasteurized Milk Ordinance (PMO).

As defined in the PMO: "**AUTOMATIC MILKING INSTALLATION (AMI):** The term Automatic Milking Installation (AMI) covers the entire installation of one (1) or more automatic milking units, including the hardware and software utilized in the operation of individual automatic milking units, the animal selection system, the automatic milking machine, the milk cooling system, the system for cleaning and sanitizing the automatic milking unit, the teat cleaning system, and the alarm systems associated with the process of milking, cooling, cleaning and sanitation."

This M-I is intended to provide guidance and clarification as to how AMIs are to be constructed, installed, perform, monitored, maintained, etc. in order to be in compliance with the requirements of the PMO. Specific Grade "A" dairy farm PMO requirements and related guidance to Regulatory/Rating Agencies and AMI manufacturers and

installers are provided below. This M-I cannot address all of the issues that may be raised by a Regulatory Agency when reviewing an AMI for their approval; however, it attempts to address some of the issues and concerns that have been observed in the field at this time.

Following are answers to AMI questions received from State Regulatory Agencies, AMI Manufacturers and FDA Milk Specialists that were not addressed in M-I-14-8 and M-I-14-8, Supplement 1.

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.

M-I-17-5-Guidance Related To The Check Ratings For Automatic Milk Installations (AMIs) (October 6, 2017)

“Based on FDA’s evaluations, the maximum debit any non-compliant AMI equipment will incur for design deficiencies will be a single debit, not to exceed 4 points. No repeat violation penalties will be assessed for any debits on federal check ratings of AMI equipment for design.”

- Does AMI equipment design deficiencies apply only to Item 9r-Utensils and Equipment – Construction violations or would design deficiencies be all-inclusive; therefore, an AMI installation would only lose a total of four (4) points on a check rating no matter what is determined to be in violation of the PMO?

This four (4) point limit on design deficiency debits applies to the equipment that is part and parcel to the AMI system as supplied by the manufacturer. This would include Item 9r violations, but also may include Item 12r-Utensils and Equipment - Storage and Item 14r-Protection from Contamination violations commonly associated with, but not limited to jetter cup storage and fail-safe valve systems.

This limit does not apply to equipment and conditions not associated with the design and construction of the AMI system. Examples are milking area construction and cleanliness, equipment cleaning and sanitization, water supply protection, milking-flanks, udders and teats, etc.

NOTE: Regardless of the four (4) points limit on debits addressed in M-I-17-5, any situation that represents an immediate risk to public health shall be resolved to protect public health.

- Does M-I-17-5 imply that debits may be prorated on AMIs? Such that an Item 9r violation may be debited one (1) point up to four (4) points.

No. M-I-17-5 does not change the point value of individual Items that are debited. **For example:** An Item 9r violation would be given the usual four (4) point debit and an Item 14r violation would be given the usual three (3) point debit. However, if both violations are present in the AMI equipment and the 14r violation is related to equipment design, i.e. fail-safe valve system, only the Item 9r violation would be debited on the check rating for a maximum debit of four (4) points.

PMO-Section 6

AMIs utilize conductivity sensors to indirectly measure somatic cell counts (SCCs). May the data obtained from these conductivity sensors be used by the Regulatory Agency as the official Section 6-The Examination of Milk and/or Milk Products, SCC test results?

No. It is the responsibility of the bulk milk hauler/sampler to collect a representative sample of milk from each farm bulk milk tank and/or silo or from a properly installed and operated in-line sampler that is approved for use by the Regulatory Agency and FDA. In addition, the PMO requires all official regulatory samples be analyzed at an IMS listed laboratory by a certified analyst using an approved analytical method.

ITEM 1r. ABNORMAL MILK

Appendix Q, Item 1r states that when milk with abnormalities is diverted, the parts of the milking system that came into contact with the milk with abnormalities are immediately cleaned and sanitized.

- Is milk that is diverted for color considered milk with abnormalities (abnormal milk)?

Yes.

- Are AMIs required to have a separate vacuum source that is used when animals producing milk with abnormalities are being milked?

No. As stated in Appendix Q, Item 1r, AMIs shall have the capability to identify and discard milk from animals that are producing milk with abnormalities. Animals producing milk with abnormalities shall be diverted to a holding pen to be milked immediately prior to the AMI system being cleaned and sanitized, or the animals are identified through an appropriate identification system so that their milk will be automatically excluded from the milk offered for sale, provided that the parts of the AMI system that came in contact with the milk with abnormalities are immediately cleaned and sanitized prior to milking the next animal that is not producing milk with abnormalities.

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

May a storage vessel/buffer tank that is used to store milk while the farm bulk milk tank/silo is being emptied, cleaned and sanitized be located in the AMI milker box?

No. The AMI milker box is to be treated the same as any other milking parlor. The storing of milk shall be conducted in a room that meets all milkhouse construction requirements.

ITEM 9r. UTENSIL AND EQUIPMENT - CONSTRUCTION

Are all gaskets used in milk pipelines and on equipment required to be self-positioning?

Item 9r states that for CIP cleaned milk pipelines and return-solution lines, if gaskets are used, they shall be self-positioning and shall be of such design, finish and application to form a smooth, flush interior surface. When gasketed joints are used in other applications, self-positioning gaskets are not a specified requirement, but the joints shall be smooth and free of pits, cracks or inclusions.

Some AMIs are designed with a fitting at the top of the receiver and the fitting is attached to the receiver through an opening that does not have a flange. Is it acceptable?

Yes. The opening is intended to be sealed when the fitting is attached.

ITEM 12r. UTENSIL AND EQUIPMENT - STORAGE

Appendix Q, Item 12r states AMIs shall have positive air ventilation systems in operation whenever the milking system is being cleaned and/or sanitized.

- How much air flow is needed to be considered “positive”?

The PMO does not cite air flow requirements. However, as per Appendix Q, the air flow should be sufficient to minimize odors, moisture and/or pests.

- Is the positive air ventilation system required to operate during the cleaning and/or sanitizing of an individual AMI, or is it only required to operate when the entire AMI system is being cleaned?

The PMO does not distinguish between the cleaning and sanitizing of individual AMIs and the entire AMI system. Therefore, the positive air ventilation system would be required to operate when either an individual AMI is being cleaned and sanitized or the entire AMI system is being cleaned and sanitized.

AMI jetter cups are not shielded during milking. Is this an Item 12r violation?

No. AMI jetter cups are used between individual cow milkings. If the outside surfaces of the jetter cups are found dirty or contaminated with manure, it would be considered an Item 3r violation.

NOTE: This is a change from previous guidance and is intended to simplify evaluating the cleanliness of the outside of milking and related equipment.

ITEM 13r. MILKING – FLANKS, UDDERS AND TEATS

Appendix Q, Item 13r states that each dairy producer shall keep a copy of the accepted teat prep protocol on file at the dairy farm. Is it acceptable for the dairy producer to maintain an electronic copy?

Yes. Electronic records are considered to be onsite if they are accessible from an onsite location. The accepted teat prep protocol must be available onsite for review by the Regulatory Agency, Rating Agency and FDA Milk Specialist (MS).

ITEM 14r. PROTECTION FROM CONTAMINATION

Between the milking of individual cows, are the teat cups required to be protected with a "fly tight" shield?

No. Appendix Q, Item 14r states that the teat cups (inflations) of the milking cluster are to be adequately shielded. Adequately shielded does not imply that shielding is required to be "fly tight".

M-I-14-8 (Supplement 1) states that when valves, or valve seats in the case of single-bodied double seat valves, are part of an automatic fail-safe system that prevents contamination of milk with cleaning and/or sanitizing solutions, the controls for this fail-safe system are to be tested by the Regulatory Agency at commissioning and at a frequency deemed appropriate by the Regulatory Agency.

- Does this mean that all valves or valve seats in the case of single-bodied double seat valves are required to be tested?

Verification of all computer system's controlled functions responsible for the fail-safe valve system(s) providing separation between milk with abnormalities and milk intended for sale; and between cleaning/sanitizing solutions and milk intended for sale shall be conducted at the commissioning of the computer system and at a frequency deemed appropriate by the Regulatory Agency. The PMO does not specifically state that each valve or valve seat shall be tested. But the Regulatory Agency must be assured that the computer system's controlled functions work as designed and the number of valves or valves seat tests that need to be conducted to give the Regulatory Agency the assurance that is needed will be determined by the Regulatory Agency.

- Does this testing have to be documented and does this documentation and all written or electronic information associated with the testing required to be maintained at the dairy farm and made available upon request to the Regulatory Agency, Rating Agency and/or FDA?

Yes.

M-I-17-3 states that until further notice, computer system(s) verification requirements related to Appendix Q, Item 1r, 13r, and 14r will not be debited on federal check ratings. Does this prohibit a Regulatory Agency from verifying and documenting an AMI computer system's monitoring and controlling functions related to Items 1r, 13r and 14r?

No.

If an AMI has a block-bleed-block valve assembly that incorporates individual valves within a single manifold, which is designed to be removed and/or replaced as a single unit (plug and play). Is the Regulatory Agency required to test the valve assembly every time that the valve assembly is replaced?

No. Verification of all computer system's controlled functions shall be conducted and documented at the commissioning of the computer system and at a frequency deemed appropriate by the Regulatory Agency.

Is the "bleed" or "vent" valve required to be physically located between the two (2) blocking valves in a block-bleed-block valve assembly?

No. Provided the drainable opening (bleed" or "vent") is located such that the space between the two (2) blocking valve seats is drainable by gravity.

ITEM 14r. PROTECTION FROM CONTAMINATION AND APPENDIX H

As part of a teat prep protocol, air under pressure is used to blow iodine and/or sanitizer through a valve assembly into each teat cup and/or onto the teats. Appendix H requires that the final filter media be located "as close as possible" to the point of application. Is an individual check valve and final air filter required to be installed at each teat cup?

No. In this case, the point of application as described in Appendix H could be the point at which the air enters a group of multiple teat prep valve assemblies.

NOTE: *Air distribution piping and fittings after the final filter shall be of corrosion-resistant materials.*

Item 14r, Administrative Procedures #2 requires the separation of all connection points between cleaning/sanitizing circuits and milk by at least two (2) automatically controlled valves with a drainable opening to the atmosphere between the valves; or by a single-bodied double seat mixproof valve, with a properly designed drainable opening to the

atmosphere between the seats. Subsection 2.b.(3) permits that the drainable opening to the atmosphere (valve vent) between the blocking valves may be cleaned while milk is isolated by one (1) of the blocking valves, provided that certain conditions are met. One (1) of the required conditions (2.b.(3)i) states:

“...there shall not be pressurization of cleaning solutions on the exterior of the valve isolating milk that can equal or exceed the pressure of the milk being isolated...”

- In an application where the connection point is at the bulk milk tank, is the pressure at the valve required to be measured and monitored?

No. This condition would be considered to be satisfied if the blocking valves and vent are designed and installed to meet the following conditions to prevent the pressurization of the vent during cleaning and to minimize the risk of contamination:

- 1. The blocking valves are fail-safe and move to a closed position upon loss of air or power.*
- 2. The opening to the atmosphere (vent) is at least as large as the largest pipeline connected, and the vent is not restricted in any fashion (valves, fittings, etc.) except as is necessary to channel flow through the vent directly to a nearby floor drain.*
- 3. If a screen is installed on the vent, the screen must be sized so that the effective area of the screen is equal to or greater than the cross-sectional area of the largest pipeline connected.*
- 4. All other requirements of Item 14r are still applicable.*

ITEM 18r. RAW MILK COOLING

Appendix Q, Item 18r requires raw milk to be cooled to 50°F (10°C) within four (4) hours or less after starting the milking operation and the milk shall be cooled within two (2) more hours to 45°F (7°C). The milk in the farm bulk milk tank/silo shall not exceed 45°F (7°C) after that time. What is considered the starting of the milking operation for an AMI system? When the first cow starts milking after the AMI system has been cleaned and sanitized, when milk enters the buffer tank, when milk enters the farm bulk milk tank/silo/direct load milk tank truck, or when the farm bulk milk tank/silo is emptied?

For the milk cooling requirements specified in item 18r, the start of the milking operation is the moment when milk is first transferred to an empty, clean and sanitized farm bulk milk tank/silo/direct load milk tank truck.

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

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



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