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M-I-14-8
Supplement 1

November 27, 2017

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 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. to follow 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 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 since the issuance of M-I-14-8 on April 21, 2014.

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.

M-I-17-4-Submission of Questions Related to Automatic Milking Installations (AMI's)

- M-I-17-4 states that FDA will be creating a task force that will be responsible for considering all matters relative to AMIs and recommending policy on the same. Will State Regulatory/Rating Agencies or AMI Manufacturers have representation on this task force?

  The internal ad hoc task force established by FDA earlier this year was created in order to ensure that FDA positions on matters relating to the sanitary design and operation of AMIs were well-grounded in science and engineering principles of sanitary design. Its purpose is to ensure that FDA provides States with the best possible advice that is well grounded and based on scientific and engineering principles. FDA looks forward to continuing its work with the States in the manner prescribed by the National Conference on Interstate Milk Shipments (NCIMS) Procedures Governing the Cooperative State-Public Health Service/FDA Program of the National Conference on Interstate Milk Shipments (Procedures).

  Since M-I-17-4 was issued, the NCIMS Executive Board has charged the NCIMS Technical Engineering Review Committee to establish an inclusive working sub-committee to identify obstacles and potential solutions to align the PMO requirements with current and next generation AMI equipment and operations. This new sub-committee with have representation from State Regulatory/Rating Agencies, FDA, AMI manufacturers and industry.

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

- Are floor mats that are placed on the cow standing surfaces in the milking area of an AMI system acceptable?

FDA's position on using floor mats in the milking area of a milking facility was addressed in M-I-03-13 (Question 21). This M-I states that the use of floor mats on cow standing surfaces in the milking area is acceptable only under the following conditions:

1. They are relatively smooth, impervious, easily cleanable and in good repair.
2. They are maintained in a clean condition and are not fastened permanently to the floor.
3. They are installed so they may be easily lifted, inspected and cleaned underneath.
4. They may not be one long continuous section, which makes them impossible to maintain and inspect.
5. When cracked, worn, or frayed, they must be replaced or removed.
6. If the producer is not able to maintain or clean them, the Regulatory Agency shall take action to have them removed.

ITEM 9r. UTENSILS AND EQUIPMENT – CONSTRUCTION

- In the course of a FDA check rating, will rolled ferrule pipe couplings automatically be debited as a PMO equipment violation?

  No. They should be debited only if those fittings fail to meet the sanitary construction criteria for milk product contact surfaces; however, these type fittings should be evaluated thoroughly since they tend to have openings, crevices, etc., at the joint between the pipe and the fitting.

  NOTE: *3-A Accepted Practice for the Design, Fabrication, and Installation of Milking and Milk Handling Equipment, Number 606-05 and 3-A Sanitary Standards for Sanitary Fittings, Number 63-03 allows for these to be installed on dairy farms when existing systems are modified or repaired on site; if the fittings are installed with no cracks; and if they meet other applicable product contact surface requirements in 3-A Accepted Practice 606-05.*

- M-b-246 addresses polypropylene plastic fittings (tees and elbows) and states that because of alterations to the gasket area when these fittings are connected to other plastic fittings, they shall only be connected to stainless steel or glass connections. Does this mean that glass-to-silicone-to-plastic-to-silicone connections are not allowed?

  No. The requirement noted in M-b-246 was specific to clamped plastic-to-plastic fittings (tees and elbows) for milking pipelines and receiver assemblies on Grade "A" dairy farms. All connections shall comply with the requirements noted in Item 9r of the PMO.

ITEMS 10r and 11r. UTENSILS AND EQUIPMENT – CLEANING AND SANITIZING

- If an AMI system uses a buffer tank to store milk while the bulk milk storage tank is being emptied, cleaned and sanitized, what are the cleaning and sanitizing requirements of the buffer tank?

  The buffer tank shall be cleaned after each milking or once every twenty-four (24) hours for continuous operations and shall be sanitized after each cleaning and/or before each use.

ITEM 14r. PROTECTION FROM CONTAMINATION

- When valves, or valve seats in the case of single-bodied double seat valves, are part of an automatic fail-safe system that prevents the contamination of milk with cleaning and/or sanitizing solutions, the controls for this fail-safe system are to be tested and secured as directed by the Regulatory Agency in order to prevent unauthorized changes. How often is the Regulatory Agency required to test this fail-safe system?

  When initially commissioned and at a frequency deemed appropriate by the Regulatory Agency.

- What type of valve(s) is acceptable to use on an AMI milking system to separate milk from water?

  A valve(s) that upon loss of air or power will move to a position that will close and block the water line(s) from the milk product line(s).

  NOTE: *Butterfly valves would not be acceptable for use in this application.*

ITEM 14r. PROTECTION FROM CONTAMINATION AND APPENDIX H

- When a sanitary check-valve is required to be installed in air piping, may threaded fittings be used on the air distribution piping between the final air filter and the sanitary check-valve that is installed at the point of application?

  Yes. The only requirement is that the air distribution piping and fittings after the final air filter and before the sanitary check-valve be constructed of corrosion-resistant materials. Air distribution piping, fittings and gaskets between the discharge of the sanitary check-valve to the point of application shall be sanitary piping that conforms to the requirements of Item 10p-Sanitary Piping of the PMO.

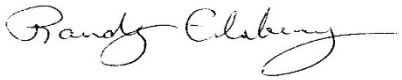
- When a sanitary check-valve is **not** required to be installed in air piping because the air piping enters the milk or milk product zone from a point higher than the milk or milk product overflow level, which is open to atmosphere, may threaded fittings be

used on the air distribution piping between the final air filter and the point of application?

*Yes. When a sanitary check valve is **not** required to be installed in air piping, plastic or rubber or rubber-like tubing and suitable compatible fittings and connections made of plastic or stainless steel are to be used between the final air filter and the point of application.*

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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