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M-I-14-8

April 21, 2014

TO: All Regional Food and Drug Directors
Attn: Regional Milk Specialists

FROM: Dairy and Egg Branch/Milk Safety Team (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.

GENERAL REQUIREMENTS FOR AMI COMPUTER SYSTEMS

- AMIs have computer systems that are programmed for monitoring and/or controlling various sensors, instrumentation and the operational state of various devices such as pumps and valves; have data collection, storage and reporting systems; and have communication network capabilities for multiple uses and locations. What minimum documentation is required for the proper commissioning and verification of these computer systems?

A written or electronic user's guide addressing the computer system's monitoring and controlling functions, and of the computer system's data collection, storage and reporting information shall be provided and shall explain the computer system's architecture, the software used, the devices controlled, the sensors or instruments monitored, and testing procedures for all of these computer system components. This overview may be presented in text or in a graphical representation. This document shall bear the name of the identified representative of the dairy farm assigned to administer this computer system and shall be available for review at the dairy farm upon request by the Regulatory Agency, Rating Agency and/or FDA. This documentation shall explain:

- 1. The computer system's architecture, the software used, the devices controlled or monitored and their locations, and the sensors or instruments monitored and their locations;*
- 2. The reporting interface of the computer system's data collection, storage and reporting information;*
- 3. The testing procedures for all of the computer system's components;*
- 4. The backup procedure for ensuring the safe collection and storage of the data of all reports;*
- 5. The procedure for any changes or maintenance to the computers, devices, instrumentation, sensors hardware, etc. This procedure shall explain how the identified dairy farm representative shall ensure that when a physical change occurs the information affected has been checked for accuracy and which personnel are authorized to make such changes; and*
- 6. The listing and explanation of the reports available on the computer system, instructions on how to access the reports and examples of each report with a description of their content.*

The data supporting the electronic reports shall be stored in a database or data archival system in a Write Once, Read Many (WORM) or equivalent.

The computer system shall provide an anomalies report indicating any computer system or communication failure that could have affected the validity of the required reports. This anomalies report shall be automatically attached to any report that may have been affected by the computer system anomaly. A separate error log or computer system log will not suffice for meeting this requirement, since any anomaly requires an evaluation and investigation to correlate the anomaly.

A written or electronic record shall be maintained at the dairy farm identifying any changes or updates to the devices, computer system's data collection, storage and reporting information, software, drivers, networking or servers in order to assure the collection, storage or reporting of any data required for compliance with the PMO has not been compromised. This record shall contain the name of the identified dairy farm representative assigned to administer this computer system and the record shall be available for review at the dairy farm upon request by the Regulatory Agency, Rating Agency and/or FDA.

A verification of all computer system's controlled functions shall be conducted and documented at the commissioning of the computer system and at additional frequencies as deemed necessary by the Regulatory Agency. Whenever any changes, updates or observed anomalies that could have affected the reliability or accuracy of the computer system's reporting system occur following the commissioning of the computer system, these changes, updates or observed anomalies shall be immediately evaluated and investigated; and if corrections are warranted, they shall be addressed. The records addressing any of these actions shall bear the signature of the authorized vendor representative and/or the identified dairy farm representative; and shall be reviewed and verified by the Regulatory Agency during routine dairy farm inspections and by the Rating Agency and FDA Regional Milk Specialists (RMSs) during ratings and check ratings, respectively. Written or electronic records for all of these required actions shall be maintained at the dairy farm and shall be made available upon request to the Regulatory Agency, Rating Agency and/or FDA.

NOTE: *While electronic and computer systems can furnish a wide range of process verification and anomaly reporting, these criteria only require appended reporting of data loss that could have affected the reports that are required for compliance with Appendix Q, Items 1r, 10r, 11r, 13r and 14r of the PMO.*

ITEM 1r. ABNORMAL MILK

“AMIs shall have the capability to identify and discard milk from animals that are producing milk with abnormalities. Odor is currently evaluated on a farm bulk milk tank/silo basis and shall not be any different for a herd using AMI technology.

Animals producing milk with abnormalities shall be diverted to a holding pen to be milked immediately prior to the milking system being cleaned and sanitized, or the animal(s) 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 milking system that came into contact with the milk with abnormalities are immediately cleaned and sanitized.”

- How would a Regulatory Agency identify which personnel are authorized to make changes to the computer programs and settings used to assure milk with abnormalities is properly detected and diverted?

The dairy farm shall have an identified representative(s) that has been trained and certified by the manufacturer of the AMI to make program changes to the AMI system. In addition, the dairy farm shall have a documented written procedure in place to ensure that milk with abnormalities is properly detected and diverted; and that equipment used for the milking of healthy animals has not become contaminated. The procedure shall also document when a physical change to the AMI system has occurred; that the recorded information affected has been checked for accuracy; and which personnel are authorized to make those changes.

A verification of all computer system’s controlled functions responsible for properly detecting and diverting abnormalities in milk, to include conductivity and color sensors, shall be conducted and documented at the commissioning of the computer system. This verification means the visual observation by Regulatory Agency personnel; or documentation indicating the testing that was completed by the manufacturer’s technician; or other means accepted by the Regulatory Agency. Whenever any changes, updates or observed anomalies that could have affected the reliability or accuracy of the computer system’s reporting system occur following the commissioning of the computer system, these changes, updates or observed anomalies shall be immediately evaluated and investigated; and if corrections are warranted, they shall be addressed. The records addressing any of these actions shall bear the signature of the authorized vendor representative and/or the identified dairy farm representative; and shall be reviewed by the Regulatory Agency during routine dairy farm inspections and by the Rating Agency and RMS during ratings and check ratings, respectively.

Written or electronic records for all of these required actions shall be maintained at the dairy farm and shall be made available upon request to the Regulatory Agency, Rating Agency and/or FDA.

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

“The AMI milker box shall be treated the same as any other milking parlor. The goal is a clean environment in which to milk animals. All ventilation air shall come from outside the cattle housing area. The AMI should be located to provide a clean access for all personnel.”

- AMIs are being installed with a floor drain in the middle of the AMI’s milking box/stall. May this floor drain be connected to a manure pit?

Yes. The floor drain shall be properly installed to assure that there is not a direct opening between the milking area and the manure pit. It is recommended that the drop pipe connected to the discharge line be extended below the surface of the liquid in the manure pit; or that a flapper valve be properly installed on the drop pipe; or that other means acceptable to the Regulatory Agency be provided to prevent potential odors from entering the AMI milking box/stall.

- May an AMI, including the milking platform area, be installed directly over a slotted floor/manure pit in the cattle housing area?

Yes, provided the installation complies with Appendix C-Dairy Farm Construction Standards and Milk Production, Item IV-Guidelines for Conventional Stall Barn with Gutter Grates over Liquid Manure Storage of the PMO.

- Are ceilings and walls required for AMI milker boxes/stalls?

The AMI milker box/stall shall be treated the same as any other milking area (barn, stable or parlor). The goal is a clean environment in which to milk dairy animals. The PMO states: "When conditions warrant, the Regulatory Agency may approve a barn without four walls extending from floor to roof, or a shed-type barn provided the requirement of Item 3r, prohibiting animals and fowl from entering the barn is satisfied".

ITEM 5r. MILKHOUSE – CONSTRUCTION AND FACILITIES

- May AMI milking equipment parts located in the AMI robot room, such as filter housings, air purge fittings, pipeline clamps and gaskets, etc. be manually washed and sanitized on a daily basis in a two (2) compartment wash vat located in the robot room?

Yes, provided that the AMI robot room complies with the requirements of Item 5r-Milkhouse - Construction and Facilities of the PMO.

ITEM 8r. WATER SUPPLY

- Is the water supply used in the AMI(s) required to comply with Item 8r of the PMO to include potential cross connection issues, e.g., boiler system, teat prep connections, CIP systems, jetter cups, etc.?

Yes. Permanent connections between components of the AMI milking system and the potable water system are required to be protected.

- Is a boiler water connection to the AMI that may also provide boiler water used for heating the floor in the AMI milking box/stall acceptable?

Yes, provided that the boiler water is properly protected or the heat exchange is conducted in a separate closed system.

ITEM 9r. UTENSILS AND EQUIPMENT - CONSTRUCTION

“AMIs are the same as any other milking system from a sanitary construction and installation standpoint and shall meet the same standards as a conventional milking system in respect to construction, installation, inspectability, the fit and finish of the milk product-contact surfaces, etc.”

- What areas of an AMI and associated piping and storage vessels should be closely inspected for proper sanitary construction?

The Regulatory Agency shall conduct a thorough review of all AMIs and their associated piping and storage vessels related to the construction and sanitary design of equipment to ensure compliance with Item 9r of the PMO. This should include, but not be limited to, threaded sensors, nonmetal to nonmetal connections, quality of stainless steel, quality of welds on the inside of the milk pipeline, surge vessels, etc.

- May AMIs that have milk pipelines with clamped connections be installed in free stall/loafing areas?

Milk pipeline systems for AMIs located outside the AMI robot room shall be constructed with minimal clamp connections (welded flanges, not rolled on ferrules) to allow for inspection and breakdown.

- All AMIs are required to be inspectable, even when an AMI technician, dairy producer or identified dairy farm representative is unable to be present during routine Regulatory Agency inspections, ratings or check ratings. When none of these individuals are available how would the Regulatory Agency, Milk Sanitation Rating Officer (SRO) or RMS address this issue?

All AMIs shall meet all of the requirements of Item 9r of the PMO, including Administrative Procedures #9 that addresses that all milking machines, including heads, milk claws, milk tubing and other milk-contact surfaces can be easily cleaned and inspected. Numerous locations within an AMI, tools are required for the disassembly of equipment, so that the equipment can be easily accessible for inspection. All applicable tools required for the disassembly of equipment shall be available at the milkhouse to the Regulatory Agency, SRO, or RMS for this purpose.

All equipment shall be thoroughly inspected during the commissioning of the AMI installation by the Regulatory Agency before granting permission to use the AMI. The Regulatory Agency shall be notified by the dairy producer and/or AMI installer/technician when routine maintenance is scheduled for the AMI milking equipment; so that the milking equipment may be inspected during non-milking times

as deemed necessary by the Regulatory Agency. This notification shall be made in a manner acceptable to the Regulatory Agency.

NOTE: The AMI manufacturers should provide an operational inspection document for each AMI installation.

- May a sanitary/moisture trap be installed directly above the milk receiver?

No. The following guidance is utilized when evaluating the sanitary/moisture trap location and installation: In a pipeline milking system, a self-draining sanitary vacuum/moisture trap shall be provided whenever the milk pipeline or a permanently installed solution pipeline (wash line) is connected to a vacuum supply line. The sanitary vacuum/moisture trap shall be installed adjacent to the milk receiver, releaser, wash vacuum pipeline or vacuum milk holding tank and connected by readily disassembled sanitary piping. From the top intersection of the outlet on the receiver, the vertical rise of this connection shall not exceed 12 in. (30.5 cm) as measured to the bottom of the connecting elbow. The connecting sanitary piping shall slope toward the sanitary vacuum/moisture trap at least 1/2 in. (13 mm) in the first 2 ft. (61 cm) and the remainder of the pipe shall slope a minimum of 0.8%. The sanitary vacuum/moisture trap shall be installed so that any liquid collected in the sanitary vacuum/moisture trap cannot get back into the receiver, releaser, or vacuum milk holding tank. Sanitary vacuum/moisture traps designed for mechanical cleaning may be cleaned by reverse flow.

ITEM 10r. UTENSILS AND EQUIPMENT – CLEANING

“AMIs are a continuous milking system and shall be shut down to clean at an interval sufficient to prevent the milking system from building up with soils. It is recommended that this interval not to exceed 8 hours.”

- At what frequency should AMIs be shut down for a complete wash cycle?

The interval between each complete wash cycle shall not exceed twenty-four (24) hours.

ITEM 11r. UTENSILS AND EQUIPMENT – SANITIZATION

“AMIs shall be sanitized after each cleaning and/or before each use, as is the case with any other milking system.”

- At what frequency should AMIs be shut down for a complete sanitization cycle?

The interval between each complete sanitization cycle shall not exceed twenty-four (24) hours. The product-contact surfaces of all multi-use containers, equipment and utensils used in the handling, storage or transportation of milk shall be sanitized before each usage.

ITEM 12r. UTENSILS AND EQUIPMENT – STORAGE

“AMIs shall have positive air ventilation systems in operation whenever the milking system is being cleaned and/or sanitized. The air for this ventilation system shall come from outside the cattle housing area and shall be as clean and dry as practical. This positive air ventilation system shall also run during milking if needed to minimize odors, moisture and/or for pest control.”

- Are the jetter cups required to be appropriately protected from potential sources of contamination when not being used to store the teat cups (inflations) of the milking cluster between individual dairy animal milkings?

Yes. The jetter cups shall be adequately shielded, or variations may be individually evaluated and found to also be acceptable by the Regulatory Agency and FDA, during the teat prepping and milking process to assure that contaminants shall not enter through the jetter cups and get into the milk.

ITEM 13r. MILKING - FLANKS, UDDERS AND TEATS

“AMI manufacturers shall submit data to FDA to show that the teat prepping system employed in their milking system is equivalent to Item 13r., **ADMINISTRATIVE PROCEDURES #4** of this *Ordinance*: “Teats shall be treated with a sanitizing solution just prior to the time of milking and shall be dry before milking.” Each AMI installer shall provide the dairy producer and the Regulatory Agency with a copy of this FDA acceptance, including a detailed description of the accepted equivalent procedure. Each dairy producer shall keep a copy of the accepted teat prep protocol along with the appropriate AMI manufacturer’s teat prep protocol verification procedures on file at the dairy farm.”

- Is it required that the manufacturer of an AMI submit their teat prep protocol to FDA for their review and acceptance prior to the AMI’s teat prep protocol being implemented on any of their dairy farm AMI installations?

Yes. Specific AMI teat prep protocols are submitted to FDA for their review and acceptance. Once reviewed and accepted as being equivalent to ITEM 13r., Administrative Procedures #4: “Teats shall be cleaned, treated with a sanitizing solution and dry just prior to milking”, an M-I will be issued for that specific AMI teat prep protocol, equipment model and AMI manufacturer.

NOTE: *The acceptance of a teat prep protocol as specified for use in an M-I for a specific AMI manufacturer and equipment model will remain in effect with future versions (models) of this equipment as long as this accepted Teat Preparation Protocol can be applied as written. If the Protocol has not been changed, the manufacturer shall provide this accepted protocol with future versions (models) of their AMIs.*

Each AMI installer shall provide the dairy producer and the Regulatory Agency with a copy of this FDA acceptance, including a detailed description of the accepted equivalent teat prep protocol. Each dairy producer shall keep a copy of the accepted teat prep protocol along with the appropriate AMI manufacturer's teat prep protocol verification procedures on file at the dairy farm. If the teat prep protocol is not available at the dairy farm, this would be considered a violation of Item 13r–Milking – Flanks, Udders and Teats of the PMO.

- Computer programs and settings used to assure proper teat prep, washing and sanitization can be readily changed. How often should the computer program or setting calibrations and authorized personnel access settings be checked and by whom?

Please refer to the General Requirements for AMI Computer Systems on page 2 of this M-I.

A verification of all computer system's controlled functions responsible for proper teat prep, washing and sanitization shall be conducted and documented at the commissioning of the computer system. This verification means the visual observation by Regulatory Agency personnel; or documentation indicating the testing that was completed by the manufacturer's technician; or other means accepted by the Regulatory Agency. Whenever any changes to the teat prep protocol, updates or observed anomalies that could have affected the reliability or accuracy of the computer system's reporting system occur following the commissioning of the computer system, these changes, updates or observed anomalies shall be immediately evaluated and investigated; and if corrections are warranted, they shall be addressed. The records addressing any of these actions shall bear the signature of the authorized vendor representative and/or the identified dairy farm representative; and shall be reviewed by the Regulatory Agency during routine dairy farm inspections and by the SRO and RMS during ratings and check ratings, respectively. Written or electronic records for all of these required actions shall be maintained at the dairy farm and shall be made available upon request to the Regulatory Agency, SRO and/or FDA.

ITEM 14r. PROTECTION FROM CONTAMINATION

“The teat cups (inflations) of the milking cluster shall be adequately shielded, or variations may be individually evaluated and found to also be acceptable by FDA and the Regulatory Agency, during the teat prepping process to assure that contaminants shall not enter through the teat cups and get into the milk.

AMIs are designed to automatically shift from milking to cleaning/sanitizing positions; therefore, adequate separation of milk and CIP solution shall be provided to minimize the risk of cross contamination of milk with cleaning and/or sanitizing solutions. A fail-safe valve system providing protection equivalent to an inter-wired block-and-bleed valve arrangement, as referenced in Item 14r of this *Ordinance*, shall be located as needed to prevent cross contamination. Separation shall be provided between milk with

abnormalities and milk intended for sale, and between cleaning/sanitizing solutions and milk intended for sale.

Each dairy producer shall keep a copy of the AMI manufacturer's testing verification procedures for the fail-safe valve systems on file at the dairy farm.

AMIs, which have a wash line extending into the wash vat that is continuously connected to the milking system, shall have a valve arrangement that provides for an air break equal to the diameter of the wash line."

- AMIs use position detectable sensors to monitor block-bleed-block valve arrangements or single-bodied mix proof valves. How should these position detectable sensors be tested; how often should they be tested; and who should test these position detectable sensors?

Each dairy producer shall keep a copy of the AMI manufacturer's testing verification procedures for the fail-safe valve system arrangements on file at the dairy farm. AMIs, which have a wash line extending into the wash vat that is continuously connected to the milking system, shall have a valving arrangement that provides for an air break equal to the diameter of the wash line.

- Some AMIs stores the teat cups (inflations) of the milking claw in the up-right position; which increases the possibility of contamination while in the teat prep position and/or stored position after the milking of a cow. How should the teat cups (inflations) be stored to adequately protect the inflations from potential contamination?

The teat cups (inflations) of the milking cluster shall be adequately shielded, or variations may be individually evaluated and found to also be acceptable by the Regulatory Agency and FDA, during the teat prepping process to assure that contaminants shall not enter through the teat cups (inflations) and get into the milk.

- AMIs use air under pressure with a single main filter, then individual air blows branch off to multi-milker box/stall installations, which may or may not be filtered as close as possible to the final point of application as required in the PMO. What are the sanitary construction standards and installation requirements for these air blow systems, including the air purge fittings?

Air blow systems shall be designed and installed in accordance with all of the requirements of the PMO, such as proper filtration as close as practical to the point of use; and all downstream air line piping shall be of sanitary design, air free of oil, excessive moisture and odor, etc.

- Would the use of butterfly valves for the required block-bleed-block valve arrangements comply with the separation requirements of Item 14r of the PMO?


No. Item 14r would be debited on routine Regulatory Agency inspections, ratings and check ratings.

An electronic version of this memorandum is available for distribution to Regional Milk Specialists, 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 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 robert.hennes@fda.hhs.gov.



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