ADMINISTRATIVE CODE

CHAPTER 420-3-16-A
APPENDICES

420-3-16-AQ **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.**

This appendix is intended to clarify how AMIs are to be constructed, installed, perform, monitored, maintained, etc. to be considered in compliance with the Grade "A" PMO. It is formatted to follow the items as outlined in Section 7. STANDARDS FOR GRADE "A" RAW MILK FOR PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING. Both requirements and recommendations are provided.

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. While electronic and computer systems can furnish a wide range of process verification and anomaly reporting, these are criteria only for compliance with Items 1r, 13r, and 14r.

The dairy farm shall have an identified representative(s) that has been trained by the AMI manufacturer or AMI manufacturer's designated representative to make program changes to the AMI system.

A manufacturer's written or electronic documentation addressing the computer system's monitoring and controlling functions related to Items 1r, 13r, and 14r shall explain the devices controlled, the sensors or instruments monitored, and testing procedures. A document shall bear the name of the identified representative of the dairy farm and shall be available for review at the dairy farm upon request by the regulatory agency, rating agency and/or the FDA.

This documentation shall address Items 1r, 13r, and 14r:

1. The software version used, the devices controlled or monitored and their locations, and the sensors or instruments monitored and their locations.

2. The testing procedures for all of the computer system's controlled and monitoring devices.

3. The procedure for any changes or maintenance to the computers, devices, instrumentation, sensors hardware, etc.

4. Instructions on how to access the information available on the computer system.

Note: Controls for the devices are verified as directed by the regulatory agency.

The data supporting the electronic reports shall be stored in a database or data archival system. Written or electronic record(s) shall be maintained at the dairy farm identifying changes and verifying compliance with this rule. This record shall contain the name of the identified dairy farm representative assigned to administer the computer system and these record(s) shall be available for review at the dairy farm upon request by the regulatory agency, rating agency and/or the 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. Computer system controlled functions should be reviewed and verified by the regulatory agency during routine dairy farm inspections and by the rating agency and the FDA.

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.

The dairy farm shall have a documented procedure in place describing how abnormal milk is properly detected and diverted; and that equipment used for the milking of healthy animals has not become contaminated. The procedure shall also document that a physical change to the AMI system has occurred.

A verification of all computer system's controlled functions responsible for properly detecting and diverting abnormal milk 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 an AMI manufacturer's designated representative; or other means accepted by the regulatory agency. Written or electronic information for all required actions shall be maintained at the dairy farm and shall be made available upon request to the regulatory agency, rating agency, and/or the FDA.

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.

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.

ITEM 3r. MILKING BARN, STABLE, OR PARLOR – CLEANLINESS

The AMI milker box shall be kept as clean as any milking and equipment cleaning area. It is recommended that the milking platform be regularly flushed with water to remove any manure that may have accumulated.

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.

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 eight (8) 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.

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.

ITEM 13r. MILKING - FLANKS, UDDERS, AND TEATS

AMI manufacturers shall submit data to the FDA to show that the teat prepping system employed in their milking system is equivalent to Item 13r., Administrative Procedures 4 of these rules: "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 Health Officer 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.

A verification of all computer system's controlled functions responsible for proper teat preparation 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 an AMI manufacturer's designated representative; or other means accepted by the regulatory agency. Written or electronic information for all required actions shall be maintained at the dairy farm and shall be made available upon request to the regulatory agency, rating agency, and/or the 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 the FDA and the Health Officer, 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 these rules, 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 valving arrangement that provides for an air break equal to the diameter of the wash line.

ITEM 18r. RAW MILK COOLING

For AMIs, the raw milk for pasteurization, ultra-pasteurization, aseptic processing, and packaging or retort processed after packaging shall be cooled to 10°C (50°F) within four (4) hours or less after starting the milking operation and the milk shall be cooled within two (2) more hours to 7°C (45°F). The milk in the farm bulk milk tank/silo shall not exceed 7°C (45°F) after that time. Farm bulk milk tank/silo recording thermometers are recommended if not already required by these rules.

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