Automatic Milking Installations NCIMS Update 2019 Eastern Milk Seminar

Chris Hylkema, Chair

NCIMS Technical Engineering Review Committee

NEW YORK STATE OF OPPORTUNITY | Department of Agriculture and Markets

Discussion Points

- AMI Subcommittee – formation and members
- Initial Challenges and Goals
- Accomplishments
- Future of the subcommittee
- Thoughts on the process as a whole
- Changes to the PMO

What were the main issues?

- Ambiguity between States / FDA / Manufacturers
- M-I-14-8 was issued – supposed to be guidance – wasn't utilized in that manner
- 2015 NCIMS Proposal 134
- 2017 NCIMS – proposals submitted by AMI manufacturers – *none passed*
- National Attention
  - Letters from US House of Representatives Committee on Agriculture and State Departments of Agriculture
  - Articles in Hoard's Dairyman
- Letter from NMPF to NCIMS

AMI Subcommittee – received letter 10/18/2017

"The Chair of the NCIMS Executive Board charges the Technical Engineering Review Committee (hereinafter the Committee) to examine the issue of compliance of Automatic Milking Installations (AMIs) with requirements of the Pasteurized Milk Ordinance (PMO), with the specific objective of identifying obstacles and potential solutions to aligning PMO requirements with current and next generation AMI equipment and operations.

As part of meeting this charge, the Committee shall establish an inclusive working subcommittee consisting of representatives from state regulatory agencies, FDA, AMI manufacturers, and other industry sectors as needed to obtain the necessary technical expertise and stakeholder input. The Committee shall provide progress reports at least quarterly to the NCIMS Executive Board, and may culminate its work with proposals for specific revisions to the PMO, or other Conference documents, for consideration by state delegates at the 2019 Conference."

Ok, sounds easy

Membership – AMI Subcommittee is a subcommittee of the NCIMS Technical Engineering Review Committee

TERC – Automatic Milking Installation (AMI) Subcommittee

Subcommittee of the Technical Engineering Review Committee

NAME	COMPANY/STATE AGENCY	LOCATION	POSITION ON SUBCOMMITTEE
Chris Hylkema, Chair	New York Dept of Agriculture & Markets	Albany, NY	TERC Member
Brian Wise	Ohio Dept of Agriculture	Reynoldsburg, OH	TERC Member
Paul Dix	Maryland Dept of Health & Mental Hygiene	Baltimore, MD	TERC Member
Gena Reich	Washington State Dept of Agriculture	Kennewick, WA	TERC Member
Helen Piotter	Dean Foods Company	Macy, IN	TERC Member

Steve Stoner	Wisconsin Dept of Agriculture, Trade & Consumer Protection	Madison, WI	Non-TERC Regulatory
Clint George	Texas Dept of State Health Services	Austin, TX	Non-TERC Regulatory
Steve McGinnis	California Dept of Food & Agriculture	Fresno, CA	Non-TERC Regulatory
David Brown	Iowa Dept of Agriculture	Des Moines. IA	Non-TERC Regulatory
Adam Sonnenburg	Dairy Farmers of America	Dodgeville, WI	Non-TERC Industry
Jason Martin	Galaxy AMS	Kutztown, PA	Non-TERC Industry
Brad Cupery	Lely North America	Randolph, WI	Non-TERC Industry
Matt Stuessel	GEA USA	Galesville, WI	Non-TERC Industry
Brad Schaller	Boumatic	Madison, WI	Non-TERC Industry
Derek Zepp	DeLaval	Kansas City, MO	Non-TERC Industry
William Bernhard	AEM	Milwaukee, WI	Non-TERC Industry
Dr. Stephen Walker	USFDA	College Park, IL	FDA Advisor
Randy Elsberry	USFDA	Exeter, CA	FDA Advisor

Surveyed Subcommittee and NCIMS Membership January 2018

1. Based on the charge to NCIMS Sub-committee, what do you feel are the obstacles facing the objective?
2. What do you feel are potential solutions to meeting this objective?
3. What are the main concerns for your agency with regard to regulating AMIs on U.S. dairy farms?
4. Remove Appendix Q (Yes – 48%; NO – 52%)
5. Please feel free to share any other comments you may have regarding the regulation of AMIs in the U.S.

Goals of the subcommittee

To have language in the PMO to regulate AMI units and installations in the same manner as all other milking systems

Have decision making done through consensus

Accomplishments

- Revisions to the PMO
  - Strike-out of Appendix Q
  - Retained necessary language and blended that back into relevant parts of Section 7
  - Added language to Appendix H
- Submitted Proposal 118 to 2019 NCIMS – PASSED AS SUBMITTED

Future of the Subcommittee

- Planning to restart meetings
  - Tentative plan is to review the existing M-Is addressing AMIs – much of the language in most of them is no longer relevant or consistent with the PMO because of the passing of Proposal 118

Takeaway from the process

My thought is this should be the model approach to making changes within the Grade A Program

Biggest Accomplishment – bringing all stakeholders into the same room and getting consensus on ***most*** issues – we did not hold a single vote during our talks

2019 NCIMS Proposal 118

Changes to the PMO

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B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

During the meetings of the subcommittee it was determined that Appendix Q of the PMO contains, in some instances, redundant language when compared to Section 7 and that the computer control requirements of Appendix Q are more restrictive than what is required on what is considered a conventional dairy. The consensus of the subcommittee is that U.S. dairy farms utilizing AMI technology should not be regulated any differently than other dairy farms in the U.S. It was decided to work on incorporating language from Appendix Q into Section 7 and then remove Appendix Q. The computer control language from Appendix Q that was identified as necessary was revised and that language is now part of a new suggested section in Appendix H.

ITEM 1r. ABNORMAL MILK

Lactating animals which show evidence of the secretion of milk with abnormalities in one (1) or more quarters, based upon bacteriological, chemical or physical examination, shall be milked last or with separate equipment and the milk shall be discarded. AMIs shall have the capability to identify and discard milk from animals that are producing milk with abnormalities. Lactating animals producing contaminated milk, that is, lactating animals which have been treated with, have consumed chemical, medicinal or radioactive agents, which are capable of being secreted in the milk and which, in the judgment of the Regulatory Agency, may be deleterious to human health, shall be milked last or with separate equipment and the milk disposed of as the Regulatory Agency may direct. ~~(For applicability to Automatic Milking Installations (AMIs), refer to Appendix Q. of this *Ordinance*.)~~

~~PUBLIC HEALTH REASON~~

Item 1r – Administrative Procedures

milk utensils.

5. AMIs shall have the capability to identify and discard milk from animals that are producing milk with abnormalities. Monitoring and controlling functions related to the identification and discarding of milk with abnormalities, shall comply with the criteria set forth in Appendix H of this *Ordinance*.

6. Lactating animals secreting milk with abnormalities are milked last or in separate equipment, which effectively prevents the contamination of the wholesome supply. Milking equipment used on animals with abnormalities in their milk is maintained clean to reduce the possibility of re- infecting or cross infection of the dairy animals.

7. Equipment, utensils and containers used for the handling of milk with abnormalities are not used for the handling of milk to be offered for sale, unless they are first cleaned and effectively sanitized.

8. Milk without abnormalities may be diverted for other uses and the parts of the milking system that came into contact with this milk are not required to be cleaned and sanitized prior to use for milk to be offered for sale.

9. Processed animal waste derivatives, used as a feed ingredient for any portion of the total

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

A milking barn, stable or parlor shall be provided on all dairy farms in which the milking herd shall be housed during milking time operations. ~~(For applicability to AMIs, refer to Appendix Q. of this *Ordinance*.)~~ The areas used for milking purposes shall:

4. Be provided with natural and/or artificial light, well distributed, for day and/or night milking.
5. Provide sufficient air space and air circulation to prevent condensation and excessive odors. In the case of AMI milking unit rooms, all ventilation air shall come from outside the cattle housing area.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

ten (10) footcandles (110 lux) of light in all working areas shall be provided.

9. Air circulation is sufficient to minimize odors and to prevent condensation upon walls and ceilings. For AMI milking unit rooms, the ventilation air shall come from outside the cattle housing area.
10. A dust-tight partition, provided with doors that are kept closed, except when in actual use,

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

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. The interior of the milking barn, stable or parlor is kept clean.
2. Leftover feed in feed mangers appears fresh and is not wet or soggy.
3. The bedding material, if used, does not contain more manure than has accumulated since the previous milking.
4. Outside surfaces of ~~pipeline systems~~ all milking and clean-in-place (CIP) equipment located in the milking barn, stable or parlor are reasonably clean.
5. Gutter cleaners are reasonably clean.
6. All pens, calf stalls and bull pens, if not separated from the milking barn, stable or parlor, are clean.

ITEM 12r. UTENSILS AND EQUIPMENT – STORAGE

All containers, utensils and equipment used in the handling, storage or transportation of milk, unless stored in sanitizing solutions, shall be stored to assure complete drainage and shall be protected from contamination prior to use. Provided, that pipeline milking equipment such as milker claws, inflations, weigh jars, meters, milk hoses, milk receivers, tubular coolers, plate coolers, ~~and~~ milk pumps and AMI milking equipment which are designed for CIP cleaning and other equipment~~, as accepted by FDA,~~ which meets these criteria, may be stored in the milking barn or parlor, provided this equipment is designed, installed and operated to protect the

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. All milk containers, utensils and equipment, including milking machine vacuum hoses, are stored in the milkhouse in a sanitizing solution, or on racks, until used. Pipeline milking equipment such as milker claws, inflations, weight jars, milk hoses, milk receivers, tubular coolers, plate coolers ~~and~~ milk pumps and AMI milking equipment which are designed for CIP cleaning and other equipment~~, as accepted by FDA,~~ which meets these criteria, may be CIP

12r – Admin. Proc. Cont.

installed and operated to protect the product and solution contact surfaces from contamination at all times. ~~Some of the parameters~~ Parameters to be considered in determining protection are:

a. Proper location of equipment;
b. Proper drainage of equipment; and
c. Adequate and properly located lighting and ventilation.

i. Provided, AMI milking unit rooms shall have positive air ventilation systems in operation whenever the milking system is being cleaned and/or sanitized.

ITEM 13r. MILKING – FLANKS, UDDERS AND TEATS

Agency.

NOTE: Additional alternative udder preparation methods, including those used on AMIs, may also be used once they have been evaluated by FDA and found acceptable. A copy of the FDA acceptance will be available for distribution to regulatory agencies, FDA and other interested parties. Verification of an AMI's control functions responsible for proper teat preparation shall comply with the criteria set forth in Appendix H of this *Ordinance*.

5. Wet hand milking is prohibited.

ITEM 14r. PROTECTION FROM CONTAMINATION

1. Equipment and operations are so located within the milking barn and milkhouse as to prevent overcrowding and contamination of cleaned and sanitized containers, utensils and equipment by splash, condensation or manual contact.
2. During the teat preparation process of an AMI, the teat cups (inflations) shall be adequately shielded to prevent contamination.
3. During milking and milkhouse operations, pipelines and equipment, used to contain or conduct milk, shall be effectively separated from tanks/silos and/or circuits containing cleaning and/or sanitizing solutions. In addition, AMIs shall provide separation between milk with abnormalities and milk intended for sale. This can be accomplished by:
   a. Physically disconnecting all connection points between tanks/silos and/or circuits containing cleaning and/or sanitizing solutions from pipelines and equipment used to contain or conduct milk; or

(3) The valve vent, including piping between blocking valves, is not cleaned until milk has been removed or isolated, except in the case of a properly designed and operated system. This drainable opening to the atmosphere may be cleaned while milk is isolated by one (1) of the blocking valves. A properly designed and operated system shall incorporate the following:

i) During CIP, ~~a valve actuation of~~ the valve blocking the cleaning/sanitizing solution ~~blocking valve~~ may be ~~used~~ pulsed open for cleaning the valve vent, including piping between blocking valves, provided the blocking valves are fail-safe and the vent is self-draining and free from restrictions. Other means of preventing ~~there shall not be~~ pressurization of cleaning solutions on ~~the exterior of~~ the valve isolating milk may be individually evaluated and found to be acceptable by FDA and the Regulatory Agency. ~~that can equal or exceed the pressure of the milk being isolated, and~~

(6) Controls for the fail-safe system are tested and secured as directed by the Regulatory Agency. ~~in order to prevent unauthorized changes.~~ Testing verification procedures shall comply with the criteria set forth in Appendix H of this *Ordinance*.

(7) The vent, including piping between blocking valves, is not cleaned until milk has

ITEM 18r. RAW MILK COOLING

Raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging shall be cooled to 10ºC (50ºF) or less within four (4) hours ~~or less, of the commencement of the first milking, and to 7ºC (45ºF) or less, two (2) hours or after the completion of milking.~~ after starting the milking operation. The milk shall then be cooled within two (2) more hours to 7ºC (45ºF) or less. Provided, that the blend temperature after the first milking and subsequent milkings does not exceed 10ºC (50ºF).

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. Raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging shall be cooled to 10ºC (50ºF) or less within four (4) hours ~~or less, of the commencement of the first milking, and to 7ºC (45ºF) or less, two (2) hours or after the completion of milking.~~ after starting the milking operation. The milk shall then be cooled within two (2) more hours to 7ºC (45ºF) or less. 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 or direct load milk tank truck. Provided, that the blend temperature after the first milking and subsequent milkings does not exceed 10ºC (50ºF).

X. CRITERIA FOR THE EVALUATION OF COMPUTERIZED SYSTEMS FOR AUTOMATIC MILKING INSTALLATIONS (AMIs) FOR GRADE "A" PUBLIC HEALTH CONTROLS

BACKGROUND

AMIs have computerized systems that are programmed for monitoring and/or controlling various sensors, instrumentation and the operational state of various devices such as pumps and valves. The following criteria are to be used for the evaluation of AMI computerized systems requirements within Items 1r, 13r and 14r of this *Ordinance*.

CRITERIA

1. A verification of all computerized system's control functions responsible for properly detecting and diverting abnormal milk; proper teat preparation; and 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 and documented at the commissioning of the computer system and at additional frequencies as deemed necessary by the Regulatory Agency.

2. This verification means the visual observation by Regulatory Agency personnel; or documentation indicating the testing that was completed by the AMI manufacturer; or other means accepted by the Regulatory Agency.

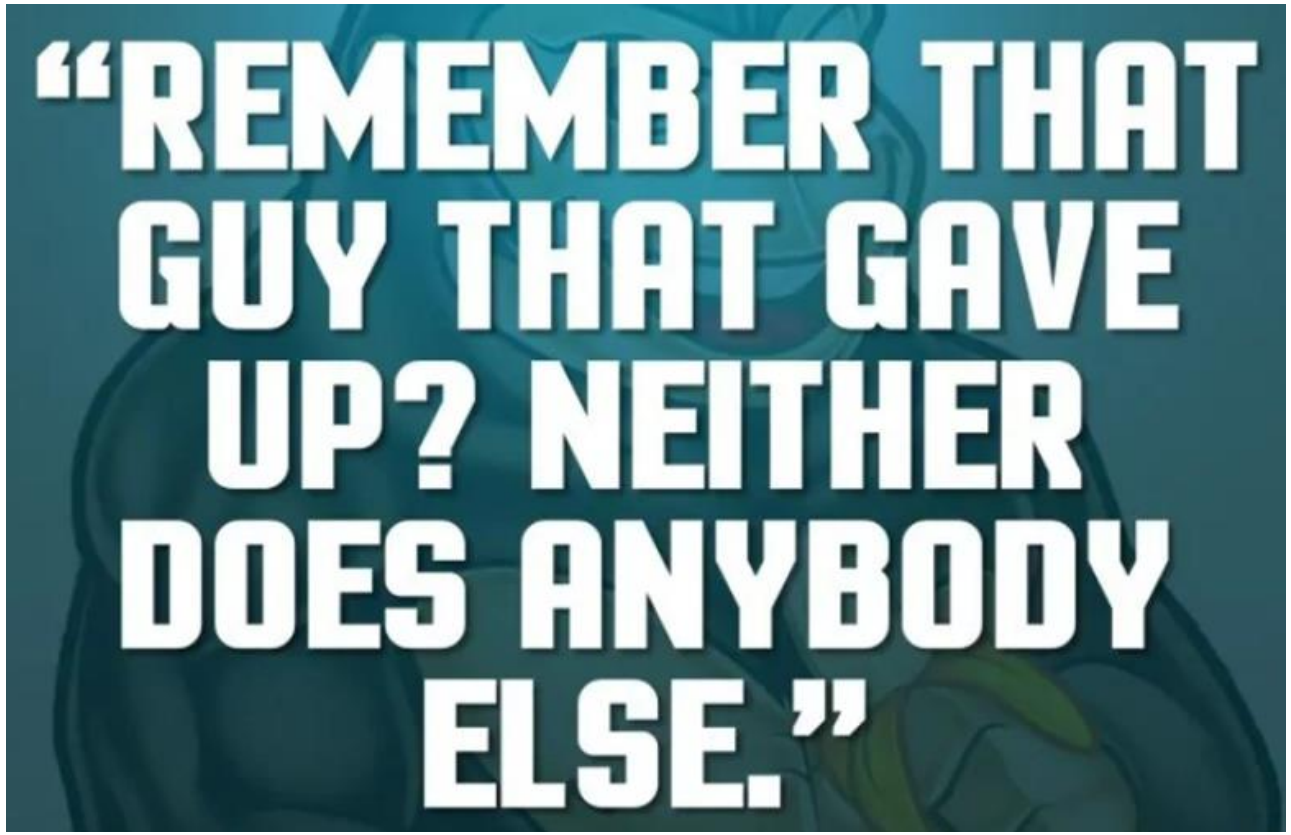
3. A manufacturer's written or electronic documentation addressing the computerized system's monitoring and controlling functions shall explain the devices controlled, the sensors or instruments monitored, and testing procedures. This document will be available to regulatory agencies, FDA and other interested parties upon request.

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~~ [RESERVED]

~~This Appendix is intended to clarify how AMIs are to be constructed, installed, perform, monitored, maintained, etc. to be considered in compliance with this *Ordinance*. It is formatted to follow the Items as outlined in Section 7. of this *Ordinance*. 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~~



THANK YOU

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