

5001 Campus Drive
College Park, MD 20740-3835

M-I-17-3

April 20, 2017

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

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

SUBJECT: Guidance Related To The Requirements For Automatic Milking Installations (AMIs) Addressing Computer System(s) Verification and General Computer Functions Related to Pasteurized Milk Ordinance (PMO), Appendix Q, Items 1r, 13r and 14r.

Proposal 134 that was submitted and passed by the delegates at the 2015 National Conference on Interstate Milk Shipments (NCIMS) added wording to the Pasteurized Milk Ordinance (PMO), Appendix Q to clarify the requirements for the operation of automatic milking installations (AMIs) addressing computer system(s) verification and general computer functions related to Items 1r, 13r and 14r. This proposal also established an implementation date of one (1) year from the issuance of the 2015 version of the electronic PMO (March 15, 2017).

It is our understanding that at this time AMIs do not comply with computer system(s) verification requirements of PMO, Appendix Q, Item 1r, 13r and 14r. FDA has been and will continue to work with AMI manufacturers to bring their computer systems into compliance with PMO, Appendix Q. Until further notice, computer system(s) verification requirements related to Appendix Q, Item 1r, 13, and 14r will not be debited on federal 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 randy.elsberry@fda.hhs.gov.



Randy Elsberry
Senior Milk Sanitation Officer
Milk and Milk Products Branch