PMO Inspection - HACCP Audit Comparison Table

Requirement	Grade A Pasteurized Milk Ordinance (PMO) *Inspection Based Milk Safety Program*	Grade A Pasteurized Milk Ordinance (PMO) *Hazard Analysis Critical Control Point (HACCP) Audit Based Milk Safety Program*
Plant Listing Procedures	May be done immediately. Frequency is a minimum of once every 2 years	First rating only after 60 days of records accumulated, thereafter, frequency is a minimum of once every two years.
	FDA Certified State Rating Officer (SRO)	FDA HACCP Certified SRO with additional HACCP audit training
State rating/listing audit	*Form FDA 2359* *Milk Plant Inspection Report*	*Form FDA 2359m* *MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT*
Listing Pass/Fail Criteria	Passing = score 90 or better on a rating	Passing = no violation of any Critical Listing Elements (CLE's)[1] on a rating. A CLE is one of the 9 essential elements that each individual plant must effectively address and control in its HACCP system to assure the production of safe dairy products on a daily basis.
State Enforcement Rating	*Form FDA 2359J Report of Enforcement Rating Page 2 parts II and III* Conducted as part of a rating. Enforcement score must be 90 or higher for Grade "A" products to be acceptable within the NCIMS system. If the enforcement score is below 90% on a rating, a re-rating must occur within six (6) months of the first rating. Both the Milk Sanitation Compliance and	*Form FDA 2359n NCIMS HACCP System Regulatory Agency Review Report* Conducted as part of a HACCP rating. Report must be completed and submitted to FDA, who will evaluate it. In the event that FDA finds reason to doubt the safety of any State's milk or milk products that are HACCP listed, FDA shall immediately investigate and may evaluate/audit the plants, receiving stations or transfer stations affected. If there are substantial milk or milk product safety program weaknesses after thirty (30) days FDA shall

[1] 1. Flow Diagram and Hazard Analysis conducted & written for each kind of group of milk or milk product processed.
2. Written HACCP plan prepared for each kind or group of milk or milk product processed .
3. CL(s) are adequate to control the hazard identified.
4. Corrective action taken for products produced during a deviation from critical limits defined in the HACCP plan.
5. Calibration of CCP process monitoring instruments performed as required and at the frequency defined in the HACCP plan.
6. Information on HACCP records not falsified.
7. Incoming milk supply from NCIMS listed source(s) with sanitation scores of 90 or better or acceptable HACCP Listing.
8. Drug residue control program implemented.
9. A series of observations that lead to a finding of a potential HACCP System failure that is likely to result in a compromise to food safety.

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	Enforcement Ratings must equal or exceed 90% on the rerating or the plant is in violation (delisted).	notify the affected industry and receiving States. After the 180 days, if milk or milk product safety remains in doubt FDA will not accept new HACCP listings from the State and FDA may audit the existing listings as necessary to protect the public health.
Regulatory Oversight	State inspections	State audits by state employees that have completed required Core Curriculum HACCP training (basic HACCP and an orientation to the requirements of the NCIMS HACCP Program and also specialized training for HACCP system audits).
Regulatory Inspection/Audit Frequency	Every 3 months	Initial Audit (after 60 days of HACCP records generated), second audit within 30 to 45 days, then every 4 months the first year*, 6 months* if no repeat violations, no CLE on last 2 audits and no product or water sample warning letters ** Unless the Regulatory Agency determines that a greater frequency is warranted*
Regulatory Insp./Audit Checklist	*Form FDA-2359* *MILK PLANT INSPECTION REPORT*	*Form FDA 2359m* *MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT*
Establishing Timeline for Correction of Inspectional or Audit Items Noted by the Regulatory Inspector or Auditor	Correction is expected by the next inspection unless another time frame is agreed upon by the plant and regulator. However the regulator may establish written correction timelines when deemed necessary by the regulator	Determined by State Auditor after consultation with industry (except in cases of imminent health hazard). State Auditor required to establish written correction times for all debited items, in consultation with plant management.
Corrective Actions after a Critical Limit (CL)[2] violation of a CCP[3]	Not applicable	Required, may pre-establish or follow 5 requirements listed in Appendix K

[2] Critical Limit: A maximum and/or minimum value to which a biological, chemical, or physical parameter must be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level the occurrence of a milk or milk product safety hazard.

[3] Critical Control Point: A step at which control can be applied and is essential to prevent or eliminate a milk or milk product safety hazard or reduce it to an acceptable level.

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Regulatory Water Sample Frequency	Every 6 months	Same as traditional PMO-based inspection program - every 6 months
Regulatory Action water samples	Comply with PMO (The applicable parts of Sections 3, 6, and 7p Administrative Procedures 7&8)	Same, plus plant must document action taken on any violative samples
Regulatory Product Sample Frequency	4 times in 6 months	Same as traditional PMO-based inspection program - 4 times in 6 months
Regulatory Action Product samples	Comply with PMO Section, 6	Same, plus plant must document action taken on any violative samples
FDA Responsibility	*Form FDA 2359* FDA Check Ratings reported to the rating agency - including sanitation compliance rating score of 80 or higher required to remain on the IMS list. Approximately every 3 years.	*Form FDA 2359m* FDA check audit reported to the rating agency - no CLE violations in order to remain on the IMS list. Approximately every 3 years. In the event that there is reason to doubt the safety of any State's milk or milk products that are HACCP listed, FDA shall immediately investigate the State's Milk Safety Program and may evaluate/audit the plants, receiving stations or transfer stations affected. This applies even if the HACCP listing of the milk plant, receiving station or transfer station being audited is sustained.
	Form FDA 2359J Report of Enforcement Rating Page 2 parts II and III Enforcement rating conducted as part of checkrating - must score 80 or higher (???). Conducted approximately once every 3 years.	Form FDA 2359n *NCIMS HACCP System Regulatory Agency Review Report* Report completed as part of FDA check audit. Based on this report, if FDA finds there may be reason to doubt the safety of the State's milk or milk products that are NCIMS HACCP listed, FDA shall immediately investigate the State's Milk Safety Program and may evaluate/audit the plant, receiving station or transfer station affected. This applies even if the *Milk Plant, Receiving Station Or Transfer Station NCIMS Haccp System Audit Report* finds that the listing of the milk plant, receiving station or transfer station is satisfactory. In the event that FDA identifies substantial milk or milk product safety program weaknesses, after thirty (30) days FDA shall notify the affected industry and receiving States. After the 180 days, if milk or milk product

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		safety remains in doubt FDA will not accept new HACCP listings from the State and FDA may audit the existing listings as necessary to protect the public health.
	Approximately every 3 years conduct State Program Evaluations. Must be in substantial compliance as defined by FDA and the NCIMS Liaison Committee.	Approximately every 3 years conduct State Program Evaluations. Must be in substantial compliance as defined by FDA, the NCIMS Liaison Committee and the NCIMS HACCP Implementation Committee.
Pasteurization	Comply with PMO item 16p	Comply with PMO item 16p (pasteurization is a required CCP)
Past. Equip. Checks	Only State Regulatory may conduct official equipment checks . Allowances may be made for temporary industry seals. Pasteurizer testing *is recorded on FDA form 2359b, Milk Plant Equipment Testing Report* and the testing and frequency is evaluated on *FDA form 2359J Report of Enforcement Rating Page 2 part II, Item #7* (a 15 point pro-rated debit.)	State may authorize industry testing and sealing, but must supervise pasteurizer timing checks at least once each 6 months. A daily seal check is required. Pasteurizers testing *is recorded on FDA form 2359b, Milk Plant Equipment Testing Report* and testing and frequency of tests is evaluated as a CLE according to the *NCIMS HACCP SYSTEM REGULATORY Audit Checklist.* (There is no pro-rating)
State Personnel-Required Training	State Inspectors – no specified NCIMS training required (state may require specific training and education for job eligibility).	State regulatory auditors shall have successfully completed training in the application of HACCP principles for milk and milk product processing and also specialized training for HACCP system audits at least equivalent to that specified under the Dairy HACCP Core Curriculum, in the PMO, Appendix K (state may require specific training and education for job eligibility)
	SRO's and State Sampling Surveillance Officers (SSO's) must be trained and FDA-certified and recertified every three years as specified in the applicable NCIMS documents.	State HACCP Listing Officers shall be FDA-certified SROs and in addition, shall have met the requirements for Original HACCP certification and be HACCP recertified every three years thereafter as specified in: SECTION VIII. "Procedures Governing The Certification Of Milk Plant, Receiving Station And Transfer Station Ncims Haccp Systems For Ims Listed Shippers" of the document, *PROCEDURES GOVERNING THE COOPERATIVE STATE-PUBLIC HEALTH SERVICE/FOOD AND DRUG ADMINISTRATION PROGRAM OF THE NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS*

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FDA Personnel - Required Training	FDA Regional Milk Specialists must be trained and FDA Standardized and Recertified every three years as specified in the *METHODS OF MAKING SANITATION RATINGS* and *PROCEDURES GOVERNING THE CERTIFICATION OF MILK PLANT, RECEIVING STATION AND TRANSFER STATION NCIMS HACCP SYSTEMS FOR IMS LISTED SHIPPERS*	FDA Regional Milk Specialists making HACCP Audits shall have met the same requirements for a state HACCP Listing Officer (see above) as specified in the *METHODS OF MAKING SANITATION RATINGS* and *PROCEDURES GOVERNING THE CERTIFICATION OF MILK PLANT, RECEIVING STATION AND TRANSFER STATION NCIMS HACCP SYSTEMS FOR IMS LISTED SHIPPERS* .
Industry Personnel - Required Training	None specified. Results of training are evaluated indirectly in the inspection and rating process.	Formal HACCP training (core curriculum and orientation to the requirements of the NCIMS HACCP program) is recommended to develop a Hazard Analysis, including delineating control measures, to develop a HACCP plan with corrective action procedures and validation activities and to perform required HACCP Plan records reviews.-Alternatively, job experience may qualify an individual to perform these functions if the experience has provided knowledge at least equivalent to that provided through the standardized curriculum.
Required Records	Raw milk source, raw milk receiving wash tags, product storage temperature records, pasteurization recording charts, pasteurization equipment check records, verification records for Appendix. N compliance, processing equipment cleaning records,, water and product sampling results.	The following written HACCP documents are required: HACCP Program Table of Contents, prerequisite program, flow diagram(s), hazard analysis, HACCP Plan, corrective actions, central deviation log, annual verification and validation exercises, verification of CCP monitoring records, HACCP records summary table, plus other records documenting implementation of the HACCP program (see p. 307 of the 2005 PMO) Additional plant records are required to document compliance with the "Other provisions of the PMO." These include: • Incoming milk supply from NCIMS listed source(s) with sanitation scores of 90 or better or acceptable HACCP Listing. • Drug residue control program implemented. • Drug residue control program records complete. • Labeling compliance as required. • Prevention of adulteration of milk products.

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		• Regulatory samples comply with standards. • Pasteurization Equipment design and construction. • Approved Laboratory Utilized
Records Retention	The above identified records shall be readily available upon request for the time specified in the PMO, Methods or Procedures. The regulatory agency shall maintain their records at least back to the last Rating.	All HACCP records (see above) must be available within 24 hours of request if stored off-site. Records must be retained 1 yr after date product was prepared or 2 yrs for shelf stable, or preserved products unless a longer time is required by other regulations. Records that relate to the adequacy of equipment or processes used shall be retained for at least 2 years, The regulatory agency shall maintain their records at least back to the last HACCP listing audit.
Written Prerequisite Program (PP)	None, although the PMO Section 7 has requirements in all 8 required prerequisite program .	8 Mandatory PP's include: a. Safety of the water that comes into contact with milk or milk products or product-contact surfaces, including steam and ice; b. Condition and cleanliness of equipment product-contact surface; c. Prevention of cross-contamination from insanitary objects and or practices to milk or milk products or product-contact surfaces, packaging material and other food-contact surfaces, including utensils, gloves, outer garments, etc., and from raw product to processed product; d. Maintenance of handwashing, hand sanitizing, and toilet facilities; e. Protection of milk or milk product, packaging material, and product-contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate and other chemical, physical and biological contaminants; f. Proper labeling, storage, and use of toxic compounds; g. Control of employee health conditions, including employee exposure to high risk situations, that could result in the microbiological contamination of milk or milk products, packaging materials, and product-contact surfaces; and h. Pest exclusion from the milk plant.

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		Others are required if they are "being relied upon in the Hazard Analysis to reduce the likelihood of hazards such that they are not reasonably likely to occur"
Central Deviation Log	None	Required
Employee Health PP	Comply with PMO section 13 & 14	Required Prerequisite, use PMO section 13 & 14 as guideline
Product flow diagrams	None Required	Required for each Grade "A" product
Written Hazard Analysis	None Required Effective and proven requirements common to all plants assure the safety of dairy products.	Written Hazard Analysis Required. Evaluate and determine likelihood of occurrence of hazards for consideration in HACCP Plan. Effectively control each hazard specific to the product and plant which will assure the safety of dairy products.
Verification - industry responsibility	None	Annual verification required, may be more frequent based on other triggers, no required frequency for CCP records verification.
Validation - industry responsibility	Compliance with all PMO inspectional and pasteurization requirements serves as validation that the plant is capable of producing safe product.	Annual validation required, may be more frequent based on other triggers.