Department of Health and Human Services
Food and Drug Administration

MILK PLANT, RECEIVING STATION OR TRANSFER STATION
NCIMS HACCP SYSTEM AUDIT REPORT

DATE	TYPE OF AUDIT
	☐ REGULATORY* ☐ REGULATORY FOLLOW-UP ☐ LISTING ☐ FDA AUDIT OF LISTING

FIRM NAME	LICENSE/PERMIT NO.	IMS PLANT NO.

ADDRESS (Line 1)

ADDRESS (Line 2)	CITY	STATE/COUNTRY	ZIP CODE

IMS LISTED PRODUCT(S) MANUFACTURED AND REVIEWED	Prerequisite Program(s) Issue Date(s)

Hazard Analysis	HACCP Plan
Issue Date(s) _____	Issue Date(s) _____

ITEMS MARKED DID NOT MEET THE NCIMS HACCP PROGRAM CRITERIA DESCRIBED BELOW
Starred ★★ Items are Critical Listing Elements

***NOTE:** This regulatory NCIMS System Audit Report of your milk plant, receiving station, or transfer station serves as a notification of the intent to suspend your permit if Items marked on this audit report are not in compliance at the time of the next regulatory audit or within established timelines. (Refer to PMO Sections 3 and 6, and Appendix K. for details.)

Section 1 HAZARD ANALYSIS

- ☐ A. Flow Diagram and Hazard Analysis conducted and written for each kind or group of milk or milk product processed.**
- ☐ B. Written Hazard Analysis identifies all potential milk or milk product safety hazards and determines those that are reasonably likely to occur (including hazards within and outside the processing plant environment).
- ☐ C. Written Hazard Analysis reassessed after changes in raw materials, formulations, processing methods/systems, distribution, intended use or consumers.
- ☐ D. Written Hazard Analysis signed and dated as required.

Section 2 HACCP PLAN

- ☐ A. Written HACCP Plan prepared for each kind or group of milk or milk product processed.**
- ☐ B. Written HACCP Plan implemented.
- ☐ C. Written HACCP Plan identifies all milk or milk product safety hazards that are reasonably likely to occur.
- ☐ D. Written HACCP Plan signed and dated as required.

Section 3 HACCP PLAN CRITICAL CONTROL POINTS (CCP)

- ☐ A. HACCP Plan lists CCP(s) for each milk or milk product safety hazard identified as reasonably likely to occur.
- ☐ B. CCP(s) identified are adequate control measures for the milk or milk product safety hazard(s) identified.
- ☐ C. Control measures associated with CCP(s) listed are appropriate at the processing step identified.

Section 4 HACCP PLAN CRITICAL LIMITS (CL)

- ☐ A. HACCP Plan lists critical limits for each CCP.
- ☐ B. CL(s) are adequate to control the hazard identified.**
- ☐ C. CL(s) are achievable with existing monitoring instruments or procedures.
- ☐ D. CL(s) are met.

Section 5 HACCP PLAN MONITORING

- ☐ A. HACCP Plan defines monitoring procedures for each CCP. **(what, how, frequency, whom, etc.)**
- ☐ B. Monitoring procedures as defined in the HACCP Plan followed.
- ☐ C. Monitoring procedures as defined in the HACCP Plan adequately measure CL(s) at each CCP.
- ☐ D. Monitoring record data consistent with the actual value(s) observed during the audit.
- ☐ E. Monitoring records reviewed as required within seven (7) working days of the records being created.

Section 6 HACCP PLAN CORRECTIVE ACTION

- ☐ A. Corrective actions when defined in the HACCP Plan were followed when deviations occurred.
- ☐ B. Predetermined corrective actions defined in the HACCP Plan ensure the cause of the deviation is corrected.
- ☐ C. Corrective action taken for products produced during a deviation from CL(s) defined in the HACCP Plan.**
- ☐ D. Affected milk or milk product produced during the deviation segregated and held, **AND** a review to determine product acceptability performed, **AND** corrective action taken to ensure that no adulterated milk and/or milk product that is injurious to health enters commerce.
- ☐ E. Cause of deviation was corrected.
- ☐ F. Reassessment of HACCP Plan performed and modified accordingly.
- ☐ G. Corrective actions documented.

Section 7 HACCP PLAN VERIFICATION & VALIDATION

- ☐ A. HACCP plan defines verification procedures, including frequency.
- ☐ B. Verification activities are conducted and comply with HACCP Plan.
- ☐ C. Reassessment of HACCP Plan conducted annually, **OR**
  - ☐ 1. After changes that could affect the hazard analysis, **OR**
  - ☐ 2. After significant changes in the operation including raw materials and/or source, product formulation, processing methods/systems, distribution intended use or intended consumer.
- ☐ D. Calibration of CCP process monitoring instruments performed as required and at the frequency defined in the HACCP Plan.**
- ☐ E. CCP monitoring records document that values are within CL(s) and reviewed as required within seven (7) working days of the records being created.
- ☐ F. Corrective action records reviewed as required within seven (7) working days of the records being created
- ☐ G. Calibration records and end product or in-process testing results defined in HACCP Plan reviewed as required.
- ☐ H. Records reviewed as required, including date and signature.

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Starred ★★ Items are Critical Listing Elements

Section 8 HACCP SYSTEM RECORDS

- ☐ A. Required information included in the record, e.g., name/location of processor and/or date/time of activity and/or signature/initials of person performing operation and/or identity of product/product code.
- ☐ B. Processing/other information entered on record at time observed.
- ☐ C. Records retained for 2 years.
- ☐ D. Records relating to adequacy of equipment or processes retained for 2 years.
- ☐ E. HACCP records correct, complete and available for official review.
- ☐ F. Information on HACCP records not falsified.**
- ☐ G. Requirements in 21 CFR 117 Subpart F are addressed.

Section 9 HACCP SYSTEM PREREQUISITE PROGRAMS (PPs)

- ☐ A. Required PP written, implemented, and in substantial compliance by firm.
  - ☐ 1. Safety of the water that comes into contact with milk or milk contact surfaces (including steam and ice);
  - ☐ 2. Condition and cleanliness of equipment milk contact surfaces;
  - ☐ 3. Prevention of cross contamination from unsanitary objects and/or practices to milk and milk products, packaging material and other milk contact surfaces, including utensils, gloves, outer garments, etc., and from raw product to processed product;
  - ☐ 4. Maintenance of hand washing, hand sanitizing, and toilet facilities;
  - ☐ 5. Protection of milk and milk product, milk packaging material, and milk contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate and other chemical, physical and biological contaminants;
  - ☐ 6. Proper labeling, storage, and use of toxic compounds;
  - ☐ 7. Control of employee health conditions that could result in the microbiological contamination of milk and milk products, milk packaging materials, and milk contact surfaces; and
  - ☐ 8. Pest exclusion from the milk plant, receiving station, or transfer station.
  - ☐ 9. Requirements in 21 CFR 117 Subparts A and B are addressed.
- ☐ B. Additional PP's required or justified by the hazard analysis are written and implemented by firm.
- ☐ C. PP conditions and practices monitored as required.
- ☐ D. PP monitoring performed at a frequency to ensure conformance.
- ☐ E. Corrections performed in a timely manner when PP monitoring records reflect deficiencies or non-conformities.
- ☐ F. PP audited by firm.
- ☐ G. PP monitoring records adequately reflect conditions observed.
- ☐ H. PP signed and dated as required.

Section 10 OTHER NCIMS REQUIREMENTS

- ☐ A. Incoming milk supply from NCIMS listed source(s) with sanitation scores of 90 or better or acceptable HACCP Listing.**
- ☐ B. Drug residue control program implemented.**
- ☐ C. Drug residue control program records complete.
- ☐ D. Labeling compliance as required.
- ☐ E. Prevention of adulteration of milk products.
- ☐ F. Regulatory samples comply with standards.
- ☐ G. Pasteurization Equipment design and construction.
- ☐ H. Approved Laboratory Utilized - (if not, Rating not conducted).
- ☐ I. Substantially compliant on the following items as outlined in Appendix T.
  - ☐ 1. Written Recall Plan;
  - ☐ 2. Written Risk Based Supply-Chain Program
  - ☐ 3. Written Environmental Monitoring Program; and
  - ☐ 4. All other applicable requirements
- ☐ J. Holding and Distribution of Human Food By-Products for use as Animal Food.
- ☐ K. Other items as noted.

Section 11 HACCP SYSTEM TRAINING (Individuals trained according to Appendix K or alternatively have equivalent job experience.)

- ☐ A. PPs developed by trained personnel.
- ☐ B. Hazard Analysis developed by trained personnel.
- ☐ C. HACCP Plan developed by trained personnel.
- ☐ D. HACCP Plan validation, modification or reassessment performed by trained personnel.
- ☐ E. HACCP Plan records review performed by trained individual.
- ☐ F. Employees trained in monitoring operations.
- ☐ G. Employees trained in PP operations and food hygiene.
- ☐ H. Records that document training shall be established, maintained and retained at the milk plant for at least two(2) years after the date they are prepared.

Section 12 HACCP SYSTEM AUDIT FOLLOW-UP ACTION

- ☐ A. Previous audit findings corrected.
- ☐ B. Previous audit findings remain corrected at time of this audit.
- ☐ C. STATE MILK PLANT, RECEIVING STATION OR TRANSFER STATION HACCP SYSTEM AUDIT REPORT issued and follow-up conducted as required (HACCP Listing Audits and FDA Audits only).
- ☐ D. A series of observations that lead to a finding of a potential HACCP System failure that is likely to result in a compromised to milk or milk produst safety**

Refer to attached Audit Discussion sheet(s) for details.

NAME OF AUDITOR(S) (Please Print)	
SIGNATURE	DATE
SIGNATURE	DATE
SIGNATURE	DATE

NCIMS HACCP SYSTEM AUDIT REPORT DISCUSSION SHEET

FIRM NAME	DATE OF AUDIT

EXPLANATION OF DEVIATIONS/DEFICIENCIES/NON-CONFORMITIES THAT DID NOT MEET THE NCIMS HACCP PROGRAM CRITERIA

(Use additional sheets as necessary if entry field is non-expandable.)

NOTE: When Regulatory Audits are conducted, timelines for corrections of all identified deviations, deficiencies and non-conformities shall be established.