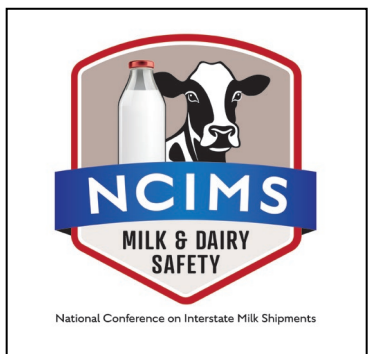




NCIMS Integrated Aseptic Inspection Guide (PMO+MMSR)

Purpose & Scope

This guide provides instructions for milk plant inspectors for evaluating Grade “A” low-acid aseptic processing and packaging systems (APPS) for milk and/or milk products. It integrates: (1) U.S. FDA LACF requirements (CFR), (2) NCIMS listing elements and forms, and (3) PMO Grade “A” program expectations.

1) Regulatory & Program Framework (What Applies Where)

- Aseptic systems are regulated as low-acid canned food (LACF) systems in which the focus is on commercial sterility of products, equipment downstream of the holding tube, packaging equipment, and packaging material.
- Within the PMO framework, dedicated aseptic system areas shall be inspected under applicable FDA LACF requirements rather than traditional PMO sanitation items (system-level focus).
- The NCIMS Aseptic Program requires documentation and evaluation of “critical listing elements” using Form NCIMS 2359p with the rating/audit package.

2) Pre-Inspection Document Request

A. Permitting / Listing Status

- Confirm the plant has an active aseptic permit and meets state requirements for NCIMS aseptic listing.

B. FDA LACF Registration & Process Filings

- Request and verify information for FDA LACF registration (Food Canning Establishment Number [FCE#] & Food Facility Registration Number [FFR#]) and FDA LACF aseptic process filings (Form FDA 2541g and/or previous version Form FDA 2541c, or equivalent electronic filing) for all aseptic Grade “A” milk and/or milk products, ensuring filings are current or updated whenever equipment or formulation changes occur (if needed).

C. Process Authority (Scheduled Process Ownership)

- Confirm the designated Process Authority and ensure scheduled processes are established by a qualified expert with defined critical factors that are current with documentation and filings updated (if needed).

D. Training / Better Process Control School (BPCS) Supervision

- Verify aseptic operators are under the supervision of an FDA-approved, BPCS-trained individual and confirm BPCS certificate(s) are available upon request.

E. Records & Program Files to Have Ready

- Verify availability of required aseptic documentation, including the latest Form NCIMS 2359p, current APPS letter (if needed), label proofs for all aseptic Grade “A” milk and/or milk products, and annual vitamin assay results.

3) NCIMS Critical Listing Elements – Pass/Fail (Form NCIMS 2359p)

- At the beginning of the State Rating, the State Rating Officer (SRO) must complete Form NCIMS 2359p and ensure each critical element is supported by objective evidence. Any failed critical element is treated as a listing failure and the State Rating ends.

4) On-Site Inspection (Aseptic System-Focused Inspection)

A. Visually Confirm the APPS (“bubble”) on the Floor

- If the default APPS begins at the constant level tank and ends at the discharge of the filler, then an APPS letter is not required (Refer to PMO Definition D). If the APPS is expanded, then visually verify the beginning and end points of the APPS.

B. Water & Utilities Interface with PMO Systems

- Verify all shared water points contacting both aseptic and PMO-related systems meet PMO requirements and confirm adequate cross-connection and backflow protection across all potable and non-potable systems.

C. Labeling & Consumer Handling Statements

- Verify aseptic labels include required handling statements (e.g. “Refrigerate after opening”) and comply with other PMO labeling requirements.

5) Reporting and Frequency

- Ensure aseptic inspections occur at the minimum 6-month required frequency, document PMO and aseptic findings separately when required (Refer to Appendix S of the PMO), and verify filings are current or updated after equipment or formulation changes (if needed).

6) Plant-Specific Coding for State Ratings

- Verify product coding and document plant-specific coding conventions (e.g., “6-02” aseptic subcodes for Ratings Officer use).

Core Reference Documents (keep in your inspection packet)

- 21 CFR Part 108 – Emergency Permit Control (FDA LACF-related program triggers).
- 21 CFR Part 113 – Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers (aseptic definitions and controls).
- NCIMS Form 2359p – Aseptic/Retort Critical Listing Elements (current revision).
- NCIMS Form 2359 – Milk Plant Inspection Report (current revision).
- Grade “A” *Pasteurized Milk Ordinance* (PMO) – current revision used by your State Regulatory program.
- FDA LACF Registration & Process Filing resources (includes Form FDA 2541g and /or previous version Form FDA 2541c, or equivalent electronic filing).