NCIMS

Appendix T / Preventive Controls Rule Inspection Pilot Program

I. Background

Proposal JC-1 passed by the Delegates at the 2019 Conference of NCIMS charged the Liaison Committee to:

"…work cooperatively with FDA to develop a pilot program which will establish a regulatory framework to find efficiencies in inspection activities for facilities that manufacture both Grade ''A" and non-Grade ''A" products and be implemented by FDA and the participating States."

Consistent with the longstanding history of NCIMS, this charge emphasized the collaboration between FDA and the States in the development and implementation of the pilot program. JC-1 (2019) also highlighted that the exploration of greater efficiencies in the implementation of the Food Safety Modernization Act (FSMA) under the pilot program is intended to reflect FDA's ongoing commitment to NCIMS and the continued safety of Grade "A" milk and milk products:

"When implemented, the pilot program will meet the Agency's commitment to the NCIMS of identifying additional ways to maximize state and federal resources and to create greater efficiencies through its obligations under the FDA Food Safety Modernization Act while maintaining the high safety of the U.S. milk supply."

In keeping with the above, the Appendix T/ Preventive Controls Rule Pilot Program (the Pilot) described below represents a multi-year collaborative effort between the Liaison Committee and FDA to achieve the shared goal of leveraging the proven framework of NCIMS for ensuring conformance with the federal Preventive Controls for Human Food Rule (PC Rule) in the dairy sector of the United States. The Liaison Committee and the NCIMS Executive Board extend our sincere thanks to FDA leadership for their vital support of this collaboration. FDA's vision of enhanced efficiencies in the protection of food safety and public health through strengthened engagement with the longstanding federal-state cooperative program of NCIMS is greatly appreciated.

II. Pilot Objectives

The objective of the Pilot is to explore and operationally develop efficient regulatory approaches that leverage the NCIMS program to effectively evaluate compliance with Appendix T of the *Pasteurized Milk Ordinance* (PMO) and the PC Rule at Interstate Milk Shippers (IMS)-listed dairy plants that also process non-Grade "A" products. Since Appendix T of the PMO is focused on Grade "A" milk and milk products, the Pilot provides a valuable opportunity to examine, evaluate, learn from, and improve audit protocols implemented at Grade "A"-only processing facilities. Further, the national

implementation of a “Limited Scope” approach to evaluate compliance with Appendix T of the PMO necessitates inclusion of Grade “A”-only plants in the Pilot to effectively explore and understand potential gains in federal and state efficiencies at all IMS-listed facilities in the current nationwide FSMA landscape.

Specifically, the Pilot will aim to exercise a unified Appendix T/PC Rule compliance audit/inspection process that:

- Effectively evaluates compliance for both Grade “A” and non-Grade “A” products at an IMS-listed plant.
- Optimizes the efficiencies of both federal and state resources.
- Minimizes or eliminates regulatory redundancies, including, but not limited to, duplicate inspections at an IMS-listed dairy plant to determine compliance with Appendix T and the PC Rule.
- Ensures utilization of the necessary technical expertise applicable to both Grade “A” and non-Grade “A” processing systems during an inspection.
- Reduces the burden to the regulated industry from inspection procedures without a reduction in public health protection.
- Develops and implements enforcement and compliance protocols at all IMS-listed plants that are aligned with other food commodities.
- Explores the feasibility and benefits of utilizing partnerships, mutual reliance or other agreements between FDA and State Dairy Regulatory Programs to achieve PC Rule compliance goals.
- Explores systems for measuring and evaluating overall effectiveness, feasibility, and sustainability of piloted procedures.
- Evaluates and identifies gaps in training and maintenance of proficiency for both FDA Milk Specialists and State personnel that would facilitate a unified approach for conducting and documenting inspections for compliance with PC Rule provisions applicable to the processing of both Grade “A” and non-Grade “A” products.

III. Implementation

Project Period: Initiated November 7, 2022, and continues through the 2025 Conference.

Facility Scope: All IMS-listed plants nationwide (Except those that FDA has separately prioritized to be assigned a Full Scope Preventive Controls Rule Inspection by FDA CFSAN).

Product Scope: All products manufactured in IMS-listed plants, with the exceptions of infant formula, seafood, and retail raw milk.

Participation:

- All FDA Milk Specialists conducting Check Ratings at IMS-listed plants in the United States.
- All State- and U.S. Territory- Rating and/or Regulatory Agencies may participate. Involvement in pilot activities is voluntary and at the discretion of each State or U.S. Territory.
- Other FDA Subject Matter Experts as warranted on a case-by-case basis.

IV. Pilot Program Framework

A) IMS-listed plants that process only Grade "A" milk and milk products

During an FDA Check Rating, compliance of the milk plant with applicable requirements of Appendix T will be determined by an FDA Milk Specialist. Conducting this activity concurrent with a Check Rating is consistent with a compliance evaluation of Appendix T at a frequency of a least once every thirty-six (36) months and is in alignment with the frequency of PC Rule inspections for facilities that FDA categorizes as "high risk".

Compliance with Appendix T will be determined by a broad assessment of an IMS-listed plant consisting of a review of the milk plant's sanitation controls, food allergen controls, and process controls, as appropriate. This broad assessment (which is analogous to a Limited Scope PC inspection) will not include the conducting of a hazard analysis by the FDA Milk Specialist, nor a review of the facility's written food safety plans, hazard analysis, preventive control programs, supply-chain programs, or recall plan. This broad assessment is the first step as shown at the top of the process flow chart in **Figure 1**.

It should be noted that a very small business (i.e., a Qualified Facility under the PC Rule) is exempt from the requirements of Appendix T of the PMO. As with any Check Rating, the presence of the State Dairy Rating and/or Regulatory Program is highly encouraged to allow for the expected direct communication between the FDA Milk Specialist and State personnel during the rating process. This on-site communication is important to promote uniformity of interpretation and to foster learning by both federal and state partners throughout the Pilot program.

As an alternative to the FDA Milk Specialist, a State Rating/Dairy Regulatory Agency, upon written agreement with FDA and in consultation with FDA-CFSAN's Milk and Milk Products Branch (MMPB), may conduct the broad assessment of the IMS-listed plant during a State Rating Agency Individual Rating or a State Regulatory Inspection. However, any given State Agency's participation in this specific role under the Pilot is voluntary, and dependent upon available state resources and training. For purposes of conducting the initial broad assessment under the Pilot, state personnel must have

completed FDA training course FD8023R or be approved by FDA to conduct Limited Scope PC Rule inspections under an FDA contract or mutual reliance agreement.

During the broad assessment, if no conditions are observed pertaining to the lack of control of significant hazards relative to compliance with Appendix T of the PMO, then the compliance determination is complete (i.e., the facility is in substantial compliance) and documented in a report shared with the IMS-listed plant and the State and filed with FDA.

If during the broad assessment, conditions are observed that pertain to the lack of control of significant hazards relative to compliance with Appendix T of the PMO, the compliance evaluation will then follow through a series of "check points" that will serve to promote uniformity, foster collaborative assessment of inspectional and operational outcomes, and provide opportunities for data collection and pilot program evaluation and improvement.

Check Point 1: Supervisory Review

If conditions are observed during the broad assessment that pertain to the lack of control of significant hazards, the FDA Milk Specialist will contact their designated Office of State Cooperative Programs (OSCP) Branch Director to discuss the specific observations and receive direction. When the broad assessment is being conducted by a State Rating Officer/Inspector they will contact their designated supervisor/manager for this purpose.

If the supervisory review determines that observations do not pertain to a lack of control of a significant hazard, then the compliance determination is complete (i.e., the facility is in substantial compliance) and is documented in a report shared with the IMS-listed plant and the State and filed with FDA.

If the initial supervisory review determines that observations may indeed pertain to a lack of control of a significant hazard, the Branch Director/State Program Manager will contact the FDA-CFSAN MMPB as part of a second "check point" as further described below.

Check Point 2: FDA-CFSAN Review and Concurrence

The Branch Director/State Program Manager will contact the FDA-CFSAN MMPB Branch Chief to discuss whether the specific observations at the facility warrant elevation of the broad assessment to a full Appendix T audit. This review and concurrence discussion will include State Dairy Program management. If FDA-CFSAN concurs that conditions observed at the facility warrant elevation, then the FDA Milk Specialist or the State Rating Officer/Inspector will conduct a full audit of the IMS-plant's

compliance with applicable requirements of Appendix T of the PMO in accordance with the protocols described in the NCIMS *Procedures* and *Methods in Making Sanitation Ratings* (MMSR) as amended at the 2023 Conference. A full Appendix T compliance audit will only be conducted by FDA Milk Specialists, State Rating Officers, or State Regulatory Officials that have successfully completed Grade "A" PMO Preventive Controls training for Regulatory/Rating Agencies (FD378) or the Preventive Controls for Human Food Regulators Course (FD254).

After completion of the full Appendix T audit, the findings will be reviewed and discussed in detail by a Review Panel prior to any final determination of compliance. The Review Panel serves as the third "check point" in the pilot program process, as further described below.

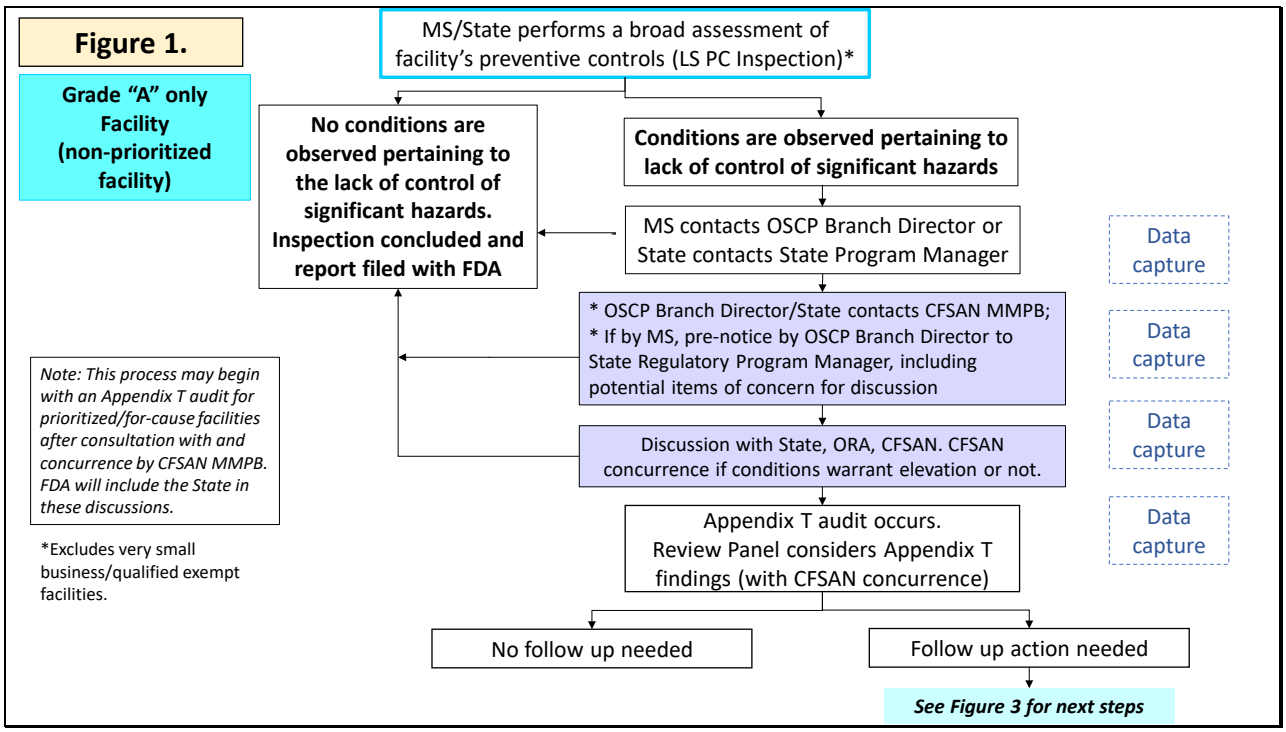
Check Point 3: Review Panel

The function of the Review Panel is to evaluate whether specific findings from the full Appendix T audit warrant a determination of substantial noncompliance for the IMS-listed plant. This final level of review and discussion will promote consistency in the interpretation of inspectional observations made during the pilot and help to ensure that resulting enforcement actions are appropriate for the conditions found at the facility and in alignment with those followed for other food commodities subject to the PC Rule.

The Review Panel will consist of representatives from FDA-CFSAN MMPB; including, but not limited to, National Standards personnel, the OSCP Branch Director, the Milk Specialist, other FDA-CFSAN PC subject matter experts, and representatives of the State Dairy Program. For consistency, the final decision that a facility is or is not in substantial compliance will be made by FDA-CFSAN MMPB.

After the Appendix T audit is complete a report will be filed by FDA or the State, as applicable. If the review finds that the facility is in substantial compliance, then the Appendix T audit is complete. If the review finds that the facility is not in substantial compliance, then follow-up activities as described below in Subsection C would be implemented.

See **Figure 1** for a flow chart representing the process and levels of review described above for IMS-listed plants processing only Grade "A" milk products.



B) IMS-listed plants that also process non-Grade "A" products.

During an FDA Check Rating, an IMS-listed plant that also processes non-Grade "A" products will be evaluated for compliance with applicable requirements of Appendix T and the PC Rule on a facility-wide basis by an FDA Milk Specialist. Like a facility that only processes Grade "A" milk and milk products, conducting this "dual-grade" activity concurrently with a Check Rating is consistent with a compliance evaluation at a frequency of a least once every thirty-six (36) months and is in alignment with the frequency of PC Rule inspections for other facilities that FDA categorizes as "high risk".

As an alternative to the FDA Milk Specialist, a State Rating/Dairy Regulatory Agency, upon written agreement with FDA and in consultation with FDA-CFSAN's MMPB may conduct the broad assessment during a State Rating Agency Individual Rating or a State Regulatory Inspection. As with state involvement for Grade "A"- only facilities, any given State Agency's participation in this specific role under the pilot is voluntary, and dependent upon available state resources and training. For purposes of conducting the initial broad assessment of a dual grade facility under the Pilot, state personnel must have completed FDA training course FD8023R, or be approved by FDA to conduct Limited Scope PC Rule inspections under an FDA contract or mutual reliance agreement.

Compliance with provisions of Appendix T and the PC Rule will be determined by a single, unified broad assessment of the milk processing plant consisting of a review of the milk plant's sanitation controls, food allergen controls, and process controls, as appropriate. This broad assessment (which is analogous to a Limited Scope PC inspection) is the first step as shown at the top of the process flow chart in **Figure 2.** It should again be noted that a very small business (i.e., a Qualified Facility under the PC Rule) is exempt from the requirements of Appendix T of the PMO.

As described under Section A above, the broad assessment will not include the conducting of a hazard analysis by FDA/Rating Agency/Regulatory Agency personnel, nor a review of the facility's written food safety plans, hazard analysis, preventive control programs, supply-chain programs, or recall plan. Importantly, this broad facility-wide assessment by the FDA Milk Specialist or State Rating/Regulatory Official will cover all areas of the plant irrespective of the "grade" of product being processed (See Product Scope above for exclusions). Thus, processing areas dedicated to non-Grade "A" products that may have been excluded from a traditional Grade "A" Check Rating will now be included in the broad assessment being conducted under the pilot program. It is recognized that significant overlap of processing areas and equipment use can occur in the processing systems of both Grade "A" and non-Grade "A" products. This "common" equipment and processing represents just one example of how leveraging the existing Grade "A" program activities can reduce redundancies and add clear improvements in overall inspection efficiencies.

As with any Check Rating, the presence of the State Dairy Rating and/or Regulatory Program during the FDA Check Rating is highly encouraged to allow for the expected direct communication between the FDA Milk Specialist and State personnel during the rating process. This on-site communication is especially important and valuable to the Pilot at "Dual-grade" plants since the broad assessment extends into non-Grade "A" processing areas where the State Dairy Regulatory Program may have valuable facility-specific technical knowledge.

During the broad assessment, if no conditions are observed pertaining to the lack of control of significant hazards relative to compliance with requirements of Appendix T of the PMO and/or the PC Rule, then the compliance determination is complete (i.e., the facility is in substantial compliance) and documented in a report shared with the IMS-listed plant and the State and filed with FDA. The inspection and final report will apply to all products for purposes of both the NCIMS Grade "A" milk program and the Limited Scope PC Rule compliance inspection objectives of FDA.

Similar to a Grade "A" only facility, if conditions are observed during the broad assessment that pertain to the lack of control of significant hazards relative to compliance with Appendix T and/or the PC Rule, the compliance evaluation will then follow through a series of "check points" to promote uniformity, foster collaborative

operational assessment of inspectional outcomes, and provide opportunities for data collection and pilot program evaluation and improvement. Since production systems and controls of significant hazards will apply to either or both grades of products, the check points will also serve to identify the appropriate regulatory pathway for elevation of the broad assessment to a "full scope" form of inspection (i.e., full audit of Appendix T of the PMO or full scope PC Rule inspection).

Check Point 1: Supervisory Review

If conditions are observed during the broad assessment that pertain to the lack of control of significant hazards the FDA Milk Specialist will contact their designated OSCP Branch Director to discuss specific observations and receive direction. When the broad assessment is being conducted by a State Rating Officer/Inspector they will contact their designated supervisor/manager for this purpose.

If the supervisory review determines that observations do not pertain to a lack of control of a significant hazard, then the compliance determination is complete (i.e., the facility is in substantial compliance) and is documented in a report shared with the milk plant and the State and filed with FDA.

If the initial supervisory review determines that observations pertain to a lack of control of a significant hazard, the Branch Director/State Program Manager will contact the FDA-CFSAN MMPB as part of a second "check point" as further described below.

Check Point 2: FDA-CFSAN Review and Concurrence

The Branch Director/State Program Manager will contact the FDA-CFSAN MMPB Branch Chief to discuss whether the specific observations at the facility warrant elevation of the broad assessment to a full scope form of audit/inspection. This review and concurrence discussion will include State Dairy Program management. If FDA-CFSAN concurs that conditions observed at the facility warrant elevation beyond the broad assessment, then the specific regulatory pathway to be utilized for the conducting of a "full scope" compliance evaluation will be determined by FDA-CFSAN based on the "highest risk" milk product being manufactured at the facility. This consultation with FDA-CFSAN at *Check Point 2* is important to a final determination of which grade of product in a "dual-grade" facility is the highest risk and to identify whether the appropriate "full scope" follow-up activity will occur within the framework of the NCIMS Grade "A" program or the compliance activities of an FDA District CSO. To ensure collaborative implementation of this key decision point in the Pilot, and to foster optimal programmatic learning and data capture, the State will always be included in the discussion of the highest risk product determination by FDA-CFSAN.

If the highest risk milk product is Grade "A", then the elevated activity will consist of a full Appendix T audit as described above in Section A and conducted in accordance with the protocols described in the NCIMS *Procedures* and MMSR, as amended at the 2023 Conference. A full Appendix T compliance audit will only be conducted by FDA Milk Specialists, State Rating Officials or State Regulatory Officials that have successfully completed Grade "A" PMO Preventive Controls training for Regulatory/Rating Agencies (FD378) or the Preventive Controls for Human Food Regulators Course (FD254).

If the highest risk product being processed at the facility is not a Grade "A" product, then the elevated activity will consist of a full scope PC Rule inspection conducted by either an FDA Consumer Safety Officer (CSO) under FDA-ORA **or** trained and qualified State Dairy Regulatory Program personnel under a written agreement with FDA (e.g., partnership, mutual reliance, or other agreement).

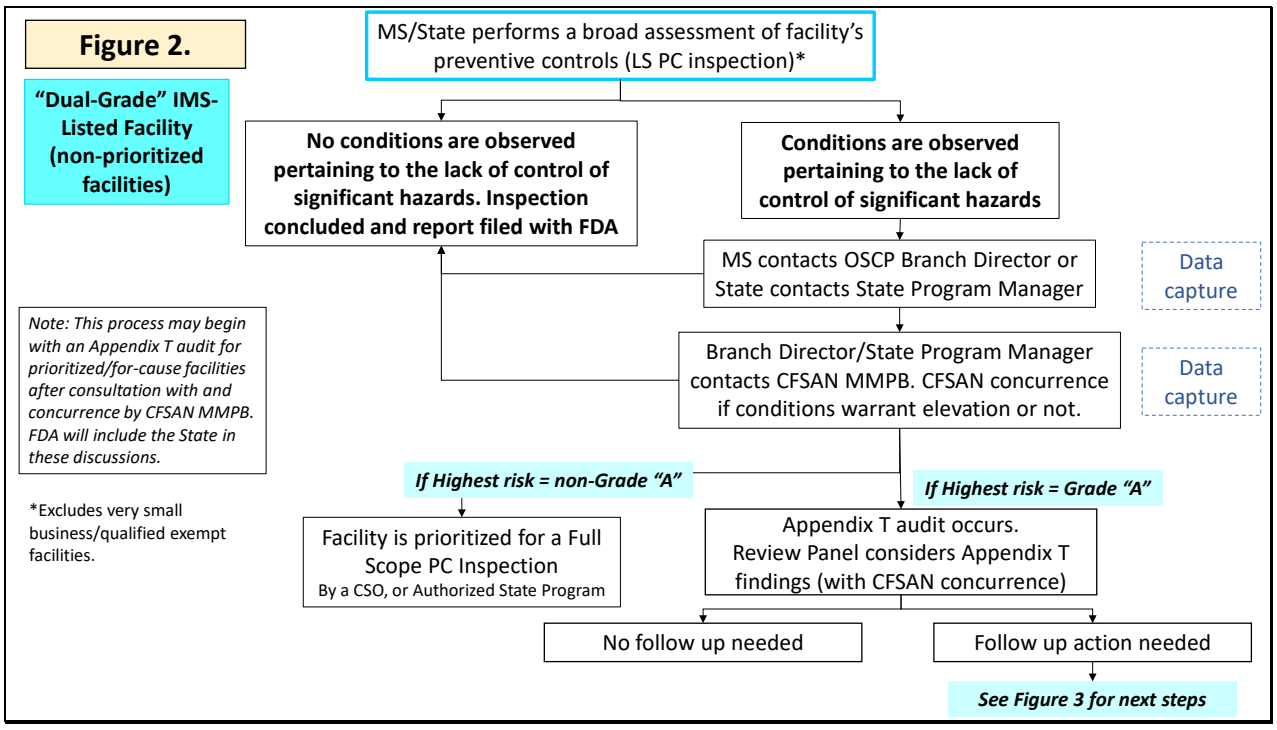
In the event the highest risk product at the plant is determined to be a Grade "A" milk product, the findings of the full Appendix T audit will be reviewed and discussed in detail by the Review Panel described above in Section A prior to any final determination of compliance. As with a Grade "A"-only facility, the Review Panel serves as an important third "check point" in the pilot program process for "dual grade" facilities.

Check Point 3: Review Panel

The function of the Review Panel is to evaluate whether specific findings from the full Appendix T audit warrant a determination that the IMS-listed plant is not in substantial compliance. As previously stated above, this final level of review and discussion will promote consistency in the interpretation of inspectional observations made during the pilot and help to ensure that resulting enforcement actions are appropriate for the conditions found at the facility and in alignment with those followed for other food commodities subject to the PC Rule. The Review Panel in the Pilot will not be used to evaluate final compliance determinations from full scope PC Rule inspections conducted by an FDA CSO or FDA-authorized State Dairy Regulatory Program inspector when the highest risk product is not a Grade "A" product.

If the review finds that the facility is in substantial compliance, then the Appendix T audit is complete and a report will be filed by either FDA or the State, as applicable. If the review finds that the facility is not in substantial compliance, then follow-up activities as described below in Subsection C will be implemented.

See **Figure 2** for a flow chart representing the process and levels of review described above for IMS-listed plants that also process non-Grade "A" products.



C) Follow-up Protocol after the Determination that an IMS-listed Plant is not in Substantial Compliance based on a Full Appendix T Audit

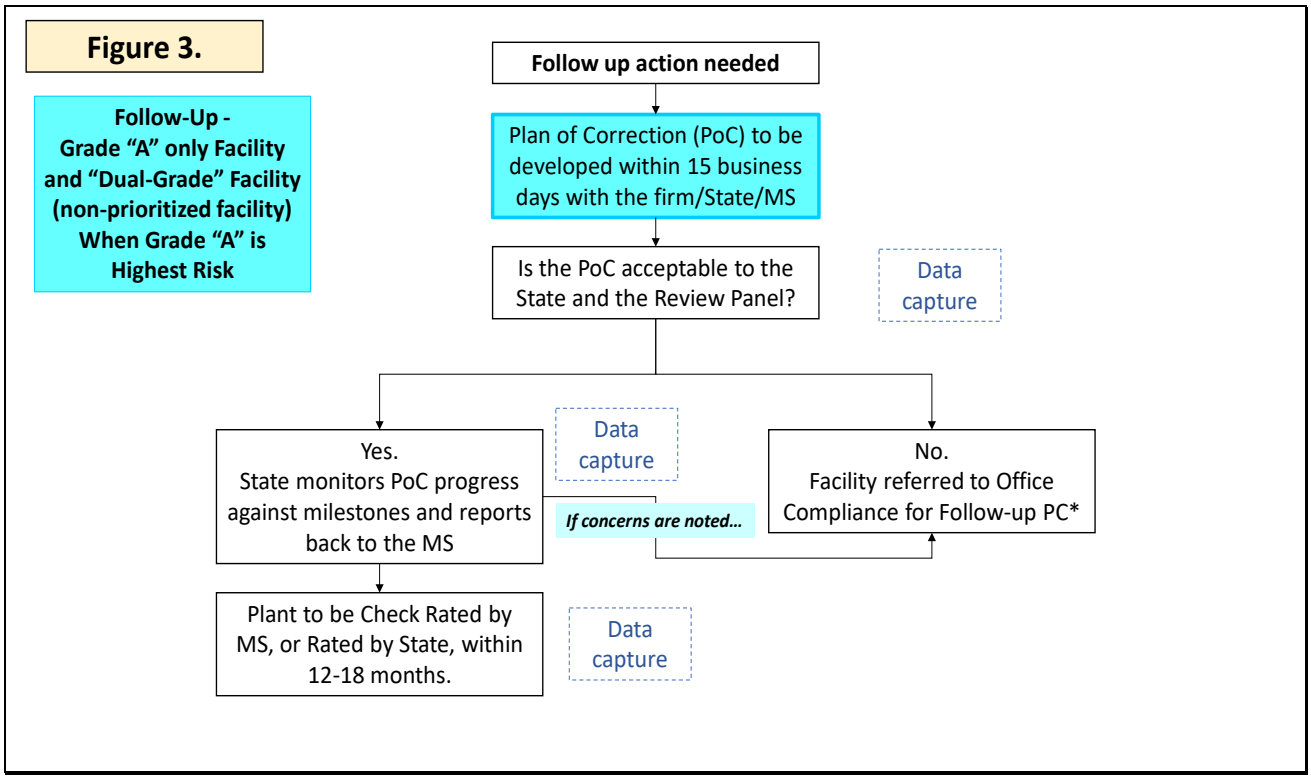
If the Review Panel determines that an IMS-listed plant is not in substantial compliance with Appendix T of the PMO, then the plant must develop and implement a written plan of correction, determined to be acceptable by FDA and the State Dairy Regulatory Program. The written plan of correction is to be submitted by the plant to FDA and the State within 15 business days of the date of notification of substantial noncompliance. The content of the written plan of correction will be evaluated by the Review Panel, which includes the State Dairy Regulatory Program.

If the written plan of correction is determined to be acceptable by the Review Panel, the State Dairy Regulatory program will monitor the IMS-plant's progress in implementing the plan against specified milestones. The State Dairy Regulatory program will provide updates to the FDA Milk Specialist regarding the plant's progress and seek assistance and guidance from FDA-CFSAN as needed. Additionally, an FDA Milk Specialist may conduct a Check Rating of the IMS-plant between 12 to 18 months of the date the facility was notified of not being in substantial compliance with Appendix T.

If the written plan of correction submitted by the firm is determined to be unacceptable by the Review Panel, which includes the State Dairy Regulatory Program, and insufficiencies are not resolved through submissions of revised written plans of

correction based on FDA/State feedback, then the facility will be referred by FDA-CFSAN to the FDA Office of Compliance for follow-up.

See **Figure 3** for a flow chart representing the process and levels of review described above for when it is determined that an IMS-listed plant is not in substantial compliance following a full Appendix T audit.



V. Data collection

Proposal JC-1 (2019) that charged the Liaison Committee with developing the Pilot, provided additional direction that the committee will *"…at least consider: the regulatory authorities of state regulatory agencies, the eligibility criteria for pilot consideration, the types of non-Grade "A" products manufactured in dual-grade facilities, the resource needs, and potential hurdles likely to be encountered, and the metrics for evaluating success."*

The Liaison Committee recognizes that the collection of data, whether quantitative or qualitative, is critical to determining whether the Pilot program as designed and implemented is meeting the objectives described above in Section II. In a national Pilot of this scope, it is likely that opportunities for gathering relevant information on efficiencies gained, resource savings, and cost/benefit improvements may reveal

themselves as the program progresses. Hence the important inclusion of data collection at the key check points identified in Figures 1 and 2, in addition to the intuitive overall quantitative metrics such as inspection numbers, inventory coverage, personnel hours, etc. Thus, the data collection list below is not intended to be final or exhaustive but may include in no particular order:

- Number of Grade-A only IMS-listed plants inspected under the Pilot.
- Number of "Dual-Grade" IMS-listed plants inspected under the Pilot.
- Types of "Non-Grade A" products being manufactured at inspected Dual-Grade plants.
- Number of compliance discussions reaching different check points in the collaborative evaluation process, and decisions made at each.
- Capture of commonly asked questions or areas of ambiguity in interpretation during the progressive review process.
- Number of elevations to a full Appendix T audit at Grade-A only plants.
- Number of elevations to a full scope form of inspection at Dual-Grade plants and the determinations of highest risk product type.
- Number of referrals to the activities of an FDA CSO or authorized State partner.
- Observations that were determined to pertain to a lack of control of significant hazards, and if attributed to either Grade "A" or Non-Grade "A" processing systems, or both, as applicable.
- An analysis of time savings from a unified Dual Grade Appendix T/PC Rule inspection process compared to previous separate PC Rule compliance inspections by two programs in FDA.
- Compare outcomes of the Sanitation Compliance Check Ratings and the Limited Scope Inspections conducted in the Pilot.
- Compile data on a number of IMS-listed facilities that are also Qualified Facilities exempt from Part C and G of the PC Rule and compare outcomes of Sanitation Compliance Check Ratings and associated Modified Requirements Inspection.

VI. Reporting

Progress reports will be developed in cooperation with FDA and provided periodically to the NCIMS Executive Board. After Executive Board approval, progress reports may be posted on the NCIMS website. Any data or metrics compiled in a report will protect individual facility and State confidentiality and be presented in a summary fashion using only aggregate statistics, as appropriate. A full summary report of Pilot data collected through December 31, 2024 will also be provided to the Executive Board and to the Delegates at the 2025 Conference.