

PC Inspections, Appendix T, and IMS-Listed Facilities

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Outline

- How did we get here?
- Why are there different PC inspections?
- What is the future vision for PC inspections in IMS-listed facilities?

Quick History Recap

- 2015 and 2017 NCIMS Conferences:
 - Addition of Appendix T to the PMO

Grade "A"		Non-Grade "A"
Appendix T	PC Requirements	21 CFR 117

- How will compliance in dual-grade facilities be addressed?

Quick History Recap

- NCIMS Proposal JC-1:
 - *[Liaison] committee is charged 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...*

Grade “A”		Non-Grade “A”
Appendix T	PC Requirements	21 CFR 117
Appendix T audit	Inspection Approach	<ul style="list-style-type: none"> • Full Scope • Limited Scope

What is Limited/Full Scope?

- Limited Scope and Full Scope PC Inspections are how FDA prioritizes inspectional resources.
- Not all facilities present the same food safety risks.

**Limited Scope PC
Inspections**

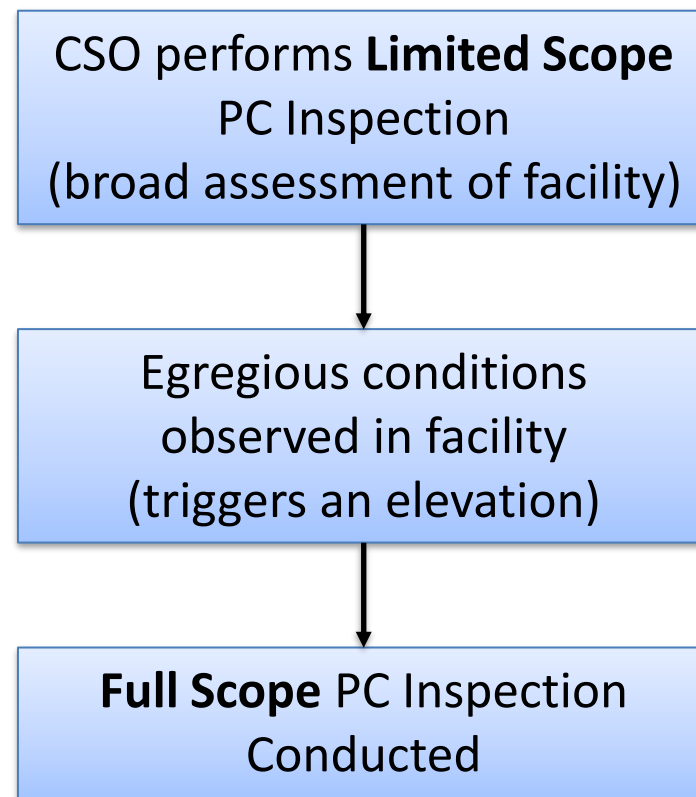
**Full Scope PC
Inspections**

What is Limited/Full Scope?

- Limited Scope PC Inspections ([CP 7303.040](#))
 - Limited Scope PC Inspections include cGMPs and a broad assessment of implementation of process, sanitation, and allergen preventive controls, as applicable.
 - Limited Scope PC Inspections do not require review of written food safety plans, the facility's hazard analysis, PC programs, supply-chain program, or recall plan.

What is Limited/Full Scope?

- Limited Scope PC Inspections can be converted to Full Scope PC Inspections by the investigator.
- This approach allows FDA to best focus our inspectional resources to protect public health.



What Is Our Vision for a Two-Scope Approach?

- Basic Principles
 1. PMO as a model food safety document
 2. Equity for PC requirements
 3. Avoid duplication

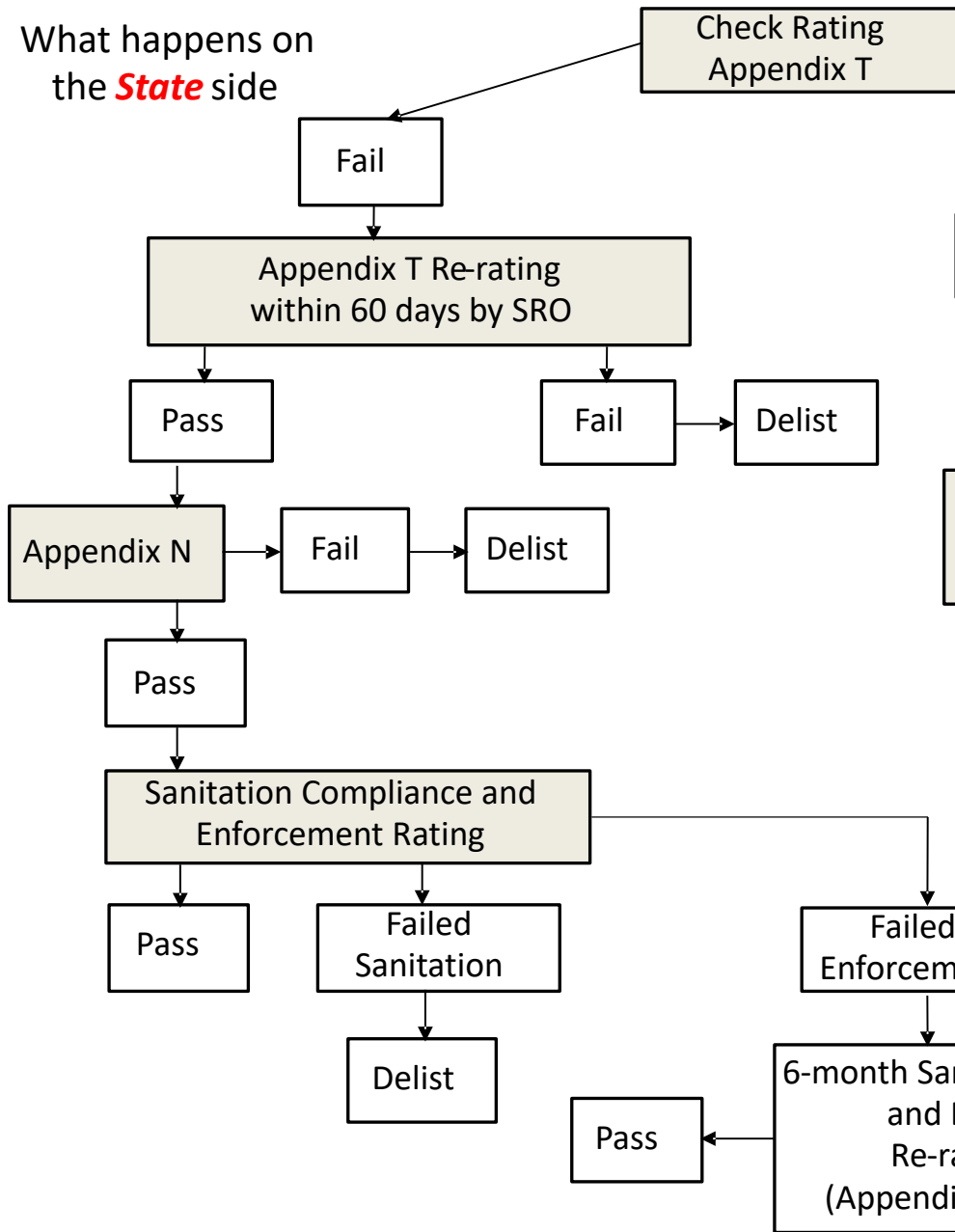
What Is Our Vision for a Two-Scope Approach?

- Basic Principles
 1. PMO as a model food safety document
 - Build upon the significant contribution to public health that is represented by the Grade “A” program and PMO requirements.
 - Goal: Milk Specialist will perform a Limited Scope PC Inspection and Check Rating simultaneously
 2. Equity for PC requirements
 3. Avoid duplication

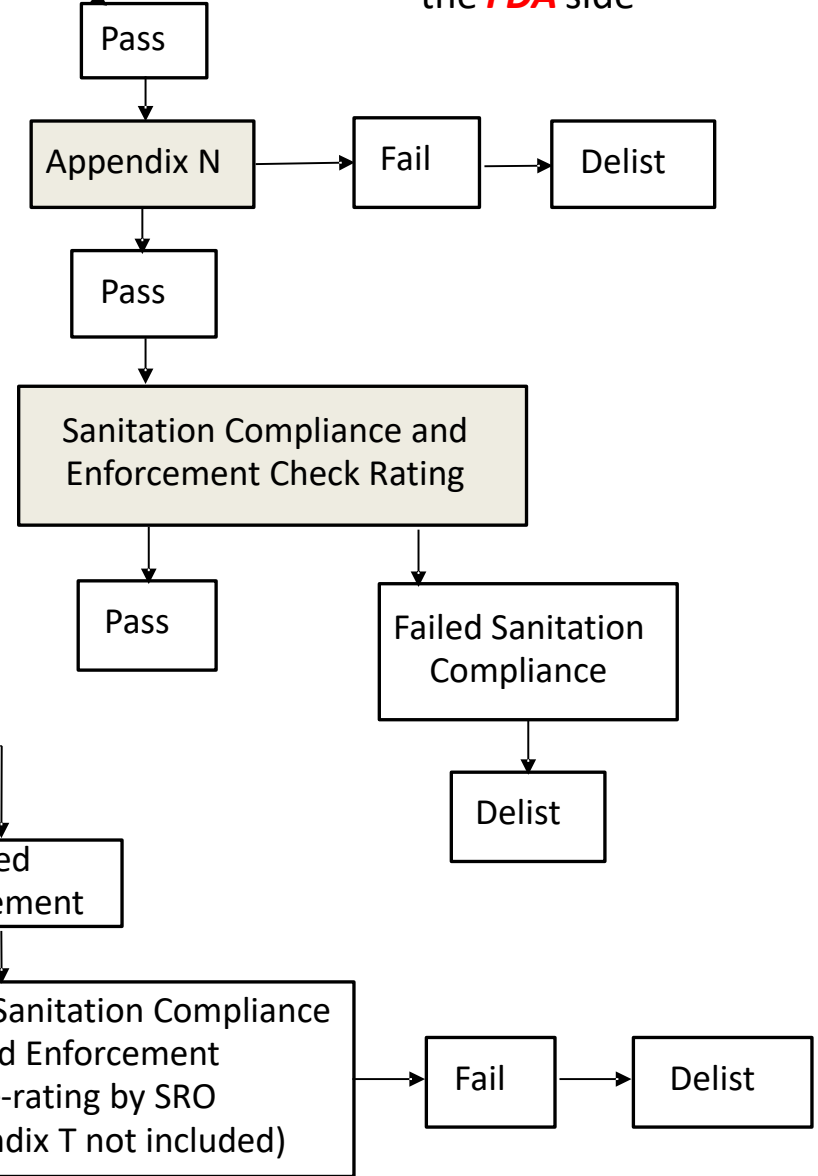
What Is Our Vision for a Two-Scope Approach?

- Basic Principles
 1. PMO as a model food safety document
 2. Equity for PC requirements
 - Discussions with the Liaison Committee identified an “Overbuild” of Appendix T.
 - Goal: Remove the penalty of facility delisting.
 3. Avoid duplication

What happens on the **State** side



What happens on the **FDA** side



What Is Our Vision for a Two-Scope Approach?

- Basic Principles
 1. PMO as a model food safety document
 2. Equity for PC requirements
 3. Avoid duplication
 - Dual-grade facilities are challenging, assessing compliance from both Appendix T and 21 CFR 117, with different enforcement outcomes.
 - Goal: A single PC inspection, without duplicate penalties for non-compliance, while bringing the facility back into compliance and protecting public health.

Opportunities and Next Steps

- Discussion of Limited Scope has highlighted areas for program improvement.
- Some changes can be made without impacting Conference documents.
- The Pilot Program gives us further opportunities to leverage State partners.

Limited Scope Activity and Check Rating

What happens on the **Stateside**

What happens on the **FDA side**

