



Washington
State Department of
Agriculture

Inspection Documentation

21 C.F.R. 507

Checklist and Tool

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Background



The 507 regulation is still relatively new and not prescriptive at times. As a result we started building tools to help with:

Goal 1:

Accuracy

Goal 2:

Consistency

Goal 3:

Efficiency

Goal 4:

Effectiveness



CGMP Inspection Checklist



- For 21 CFR 507 subpart B, and applicable requirements in subparts A and F, we decided to go with a checklist.
- Current Good Manufacturing Practices (cGMP) are considered the baseline standards
- Answer options account for flexibility at different facility types
- Observation comments required for OUT, CDI or TA.

Answer Options	
IN	In Compliance
OUT	Out of Compliance
N/O	Not Observed
N/A	Not Applicable
CDI	Corrected During Inspection
TA	Technical Assistance (option)

Marking Guide

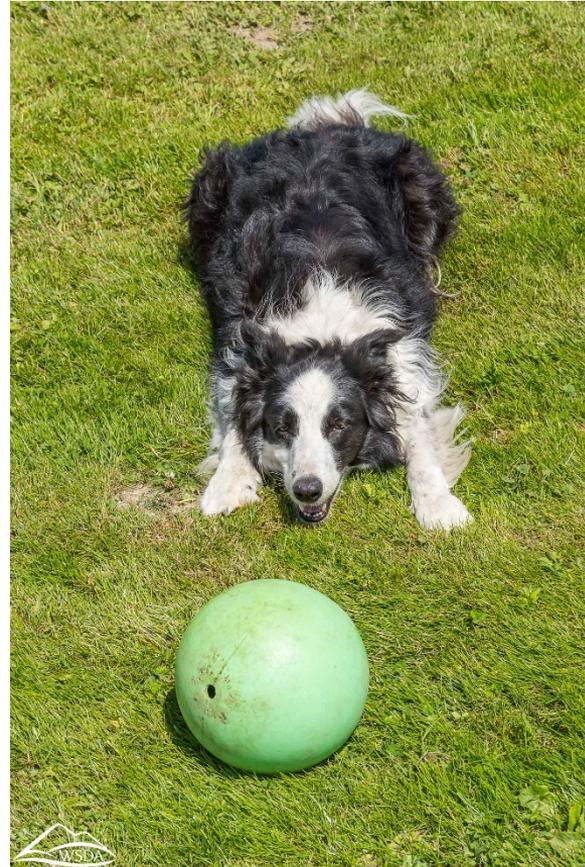


- Some of the requirements in the regulation are very similar.
- A Marking Guide will help inspectors understand all the nuances, instructions, resources and where to mark observations.
- A Marking Guide will draw from the Guidance for Industry and real-life examples

PC Inspection Tool



- For 21 CFR 507 subparts C and E.
- PC inspections can be vastly different depending on the facility
- An Inspection Tool is adaptable and helps keep the inspector organized





- Presented this concept at AAFCO
- ISC formulated a workgroup
- Beginning discussion stages
- Few states volunteered to have their inspectors provide feedback on the tool



Questions/Thoughts so far?