Across Establishment Ranking Concept For Processing and Slaughter

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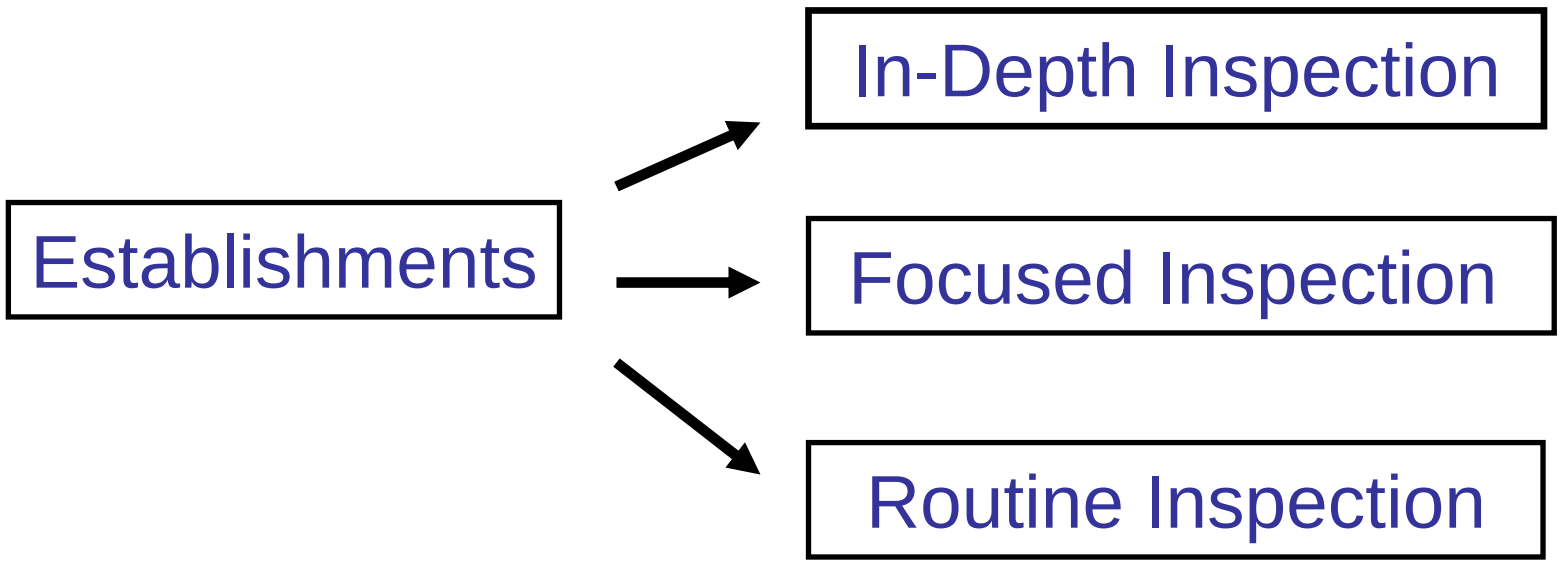
Goal of Ranking Algorithm

- Focus FSIS resources to ensure food safety systems are working effectively to further achieve FSIS' public health mission
  - Across establishments---focus on establishments with evidence of a lack of process control
  - Within establishments---focus on most vulnerable food safety system areas
  - Remain Resource Neutral

Prioritize Establishments Based on Need for Inspection



Risk Has Two Components: Magnitude and Hazard

- Risk = Magnitude x Hazard
- Both components help FSIS better focus its inspection activities
- Magnitude (attribution)
  - Focus on pathogen-product pairs that most contribute to human disease
- Hazard (effectiveness of process control)
  - Focus on establishments with less than optimal food safety process control

Conceptual Approach

	Magnitude Public Health Impact		Hazard Indicators of Process Control	
Establishment Public Health Risk Ranking =	Establishment Volume / National Volume	Public Health Attribution	Measures over time (i.e., verification testing, health based NRs)	Episodic Measures (i.e. FSAs, recalls, enforcements)

Fraction of human disease an establishment might cause if a contamination event were to occur

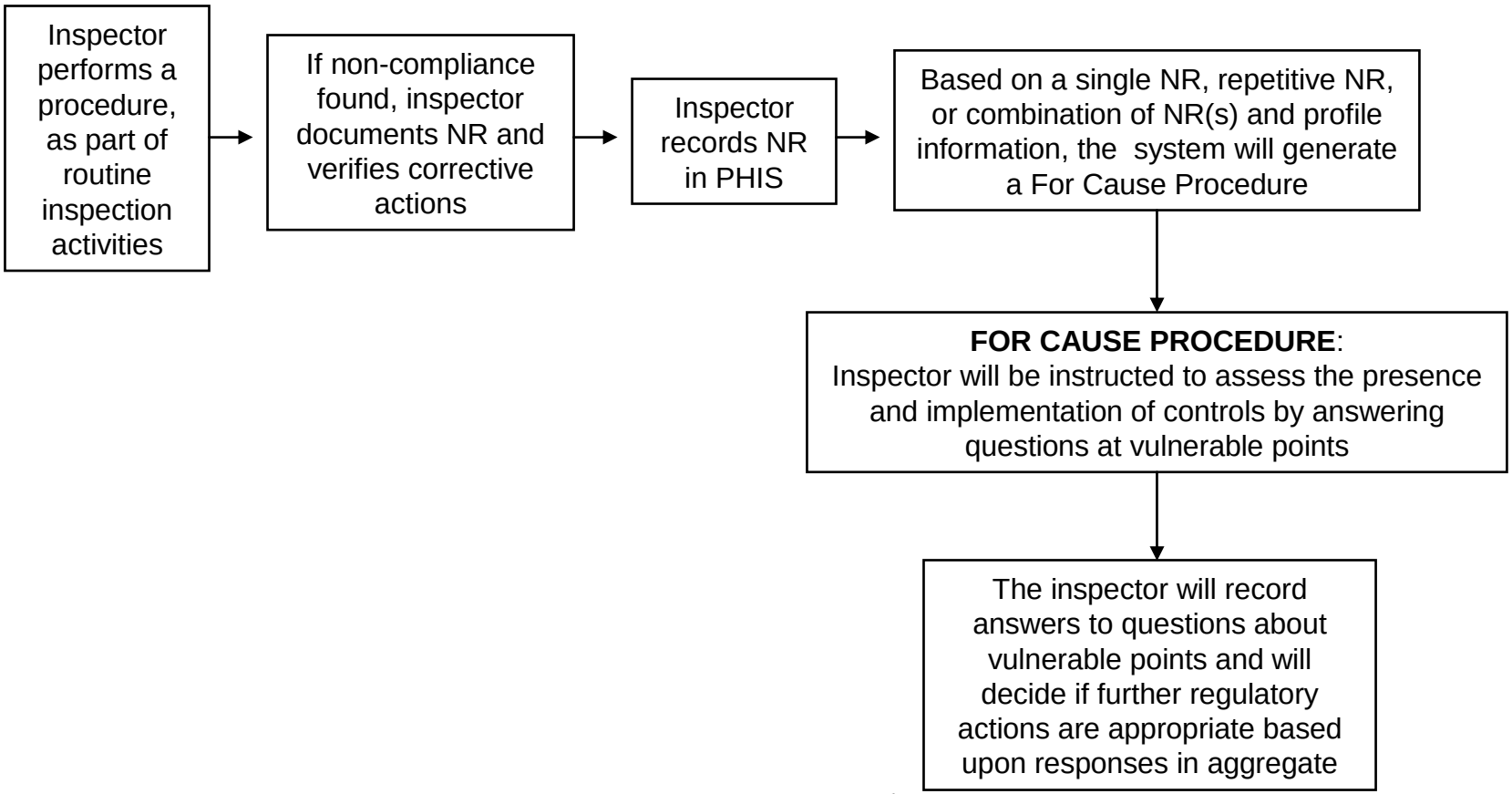
Indicator of how well establishment is maintaining process control

Determining Level of Inspection (LOI)

- Sort establishments into LOI 3 based on specified criteria
- Sort establishments into LOI 1 based on specified criteria
- Remaining establishments are placed into LOI 2
  - Within LOI 2, rank order establishments by their contribution to public health

Levels of Inspection

- Routine Inspection (LOI 1):
  - Maintain routine in-plant inspection
  - Focused verification activities, prompted by in plant results to identify and prevent possible problems (i.e. new with-in establishment inspection system) [For Cause Prompts]
- Focused Inspection (LOI 2):
  - Focus in-plant verification activities at vulnerable points to identify whether there is a food safety system problem [Directed Procedures and For Cause Prompts]
- In-Depth Inspection (LOI 3):
  - Focused in-plant verification activities [Directed Procedures and For Cause Prompts]
  - Deploy highly trained resources for in depth assessments and verification (i.e. EIAO/PHV performing FSAs and IVTs)

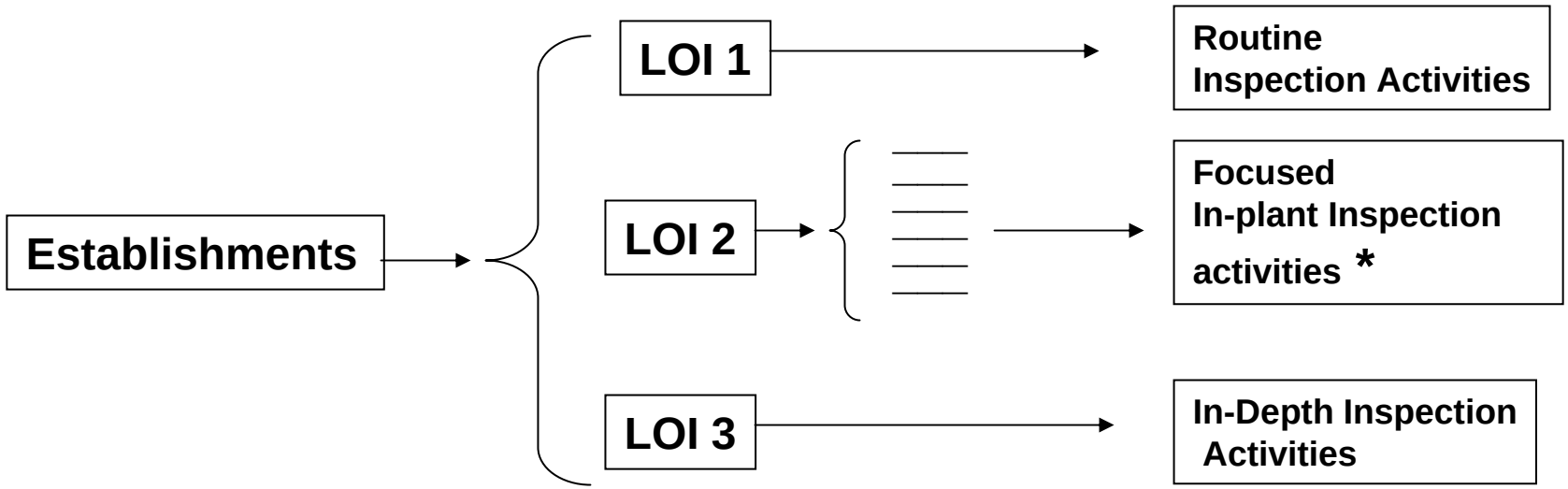


Directed Procedure:
Directed procedures are performed in Focused (LOI 2) and In-Depth (LOI 3) Inspection establishments

Overview Ranking Algorithm

Separate Based on Process Control Effectiveness

Rank LOI 2 on Potential Public Health Impact



*Focus in-plant verification activities at points where greatest microbial contamination or growth occurs if process control is not maintained

In-Depth Inspection (LOI 3) Criteria*

Satisfies ANY of the following criteria to be in LOI 3:

- A positive *E. coli* O157:H7 verification test in past month
- A positive *Lm*, *Salmonella* or *E. coli* O157 in RTE products in past month
- Establishment in *Salmonella* Category III
- Establishment is linked to a disease outbreak
- Establishment has sustained structural damage due to a natural disaster

*Establishments remain in LOI 3 until their FSA and IVT results demonstrate they are in compliance or an enforcement action is taken.

*Algorithm will be run monthly

In-Depth Inspection (LOI 3) Criteria (Cont)

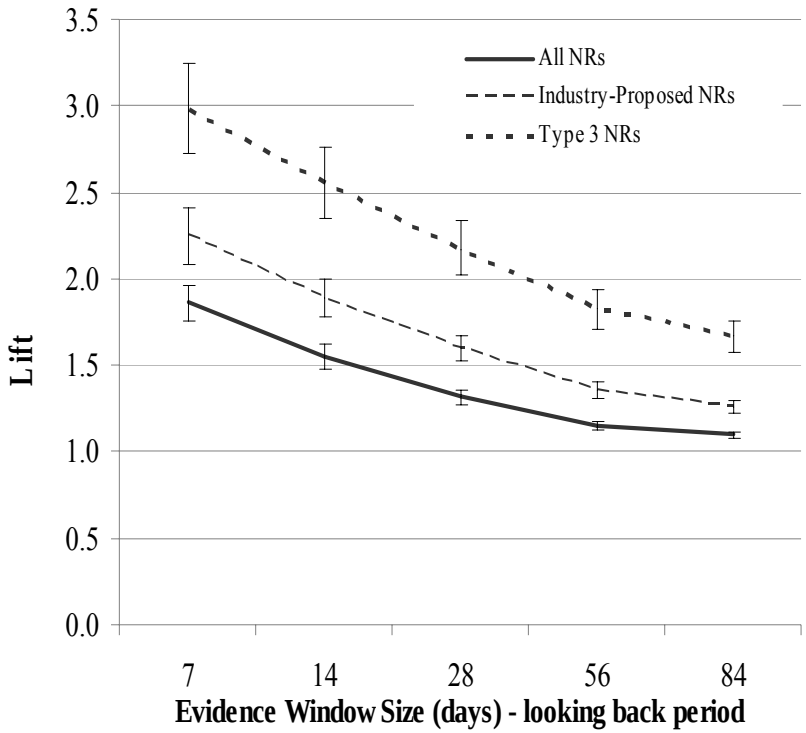
Satisfies ANY of the following criteria to be in LOI 3:

- In STEPS database more than once in past 120 days
- Shipment of Specified Risk Material
- Enforcement action (i.e. NOIE) or adulterated or misbranded product shipped (captures recalls)
- Highest percentile of health-related NR rates (e.g. SRM, Insanitary Dressing, Zero Tolerance, Residue) over some time period to be determined
  - Use of NRs justified through predictive analysis
- Repetitive *Salmonella* serotypes of human health concern or PFGE matches**

** This criterion is not currently applied. FSIS will collect this data as part of the *Salmonella* Initiative Program.

Predictive Analysis of Utility of NRs

- If NR occurs, what is increased probability of positive *Salmonella* in next two weeks?
  - Health-related NRs---probability 3 times higher
  - Industry-proposed NRs---probability about 2.3 times higher
  - All NRs---probability about 1.9 times higher
- Differences are statistically significant
- All are statistically greater than 1.0



Routine Inspection (LOI 1) Criteria

Must satisfy ALL of the following criteria to be in LOI 1:

- No positive FSIS *E. coli* O157:H7 in past 120 days or until establishment determined *E.coli* free from follow up sampling*
- No positive FSIS *Lm*, *Salmonella* or *E. coli* O157:H7 in RTE products in past 120 days
- No Enforcement action (i.e. NOIE) in past 4 months or adulterated or misbranded product in commerce in past 4 months (captures recalls including those related to human illness)

*120 days is based upon the approximate time required for 16 follow up *E. coli* samples

Routine Inspection (LOI 1) Criteria (Cont)

Must satisfy ALL of the following criteria to be in LOI 1:

- Establishment not linked to disease outbreak in past 6 months
- Lower percentile of *Salmonella* percent positives on most recent sample set, unannounced sampling or other *Salmonella* testing programs
- Lower percentile of health-related NR rates (e.g. SRM, Insanitary Dressing, Zero Tolerance, Residue) over a period of time to be determined
  - Use of NRs justified through predictive analysis

Routine Inspection (LOI 1) Criteria (Cont)

Must satisfy ALL of the following criteria to be in LOI 1:

- Lower percentile on most recent FSA score**
- Lower percentile of scores on focused in-plant verification questions—vulnerable points**
- Lower percentile of *Salmonella* serotypes of human health concern or PFGE matches***

** FSIS will collect this data in its new Public Health Information System

*** FSIS will collect this data as part of the *Salmonella Initiative Program.*

Focused Inspection (LOI 2) Criteria

Establishments not in LOI 3 or LOI 1

- *E. coli* positive within last 120 days or still undergoing follow-up sampling, for which FSA has been completed
- Positive *Lm*, *Salmonella* or *E. coli* O157 sample within last 4 months, for which FSA has been completed
- Enforcement action (e.g., NOIE) or adulterated or misbranded product shipped (captures recalls including those related to human illness) in past 4 months, for which FSA has been completed and corrective actions have been verified

Focused Inspection (LOI 2) Criteria (Cont)

- Based on past history of *Salmonella* testing, above the lower percentile cut-point for LOI 1 for percent positives on most recent sample set, unannounced sampling or other *Salmonella* testing programs
- Above the lowest health-related NR rate percentile (cut-point for LOI 1) and below the highest health-related NR rate percentile (cut-point for LO3)
- In STEPS database more than once in past 120 days, for which FSA has been completed

Focused Inspection (LOI 2) Criteria (Cont)

- Above lower percentile (cut-point for LOI 1) on most recent FSA score
- Above lower percentile (cut-point for LOI 1) of scores on focused in-plant verification questions—vulnerable points
- Above lower percentile (cut-point for LOI 1) of *Salmonella* serotypes of human health concern or PFGE matches
- Establishment confirmed to be cause of outbreak in past 6 months, for which FSA has been completed

Rank LOI 2 Establishments Based on Public Health Impact

- Rank order LOI 2 establishments based on public health impact (fractional volume x attribution)
  - Product fractional volume = $V_i / \sum V_i$,where sum is over product class (e.g. broilers, ground beef)
  - Attribution for pathogen-product class (e.g. ground beef consumption causes 34% of all E. coli O157:H7 illnesses)
  - Potential public impact = $V_i / \sum V_i$ x attribution
  - If establishment produces more than one product with same pathogen of concern, select max potential public impact

Rank LOI 2 Establishments (Cont)

- Sort the ranked establishments into one of four pathogen categories–*Salmonella*, *Lm*, *E. coli, Campylobacter*)–or place in fifth category–no pathogen results
- For each pathogen category, place upper and lower 50th percentile into categories LOI 2a and LOI 2b, respectively*

*Depending upon FSIS priorities (e.g. performance standards, seasonality) the categorization of LOI 2a and LOI 2b may be amended for specific pathogens.

Summary

- PHRBI algorithm is designed to:
  - Focus inspection on establishments most needing attention
  - Focus inspection on most vulnerable food safety system areas
  - Verify that food safety systems are working optimally

Summary

- Approach has multiple advantages
  - Transparent
  - Focuses on plants with evidence of lack of process control
  - All plants with high pathogen levels are ranked high
  - All plants with health-related problems (recalls, outbreaks, enforcement actions) are ranked high
  - Categorization independent of production volume
  - Compatible with FSIS sampling programs

Next Steps

- Apply algorithm to existing FSIS data
- External reviews
- Examine relationship to pathogen-specific sampling programs