



ifpti
**Fellowship in
Food Protection**

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IFPTI Fellowship Cohort VIII: Research Presentation

Kathleen Close, Auditor

Evaluation of Performance Factors Rated “Needs Improvement” from Field Inspection Audits

Kathleen Close, Auditor
IFPTI 2019-2020 Fellow
U.S. FDA

Background

Public
Health
Protection



Knowledge



Training



Quality Assurance
Program

Background



U.S. FDA Contract Audit Program

- FMD 76



State Audit Program

- MFRPS Standard 4

2 audits per inspector every 36 mos.

Background

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION CONTRACT AUDIT			
FDA AUDITOR		STATE INSPECTOR	
FIRM		CFN / FEI NUMBER	
FIRM ADDRESS			
PRODUCT(S) COVERED			DATE
TIME IN	TIME OUT	OVERALL RATING <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs Improvement	
I. PREINSPECTION ASSESSMENT			
1. DID THE INSPECTOR REVIEW THE STATE'S ESTABLISHMENT FILE FOR THE PREVIOUS INSPECTION REPORT AND POSSIBLE COMPLAINTS OR ACCESS OTHER AVAILABLE RESOURCES IN PREPARATION FOR THE INSPECTION? <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs Improvement COMMENTS (required for Needs Improvement)			
2. DID THE INSPECTOR HAVE THE APPROPRIATE EQUIPMENT AND FORMS TO PROPERLY CONDUCT THE INSPECTION? <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs Improvement COMMENTS (required for Needs Improvement)			
II. INSPECTION OBSERVATIONS AND PERFORMANCE			
1. WAS FDA JURISDICTION ESTABLISHED? <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs Improvement COMMENTS (required for Needs Improvement)			

FDA 3610

Appendix 4.5: Contract Audit Form (FDA 3610)

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION CONTRACT AUDIT		
FDA AUDITOR		STATE INSPECTOR
FIRM		CFN / FEI NUMBER
FIRM ADDRESS		
PRODUCT(S) COVERED		
TIME IN	TIME OUT	OVERALL RATING <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs Improvement
NOTE: EVERY ITEM MARKED "NEEDS IMPROVEMENT" MUST BE ACCOMPANIED BY AN EXPLANATION OF WHY THE ITEM WAS JUDGED AS NEEDING IMPROVEMENT.		
Overall rating		
All questions must be answered "acceptable" or "needs improvement," except for section II.A. <i>Inspection Observations and Performance for 'HACCP-Regulated' firms</i> . If the establishment is not subject to Seafood or Juice HACCP regulations, leave the scoring for these four questions blank.		
If four or more evaluated items are marked as "needs improvement," the state program manager must be notified by the appropriate FDA liaison that additional training or other performance improvement measures for then inspector being audited should be initiated. All contract inspectors who receive an overall audit score of "needs improvement" shall receive remedial training in deficient areas or as agreed upon by the FDA Project and Co-Project Officers prior to resuming contract inspection duties.		
I. Preinspection Assessment		
1. DID THE INSPECTOR REVIEW THE STATE'S ESTABLISHMENT FILE FOR THE PREVIOUS INSPECTION REPORT AND POSSIBLE COMPLAINTS OR ACCESS OTHER AVAILABLE RESOURCES IN PREPARATION FOR THE INSPECTION? <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs Improvement Comments (required for Needs Improvement)		

APPENDIX 4.5

Problem Statement

Overall, State and Federal regulatory field inspection audit performance trends are unknown.

Research Question(s)

1. Which performance factors are marked “Needs Improvement”?
2. What are the top 3 performance factors marked “Needs Improvement”?
3. Which section of the audit form has the most “Needs Improvement” ratings?

Methodology

DATA

Field
Inspection
Audit
Records

January
2015 - 2018

LOCATION

State

FDA

COLLECTION

AFDO
Survey

FDA

Methodology

Performance
Factor Results

MFRPS
Non-
Contract

FDA
Contract

ANALYSIS

Compare
Contrast
Trending

Excel

REPORTING

Graphs

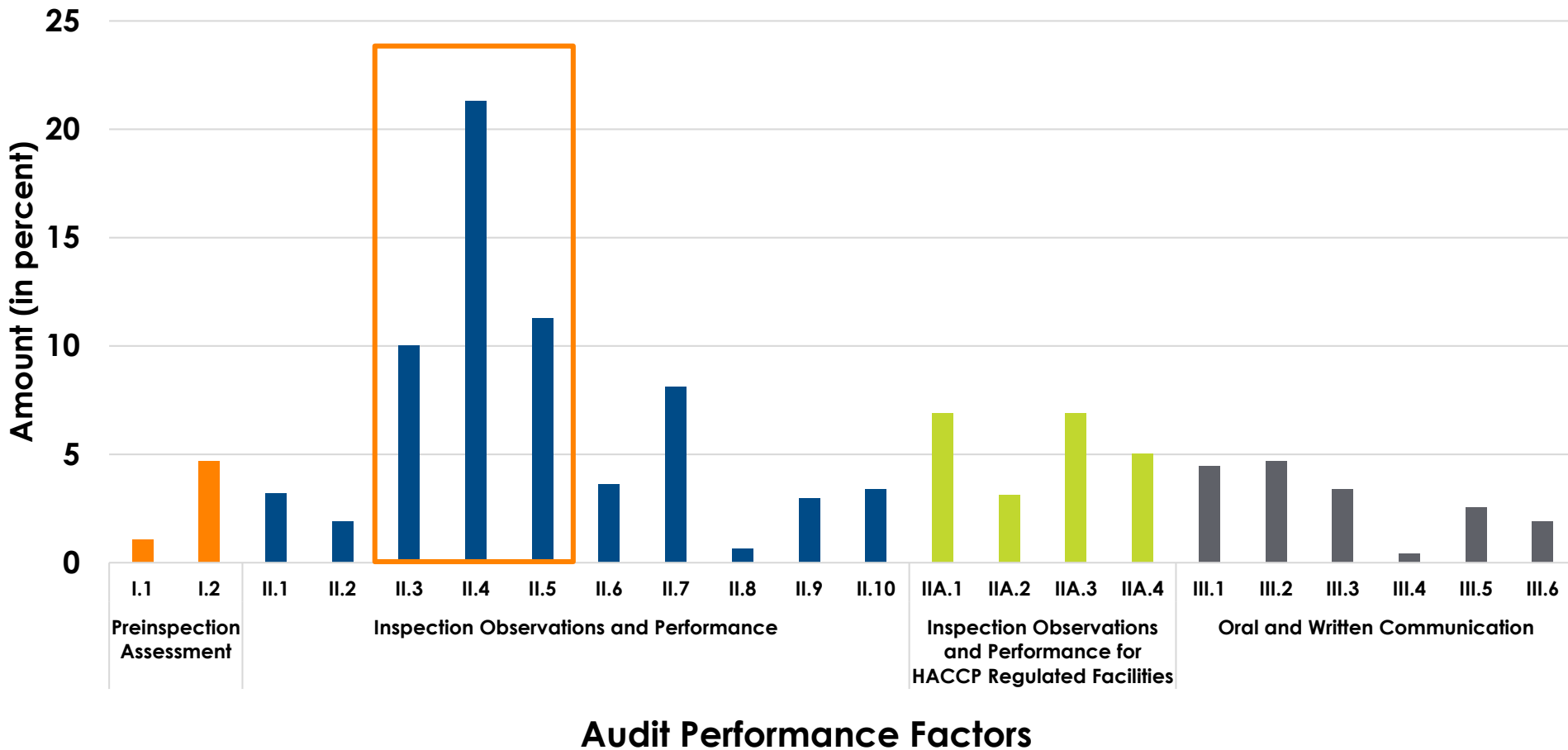
Study Population

- State and federal regulatory agencies
 - 10 state regulatory programs
 - Manufactured Food Regulatory Program Standards (MFRPS) enrollees
 - 10 FDA Human Food Contracts

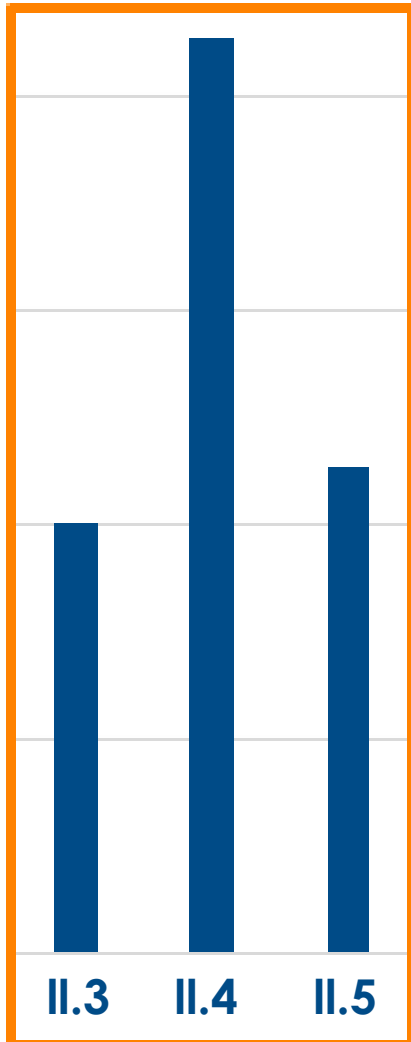


FDA contract audits + MFRPS non-contract audits

Performance Factors Rated “Needs Improvement” From Field Inspection Audits 2015-2018



Results



II.3 – Assessment of employee practices

8.40%

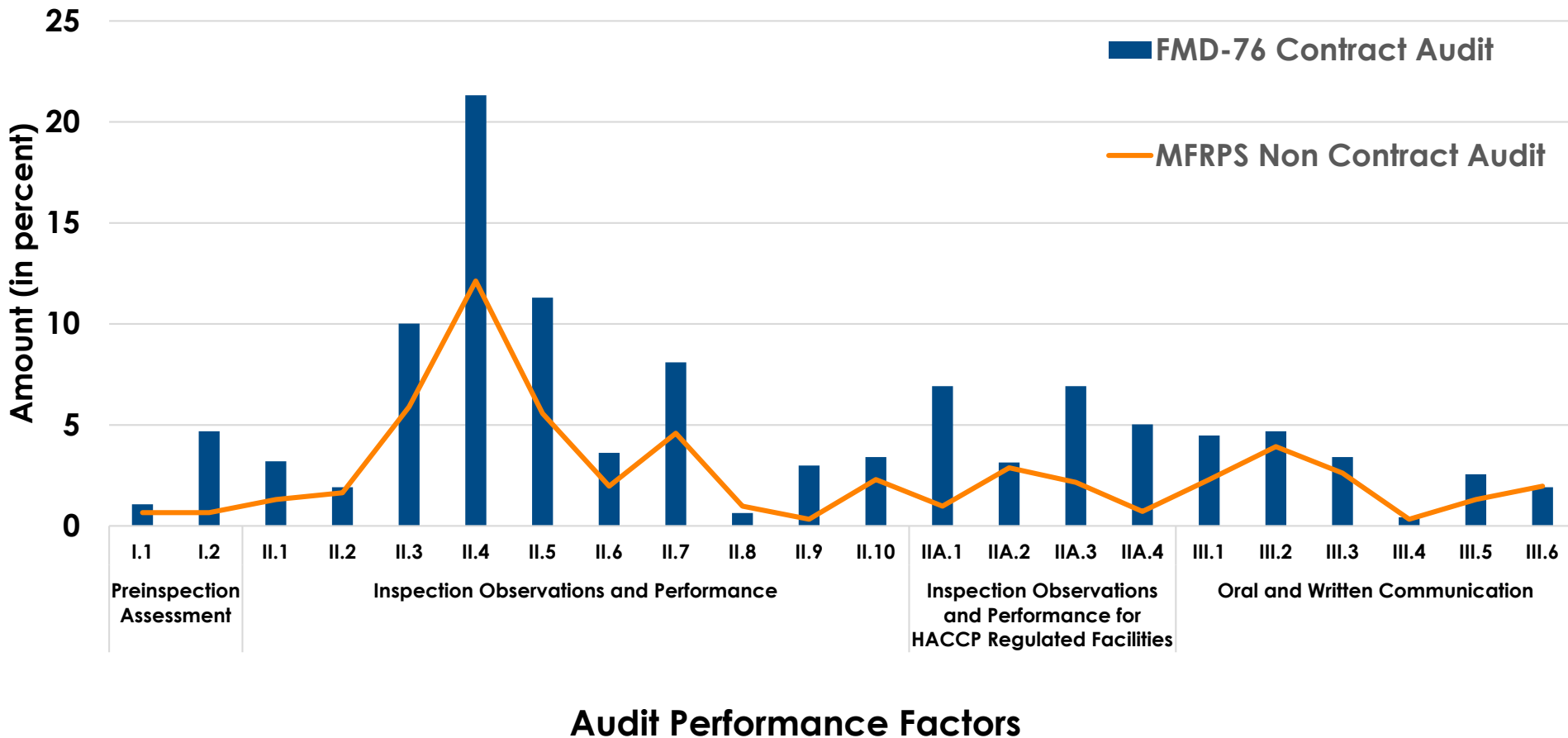
II.4 – Evaluation of potential causes of adulteration or misbranding

17.70%

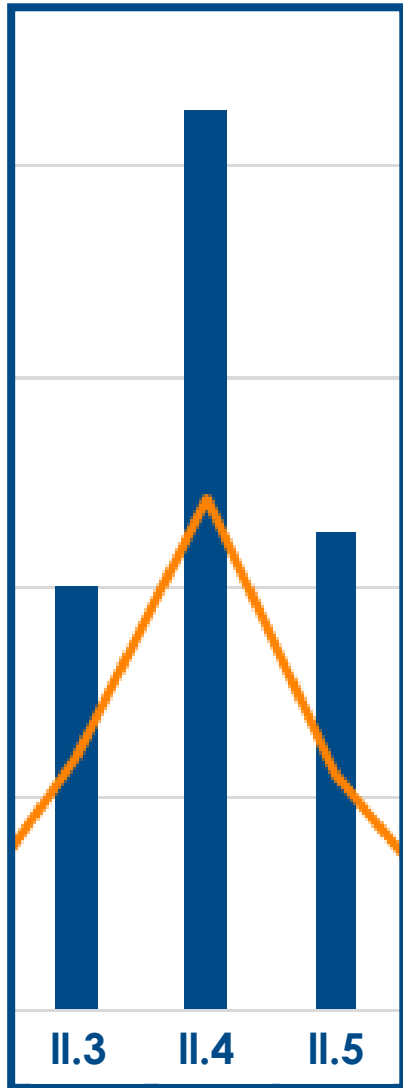
II.5 – Recognition and recording of significant violative conditions

9.04%

Performance Factors Rated “Needs Improvement” From Field Inspection Audits 2015-2018



Results



II.3 – Assessment of employee practices

FDA
Contract

10.02%

MFRPS Non-
Contract

5.90%

II.4 – Evaluation of potential causes of adulteration or misbranding

21.32%

12.13%

II.5 – Recognition and recording of significant violative conditions

11.30%

5.57%

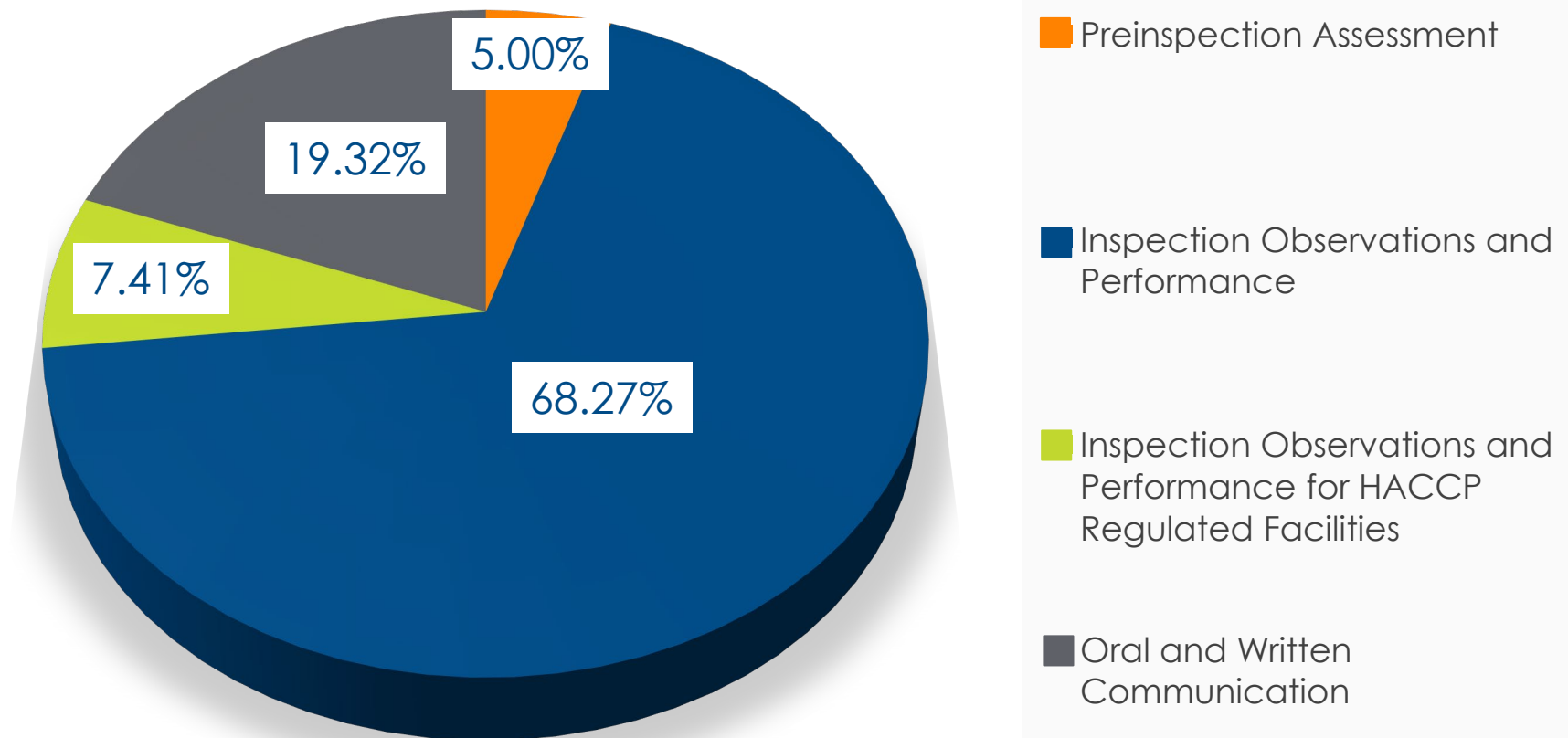
Results

Performance Factor Section Counts for “Needs Improvement” Ratings

Section	“NI” Responses
Pre-Inspection Assessment	31
Inspection Observations and Performance	424
Inspection Observations and Performance for HACCP Regulated Facilities	46
Oral and Written Communication	120

Results

"Needs Improvement" Ratings By Audit Section Compared to Total Number of "Needs Improvement" Ratings



Conclusions

- Performance trend known
 - Similar
- Most prevalent “needs improvement” performance ratings linked to **core** inspection performance
- Need to communicate and leverage resources to address national trend

Recommendations

1. Share individual audit trends
2. Share national trends
3. Brainstorm ideas on how to reduce national trend
4. State programs provide feedback to FDA OTED
5. FDA OTED relay new inspection guidance to past course participants
6. FDA audit CSOs using same 22 performance factors
 - Repeat study

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Questions?

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