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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

## FDA 3610

### APPENDIX 4.5

### Contract Audit Form (FDA 3610)

<table>
<thead>
<tr>
<th>FDA AUDITOR</th>
<th>STATE INSPECTOR</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>FIRM</th>
<th>CFN / FEI NUMBER</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>FIRM ADDRESS</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PRODUCT(S) COVERED</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TIME IN</th>
<th>TIME OUT</th>
<th>OVERALL RATING</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Acceptable</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Needs Improvement</td>
</tr>
</tbody>
</table>

**NOTE:** EVERY ITEM MARKED "NEEDS IMPROVEMENT" MUST BE ACCOMPANIED BY AN EXPLANATION OF WHY THE ITEM WAS JUDGED AS NEEDING IMPROVEMENT.

If there are four or more evaluated items 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 the 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.

### 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?**
   - Acceptable
   - Needs Improvement

   **COMMENTS (required for Needs Improvement)**

### Inspection Observations and Performance

1. **WAS FDA JURISDICTION ESTABLISHED?**
   - Acceptable
   - Needs Improvement

   **COMMENTS (required for Needs Improvement)**

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Form: FDA 3610 (10/33) Page 1 of 7

Manufactured Food Regulatory Program Standards

September 2019
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

\[469 + 305 = 774\]

- FDA contract audits
- MFRPS non-contract audits

Total: 774
Results

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

Audit Performance Factors

Preinspection Assessment
Inspection Observations and Performance
Inspection Observations and Performance for HACCP Regulated Facilities
Oral and Written Communication
Results

II.3 – Assessment of employee practices

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

II.5 – Recognition and recording of significant violative conditions

<table>
<thead>
<tr>
<th></th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>II.3</td>
<td>8.40%</td>
</tr>
<tr>
<td>II.4</td>
<td>17.70%</td>
</tr>
<tr>
<td>II.5</td>
<td>9.04%</td>
</tr>
</tbody>
</table>
Results

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

Audit Performance Factors

FMD-76 Contract Audit
MFRPS Non Contract Audit

Preinspection Assessment
Inspection Observations and Performance
Oral and Written Communication
## Results

<table>
<thead>
<tr>
<th></th>
<th>FDA Contract</th>
<th>MFRPS Non-Contract</th>
</tr>
</thead>
<tbody>
<tr>
<td>II.3 – Assessment of employee practices</td>
<td>10.02%</td>
<td>5.90%</td>
</tr>
<tr>
<td>II.4 – Evaluation of potential causes of adulteration or misbranding</td>
<td>21.32%</td>
<td>12.13%</td>
</tr>
<tr>
<td>II.5 – Recognition and recording of significant violative conditions</td>
<td>11.30%</td>
<td>5.57%</td>
</tr>
</tbody>
</table>
Performance Factor Section Counts for “Needs Improvement” Ratings

<table>
<thead>
<tr>
<th>Section</th>
<th>“NI” Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Inspection Assessment</td>
<td>31</td>
</tr>
<tr>
<td>Inspection Observations and Performance</td>
<td>424</td>
</tr>
<tr>
<td>Inspection Observations and Performance for HACCP Regulated Facilities</td>
<td>46</td>
</tr>
<tr>
<td>Oral and Written Communication</td>
<td>120</td>
</tr>
</tbody>
</table>
Results

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

- Preinspection Assessment: 5.00%
- Inspection Observations and Performance: 19.32%
- Inspection Observations and Performance for HACCP Regulated Facilities: 7.41%
- Oral and Written Communication: 68.27%
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
Acknowledgements

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- Dr. Craig Kaml – IFPTI
- Jennifer Hardy-Tindle – IFPTI
- US Food & Drug Administration (FDA)
- Josh Close
Questions?

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