Training the Auditors & Inspectors under FSMA
Overview

- 3rd Party Auditor Rule Review
- Training Standards
- Standards-based Approach to Training
Accredited Certification

International Accreditation Forum (IAF)

Peer Review by Sister Accreditation Body

Accreditation Bodies

Accredits the Certification Body (CB) Including Witness Audits of Auditor Activity

Certification Bodies

Audits the Supplier

Supplier

Supplier

Supplier

Supplier

Comprised of National Accreditation Bodies

ISO/IEC 17011

ISO/IEC Guide 65 Criteria for Certification Bodies

GFSI Recognized Standards

SQF 1000 & 2000

IFS, BRC, Dutch HACCP
Standards

ISO/IEC 17011 Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies

ISO/IEC Guide 65 General requirements for bodies operating product certification systems

ISO/IEC 17021 Conformity assessment – Requirements for bodies providing audit and certification of management systems

ISO 22000 Food safety management systems – Requirements for any organization in the food chain

ISO/TS 22003 Food safety management systems – Requirements for bodies providing audit and certification of food safety management systems
Hierarchy

FDA

Accreditation Body

3rd Party Auditor/Certification Body

Audit agent

Eligible Entity
Who Is the Auditor?

- FDA
- Accreditation Body (or FDA)
- Accreditation Body
- 3rd Party Auditor/Certification Body
- Audit agent
- Eligible Entity
Training Standards
Auditor Training in Third Party Rule

• Model accreditation standards will address training and auditor competency

• §1.642(a) A 3rd Party Auditor must have relevant knowledge, skills, and experience

• §1.650(a)(3) Annual auditor training, training to ensure competency

• FDA looks to Manufactured Food Regulatory Programs Standards (MFRPS) model
1. Regulatory foundation;
2. Inspector training program;
3. Risk-based inspection program;
4. Audits of the inspection program;
5. Protocols for food-related illnesses, outbreaks, and response;
6. Compliance and enforcement program;
7. Industry and other stakeholder relations;
8. Program resources;
9. Program assessment; and
10. Laboratory support.
MFRPS Training Requirements

• Written programs that include course curricula
  – Coursework
  – Field training
• Training histories maintained
MFRPS Training Requirements

Coursework (~40 hours)

• Prevailing statutes, regulations, and ordinances
• Public health principles
• Food defense awareness training
• Communications skills
• Microbiology
• Epidemiology
• Basics of HACCP
• Basic labeling
• Control of allergens
• Sampling technique and preparation
MFRPS Training Requirements

Field Training

Within 18 months of start date:

• Conduct at least ten joint or audit inspections
• Receive at least two acceptable evaluations
MFRPS Training Requirements

Continuing Education

Every 36 months:
• 36 contact hours of classroom training, and
• Participate in at least two joint or audit inspections with a qualified trainer.
MFRPS Training Requirements

Specialized Training

For conducting:
• Food Processing; Inspection and Investigation
• Seafood HACCP
• Juice HACCP
• Low acid canned foods
• Acidified foods
• Nutritional labeling
• Traceback investigations
• Foodborne illness investigations
Example – SQF Auditor Training

- 40 hour Lead Auditor Course
- 24 hour SQF Course
- HACCP Course
- Exam

- 20 audit days experience
- 5 years industry experience
General Competencies

- Auditing, communication techniques
- Ability to demonstrate integrity
- Knowledge and experience
- Ability to assess quality defects
- Ability to plan & lead an audit
Example – SQF Auditor Competencies

- Technical Competencies
  - Ability to assess hazards
  - Ability to assess effectiveness of controls
  - Understanding HACCP principles
  - Experience & technical process/ product knowledge
  - Knowledge of prerequisite programs, standards, guidelines
Competency-based Training
Curriculum Process

Step 1
Define Audience

Step 2
Create Competency Framework
(identify domains and professional levels)

Step 3
Identify Competencies
(combination of knowledge, skills, abilities, and behaviors required to accomplish the desired outcome)

Step 4
Create Curriculum Framework
(key content areas relevant to profession)
Curriculum Process

Draft Competency Framework

Competency Validation

Curricula Development

Food Regulatory Curriculum Framework

Foundational Knowledge
(linking science to regulation, critical thinking development of regulations, product classification, etc)
## Step 3: Identify Competencies

<table>
<thead>
<tr>
<th>Proficiency Levels / Domains</th>
<th>Technical Competency</th>
<th>Communication Competency</th>
<th>Programmatic Competency</th>
<th>Leadership Competency</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Senior administration</strong></td>
<td>• Anticipate and evaluate resource needs.</td>
<td>• Distill complex technical information for a variety of audiences.</td>
<td>• Strategically prioritize and allocate resources.</td>
<td>• Advocate for resources.</td>
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<td>• Interact with media organizations regarding sensitive issues.</td>
<td>• Collaborate in the development of new program standards.</td>
<td>• Establish organizational culture.</td>
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<td>• Disseminate the vision, mission, goals, and objectives throughout organization.</td>
<td>• Creating or modifying policy.</td>
<td>• Leads strategic planning.</td>
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<td>• Establish fee structures.</td>
<td>• Promote an integrated food safety system.</td>
</tr>
<tr>
<td><strong>Supervisor/ manager</strong></td>
<td>• Assess work performed by experts.</td>
<td>• Interact with media organizations regarding non-sensitive issues.</td>
<td>• Assess program performance using data.</td>
<td>• Motivate laboratory professionals.</td>
</tr>
<tr>
<td></td>
<td>• Determine if expert’s conclusions are valid.</td>
<td>• Write concise business reports.</td>
<td>• Suggest new methods.</td>
<td>• Implement the strategic plan.</td>
</tr>
<tr>
<td></td>
<td>• Interpret a compilation of test results and explain the implications.</td>
<td>• Conduct conflict resolution and negotiation.</td>
<td>• Interpret and apply emerging technologies.</td>
<td>• Advocate for laboratory staff members.</td>
</tr>
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<td>• Provide clear instructions.</td>
<td>• Implementing new policies.</td>
<td>• Engage in interagency collaboration.</td>
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<tr>
<td></td>
<td></td>
<td>• Inform senior administration of challenges, opportunities, resource needs, etc.</td>
<td>• Ensure compliance with work rules, policies, and practices.</td>
<td>• Engage in integrated food safety system activities.</td>
</tr>
<tr>
<td><strong>Expert</strong></td>
<td>• Troubleshoot problems.</td>
<td>• Effectively disseminate information.</td>
<td>• Employ program standards relevant to the laboratory.</td>
<td>• <strong>Entry</strong></td>
</tr>
<tr>
<td></td>
<td>• Train laboratory professionals.</td>
<td>• Interact with media organizations regarding non-sensitive issues.</td>
<td>• Administer accreditation or certification standards that pertain to the administrative operations.</td>
<td>(trainee – 2 years)</td>
</tr>
<tr>
<td></td>
<td>• Interpret and describe standard and nonstandard test results.</td>
<td>• Write concise business reports.</td>
<td>• <strong>Mid-level</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Evaluate data using statistical modeling.</td>
<td>• Conduct conflict resolution and negotiation.</td>
<td>• Assess program performance using data.</td>
<td>- expanded test scope</td>
</tr>
<tr>
<td></td>
<td>• Evaluate and implement technologies.</td>
<td>• Provide clear instructions.</td>
<td>• Suggest new methods.</td>
<td>- increased test complexity</td>
</tr>
<tr>
<td></td>
<td>• Conceptualize and develop novel approaches.</td>
<td>• Inform senior administration of challenges, opportunities, resource needs, etc.</td>
<td>• Interpret and apply emerging technologies.</td>
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</tr>
<tr>
<td><strong>Mid-level</strong></td>
<td>• Apply testing knowledge and skills to similar test methods.</td>
<td>• Effective disseminate information.</td>
<td>• Implementing new policies.</td>
<td>- limited test scope</td>
</tr>
<tr>
<td>- expanded test scope</td>
<td>• Apply knowledge and skills to use similar technologies.</td>
<td>• Produce effectively written and oral interpersonal communications.</td>
<td>• Ensure compliance with work rules, policies, and practices.</td>
<td>- limited test complexity</td>
</tr>
<tr>
<td>- increased test complexity</td>
<td>• Participate in trouble shooting problems.</td>
<td>• Develop recommendations.</td>
<td>• Employ program standards relevant to the laboratory.</td>
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</tr>
<tr>
<td></td>
<td>• Describe the results in terms of the work performed.</td>
<td>• Establish fee structures.</td>
<td>• Administer accreditation or certification standards that pertain to the laboratory testing operations.</td>
<td></td>
</tr>
<tr>
<td><strong>Entry</strong></td>
<td>• Explain laboratory testing methods.</td>
<td>• Clearly recording observations.</td>
<td>• Initiate problem resolution.</td>
<td>(trainee – 2 years)</td>
</tr>
<tr>
<td>(trainee – 2 years)</td>
<td>• Perform laboratory tests independently and correctly.</td>
<td>• Follow written and verbal directions.</td>
<td>• Recommend innovative solutions.</td>
<td>- limited test scope</td>
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<tr>
<td>- limited test complexity</td>
<td></td>
<td>• Seek assistance or clarification when necessary.</td>
<td>• Recognize and proactively address issues and gaps.</td>
<td>- limited test complexity</td>
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<td>• Discuss laboratory-related issues clearly, logically, and succinctly.</td>
<td>• Consistently behave in an ethical manner.</td>
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<td>• Present information about work performed as evidence in legal proceedings.</td>
<td>• Pursue professional growth.</td>
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<tr>
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<td>• Describe regulatory programs that the laboratory supports.</td>
<td>• Assume responsibility and accountability for actions.</td>
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</table>
## Competency Framework - Example

<table>
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<td><strong>Mid-level</strong></td>
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</table>
| - expanded test scope       | • Apply testing knowledge and skills to similar test methods.  
                               | • Apply knowledge and skills to similar technologies.       
                               | • Participate in trouble shooting problems.                   
                               | • Describe the results in terms of the work performed.       |
| - increased test complexity  |                      | • Present to peers.                                           
                               | • Write SOPs.                                                 
                               | • Write in a grammatically correct style.                     
                               | • Create data summary reports.                               
                               | • Write corrective action reports.                           
                               | • Articulate issues.                                         
                               | • Present information about work performed as evidence in legal proceedings. |
| **Entry**                   |                      |                         |
| (trainee – 2 years)         | • Explain laboratory testing methods.                         |
| - limited test scope        | • Perform laboratory tests independently and correctly.      | • Clearly recording observations.                            |
| - limited test complexity    |                      | • Follow written and verbal directions.                       |
|                             |                      | • Seek assistance or clarification when necessary.            |
|                             |                      | • Discuss laboratory-related issues clearly, logically, and succinctly. |
Step 4: Curriculum Framework

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**Certificate and CEU Issuance (IACET/ANSI)**

**Professional Level Program Certificates**

**Leadership (Leadership)**
- L4 - 4000
  - Advocacy
  - Budget
  - Change Management
  - Continuity of Operations
  - Human Resource Management
  - Legislative Affairs
  - Policy Making
  - Public Relations
  - Resource Leveraging
  - Risk Analysis
  - Strategic Planning & Communication
  - Stakeholder Support

**Technical Specialist:** (Master)
- L3 - 3000
  - Animal Drugs
  - BSE Investigations
  - Medicated Feed
  - Non-Medicated Feed
  - Rendering Plants
  - Shellfish Tissue Residue
  - Acidified Foods
  - Aseptic Processes
  - Biotechnology and Nanotechnology
  - Dietary Supplements
  - Economic Adulteration
  - Infant Formula
  - Juice HACCP
  - Low Acid Canned Food
  - Medical Foods
  - Pasteurization
  - Seafood HACCP
  - Web Site Reviews

**Journey Level:**
- L2 - 2000
  - Aquaculture
  - Dairy
  - Food Animals (Eggs)
  - Produce (Sprouts, Leafy Green Vegetables)
  - Shellfish
  - Additives
  - Animal Food Processing
  - Commodity-Specific Feed
  - Food
  - Milk or Milk Products
  - Meat & Poultry
  - Packaging
  - Seafood/Shellfish
  - Active Managerial Control
  - Catering
  - Cottage Foods
  - Food Preparations Techniques
  - Food Service
  - Grocery
  - Plan Review
  - Retail HACCP/Variance
  - Vending, Temp, Other

**Integrated Food Safety System Orientation**
- Jurisdiction
- Employee Safety
  - Communication Skills
  - Epidemiology (Not in Feed)
  - HACCP
  - Microbiology (not in Feed)
  - Prevaling Statutes, Regulations & Ordinances
  - Public Health Principles

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(ORA-U Level I - Feed, Milk & Local, Shellfish, Standard 2: Manufactured, Retail)
What is a Curriculum Framework?

• A platform/system to catalog/organize courses
• Framework is like a library
• Courses are like the books – each categorized and in sections (content areas)
# Draft Food Industry Curriculum Framework

## Private Sector
### Professional Level Program Certificates

<table>
<thead>
<tr>
<th>Facilities and Food Handling Materials Concentration</th>
<th>Unprocessed Concentration</th>
<th>Processing Concentration</th>
<th>Manufactured Concentration</th>
<th>Distribution Concentration</th>
<th>Retail Concentration</th>
<th>Food Service Concentration</th>
<th>Recollection Concentration</th>
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<tr>
<td>GMPs</td>
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<td>Allergens</td>
<td>Environmental Health Safety</td>
<td>Food Defense Awareness</td>
<td>Basic HACCP</td>
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## Leadership
### Leadership Development/Consulting

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## Food Safety Manager
### Food Safety Manager (Application)

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## Entry Level
### Entry Level: Knowledge/Measurement

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</tbody>
</table>
4. To what degree targeted outcomes occur
2. To what degree participants acquire the intended KSA, confidence, and commitment
1. To what degree participants react favorably to the training
3. To what degree participants apply what they learned when they are back on the job
Training Quality

Course standards and training entity accreditation

Category 1: Continuing Training Organization
Category 2: Responsibility and Control
Category 3: Learning Env. and Support Systems
Category 4: Learning Event Planning
Category 5: Learning Outcomes
Category 6: Planning, Instructional Personnel
Category 7: Content and Instructional Methods
Category 8: Assessment of Learning Outcomes
Category 9: System for Awarding CEUs and Maintaining Learner Records
Category 10: Program Evaluation

ISO/ IEC 17024

ANSI /ASTM E2659-09,
Standard Practice for Certificate Programs
Auditor Competence

- Training alone does not demonstrate competence
- “Shadow audits” or standardization inspections - assessment
- Certification/ credentialing efforts
Auditor Competence

- FDA conducted a Job/Task Analysis for auditors
- NEHA creating a credential for a certified auditor
- GFSI working on a credential
Conclusion

- Competency-based training should be considered when setting model accreditation standards
- Competency and comparability can be assured by personnel certification
Thank You!

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