Specific vs. Generic Program Standards

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Presentation Objectives

• Provide overview of generic standards concept
• Highlight current national program standards infrastructures and management
• Conduct interactive opportunity to solicit input and feedback
• Discuss initiative for moving forward with concept
Generic Standard Concept

• A Generic Standard can be defined as a standard whose requirements are generic and are intended to be applicable to all organizations, regardless of type, size and product and/or service provided.

• ISO 9001 is an example of a generic standard
• Over a million production and service organizations worldwide are registered to ISO 9001.

• The **Generic Standard Concept is not ISO 9001**. It is a program standard concept that may have application within regulatory programs, such as retail, feed, food or other future programs.
• If over a million production and service organizations worldwide can use one standard, can one national regulatory program standard be developed that fits all?
Advantages of a Generic Program Standard

- Less prescriptive.
- Leaves more to the end user to judge its own needs.
- Provides much more flexibility for end user to use its strengths to accomplish requirements of a standard and to achieve continual improvement for their organizations.

(IT systems along with other resources)
Advantages of a Generic Program Standard (cont.)

- Minimizes inconsistencies between multiple program standards.
- User enrolled in multiple program standards may now have one system based on one set of requirements.
- Design of standard can support a process approach that promotes continuous improvement.
Possible Disadvantages of a Generic Program Standard

- Consistency
- “Bare bones” requirements that may need to be supplemented. (Addendum)
Process Approach for Continual Improvement
Some Features of a Generic Program Standard

- All standards may be included.
- Less prescriptive – provides flexibility.
- Process approach written includes Management Review and CAPA programs.
- Does not include Strategic Improvement Plans, prescriptive requirements, or appendices.
Current Management of National Program Standards

Voluntary National Shellfish Regulatory Program Standards (Draft)
ISSC
Involving Regulatory Program Standards Stakeholders

- CFSAN & CVM
- ORA OP/DSI
- ORA OP/DPIA
- ORA ORS
- ORA OHAFO/Audit Staff
- ORA OHAFO/ORS
- ORA OHAFO/OSTED
- ORA OHAFO/OSCP
- ORA OHAFO/RFSC/Standards Cmt
- CFP Program Standards Committee
- MFRPA
- ISSC (Task Force III)
Enrolled Jurisdictions

• **MFRPS**: 42 state agencies
  – 35 dual enrolled in VNFRFRPS, 10 dual enrolled in AFRPS, 7 states enrolled in MFRPS/AFRPS/VNFRFRPS

• **AFRPS**: 22 state agencies
  – 10 dual enrolled in MFRPS

• **VNFRPS**: 825 agency
  – 61 states, 5 territories, 482 county, 116 cities, 60 towns, 11 tribal, 9 universities, 1 park, 3 federal agencies (as of 12/31/2017)
  – 35 state are dual enrolled in the MFRPS

• **FDA Districts (Future)**?
Soliciting Feedback and Input

- What are the desired goals and reliance on Integrated Food Safety Systems (all stakeholders)?
  - Recognition and mutual reliance
  - Information exchange
  - Leveraging resources
  - Reducing and preventing foodborne illness
  - Promoting national uniformity

- Diversity of regulatory programs and operational structures/jurisdictions?

- Administrative change vs. public health change?

- Harmonization of program standards?

- Training and training resources?
Soliciting Feedback and Input (cont.)

• Integration or reference of other programs and best practices?
  – Rapid Response Teams (RRTs)
  – CIFOR
  – Partnership for Food Protection (PFP)

• Existing governing bodies, e.g.,
  – Conference for Food Protection (CFP)
  – MFRP Alliance
  – AFRPS Leadership Council
  – Interstate Shellfish Sanitation Conference (ISSC)

• Deliverables and assessments?
• Future federal investments and?
• Return on Investments?
Next Steps

• Project/Initiative: Moving to an ISO Standard Framework.

• Objective: Socialization/consensus on an ISO-type standards framework among internal and external stakeholders.

• Stakeholders: OHAFO/AS, CFSAN Retail, CFSAN (others), OSCP, ORS, OP, OTED, CVM, MFRPA. Others?
Questions
Contact Information

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