2018-2019 MFRPS Change Proposals

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Richard Beckstrand
Adam Inman
Maria Ishida
MFRPS Change Process

• Proposals were solicited Starting June 19, 2018
• Submission deadline was October 1, 2018
• 18 proposals were received
• 17 proposals were accepted by the Board
  – 1 proposal was returned because the spreadsheet the proposal was requesting already existed.
MFRPS Change Process

- MFRPA Board assigned the proposals to one of four workgroups:
  - WG1: Standards 1, 2, 8, & 9
  - WG2: Standards 3, 4, & 6
  - WG3: Standards 5 & 7
  - WG4: Standard 10
Workgroup 1

Chair: Pamela Miles

Workgroup Members:

Delnaaz Daruwala
Kara Miller
Gena Reich
Jennifer Pierquet
Frank Greene
Susan Shedd
Amir Javed
Elisabeth Wirsing
Ryan Knox

Dr. Norman Arroyo-Llantin
Jennifer Bonsky
Patrick Kennelly
Tressa Madden-McGill
Michelle Motsinger
Dawn Smith
Christina Castineyra
Matt Craft
Workgroup 1 Proposals

18-012 Proposal – Related to Definitions

Standard 2 addresses evaluations based on the types of training received and the experience level of staff. Updating the “Evaluation” definition by deleting the sentence requiring 2 evaluations, removes a potential conflict between the definition and the language in Standard 2.

Workgroup Recommendation:

➢ Update the Definition as Proposed
Workgroup 1 Proposals

18-009 Proposal – Related to Standard 1

Develop a Self Assessment Worksheet for Standard 1 that includes verification of the requirements of a written procedure for evaluation of the state's legal and regulatory authority.

Workgroup Recommendation:
- Update Standard 1 as Proposed
Workgroup 1 Proposals

18-010 Proposal – Related to Standard 1

Add language defining records requests and have the state describe their system for reviewing and approving records requests and protection of confidential or trade secret information.

Workgroup Recommendation:
➢ No Modification to the Standard
Workgroup 1 Proposals

18-002 Proposal – Related to Standard 2

Change the 36 month continuing education requirement initiation date from the qualified date when basic training is completed to the date the employee starts with the agency.

Workgroup Recommendation:

- No Modification to the Standard
A written training plan is required by sections 2.2 and 2.3. Add the training plan to the list of required documents specified in section 2.5.

Workgroup Recommendation:
- Update Standard 2 as Proposed
Workgroup 1 Proposals

18-004 Proposal – Related to Standard 8

Modify Appendix 8.2 related to determining the number of inspectors necessary to complete workload within the state and develop the appendix as a spreadsheet that will calculate the resource needs.

Workgroup Recommendation:

➢ No Modification to the Standard
Workgroup 1 Proposals

18-005 Proposal – Related to Standard 9

Provide clarification on how to calculate the "hours used" under the Self Assessment section on Appendix 9.1.

Workgroup Recommendation:

- Recommend modification of the Appendix 9.1 Guidance Document to provide clarification on calculation of hours used.
Workgroup 1 Proposals

18-006 Proposal – Related to Standard 9

Document control requirements should be further explained and "Master List" requirements should be defined in the standard.

Workgroup Recommendation:
- Update Standard 9 as Proposed
Workgroup 1 Proposals

18-001 Proposal – Related to Standards 2 & 4

Harmonize audit requirements between Standards 2 & 4. Submission targets the advanced training verification audit requirement of Standard 2 and the routine audits required under Standard 4.

Workgroup Recommendation:

- No Modification to the Standard
Workgroup 2

Chair: Richard Beckstrand

Workgroup Members:

Kate Tozzi
Jane Reick
Jon C Strauss
Skya Murphy
Virginia Phillips
Frank C Kilgore
Darren Lowe
Lucy Severs
Robin Henderson
Jan Kelly

Vonda Canaan
Kara Miller
Gena Reich
Jennifer Pierquet
Steve Stich
Tressa Madden-McGill
Michelle Motsinger
Dawn Smith
Christina Castineyra
James Chan
Workgroup 2 Proposals

18-007 Proposal – Related to Standard 3

Update Appendix 3.1 to specify the required sampling elements that need to appear in the state's sampling procedure.

Workgroup Recommendation:

- Update Standard 3 and Appendix 3.1
Workgroup 2 Proposals

18-013 Proposal – Related to Standard 3

Replace the undefined phrase "food safety and defense incident" in section 3.3.1 with the defined phase "food related incident" that is used in other areas of the standards.

Workgroup Recommendation:

- Update Standard 3 as Proposed
Workgroup 2 Proposals

18-008 Proposal – Related to Standard 4

Update Appendix 4.6, Item 1.4, to clarify that the investigator followed state inspection protocols, rather than followed protocols and correctly applied the law/regulations, since this would not be able to be determined through a desk audit.

Workgroup Recommendation:
➢ Update Appendix 4.1 as Proposed
Workgroup 2 Proposals

18-014 Proposal – Related to Standard 4

Redesign Appendix 4.8 to more appropriately capture deficiencies identified during audits and the corrective action that was implemented to address the non-conformance.

Workgroup Recommendation:

➢ No Modification to the Standard
Workgroup 3

Chair: Adam Inman

Workgroup Members:

Danielle Grady  Mark Sestak
Lisa Marie Pierson  Michael Moore
Phillip Fruechting  Kara Miller
Richard Stephens  Jim Melvin
John Luker  Tressa Madden-McGill
Alida Sorenson  Michelle Motsinger
Bianca Arriaga  Dawn Smith
Jessica Badour  Christina Castineyra
Workgroup 3 Proposals

18-017 Proposal – Related to Definitions

Revise the definition of "food-related incident" to be more specific and use less ambiguous terminology.

Workgroup Recommendation:
- No Modification to the Standard
18-015 Proposal – Related to Standard 5

Eliminate section 5.3.5.2 related to providing environmental investigation reports to agencies that report findings to CDC.

Workgroup Recommendation:
- No Modification to the Standard
Workgroup 3 Proposals

18-016 Proposal – Related to Standard 5

Add the requirement to standard 5 that programs have a Continuity of Operations (COOP) Plan.

Workgroup Recommendation:
- No Modification to the Standard
Workgroup 4

Chair: Maria Ishida

Workgroup Members:

Sally Flowers  Richard Stephens
Karen Stephani  Yvonne Salfinger
Amy Bryant  Tressa Madden-McGill
Rebecca Sciulli  Michelle Motsinger
Jason Channels  Dawn Smith
Joseph Shell  Christina Castineyra
Amber Grisamore
Workgroup 4 Proposals

18-018 Proposal – Related to Standard 10

Update Standard 10 language to conform with the 2017 ISO revisions.

Workgroup Recommendation:

- Update Standard 10 as Proposed
Voting on Proposals

• Voting delegates will assemble to discuss and vote on the proposals.

• Proposals will be presented and an opportunity for discussion provided.

• No modifications to language will be allowed during this process.

• Voting delegates will vote to accept or reject the proposal.
Accepted Proposals

• Those proposals receiving a majority vote to accept, will be compiled and transmitted to the FDA.

• FDA is not automatically obligated to accept every request for modification that comes from the MFRPA.

• FDA will evaluate the merits of each recommendation and must make any changes through their administrative process, which includes providing notice in the Federal Register.