



2018-2019 MFRPS Change Proposals

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Richard Beckstrand
Adam Inman
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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

Workgroup 1 Proposals

18-011 Proposal – Related to Standard 2

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 phrase "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

Lisa Marie Pierson

Phillip Fruechting

Richard Stephens

John Luker

Alida Sorenson

Bianca Arriaga

Jessica Badour

Mark Sestak

Michael Moore

Kara Miller

Jim Melvin

Tressa Madden-McGill

Michelle Motsinger

Dawn Smith

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

Workgroup 3 Proposals

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

Karen Stephani

Amy Bryant

Rebecca Sciulli

Jason Channels

Joseph Shell

Amber Grisamore

Richard Stephens

Yvonne Salfinger

Tressa Madden-McGill

Michelle Motsinger

Dawn Smith

Christina Castineyra

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.