

Manufactured Food Regulatory Program Standards

Summary of Changes



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SUMMARY OF CHANGES

This summary provides a synopsis of the changes made to the 2016 Manufactured Food Regulatory Program Standards (MFRPS). The primary intent of this summary document is to provide a broad overview of the changes found in the 2016 Manufactured Food Regulatory Program Standards (MFRPS) rather than to identify every word or editing change. This summary document should not be relied upon as an absolute comparison that identifies each modification.

Changes Recommended by the Manufactured Food Regulatory Program Alliance (MFRPA)

FDA works closely with stakeholders through the Association of Food and Drug Officials (AFDO) Manufactured Food Regulatory Program Alliance (MFRPA) to review proposed changes to the Manufactured Food Regulatory Program Standards. Changes may be proposed by FDA, or by regulatory state programs. MFRPA proposed changes were provided to the Partnership for Food Protection (PFP) Governing Council (GC) for review and comment. The PFP GC does not serve as a voting body on the MFRPS change recommendations, but instead provides technical review and overall executional and policy comments for the Alliance Board and FDA to consider.

CHANGES MADE THROUGHOUT THE MFRPS

- **Definitions.**
 - The addition of a definitions section was included in the 2016 MFRPS. Defined words are found throughout the 2016 MFRPS in SMALL CAPS.
- **Numbering of sections.**
 - The new numbering layout of the 2016 MFRPS allows for quick reference and aligns with the layout used in the international standards and assessment tools and FDA manuals (such as the FDA's Investigations Operations Manual (IOM)).
- **Instructions for calculation worksheets.**
 - Combining appendices that are instructions for how to complete a calculation worksheet with their respective calculation worksheets. For example, within the 2013 MFRPS, Worksheet 4.4 *Performance Rating for Sample Report Audits* had accompanying instructions documented separately in Appendix 4.4 *Summary of Sample Report Audit Findings*. These two documents are combined together into a single appendix within the 2016 MFRPS retitled Appendix 4.4 *Performance Rating for Sample Report Audits* and Appendix 4.4a *Summary of Sample Report Audit Findings*.

STANDARD ONE – REGULATORY FOUNDATION

NEWLY DEFINED TERMS

- Equivalent
- Equivalent in Effect
- Not Equivalent
- Regulatory Foundation

NEW SECTIONS AND APPENDICES

- No new sections added.
- No new appendices added.

UPDATES MADE TO THE STANDARD

- **1.1 Purpose.**
 - No change
- **1.2 Requirement Summary.**
 - Amended to provide clarity and remove any program element requirements and place them within the Program Elements section. This includes removal and proper placement of the requirement that a state must evaluate its legal authority.
- **1.3 Program Elements.**
 - Added requirement for a written procedure for the evaluation of legal authority that includes timeframes, the assessment process, and addresses the regulatory requirements that applies to the manufactured food program. (1.3.1)
 - Amended for clarity that a consultation with legal counsel for review of equivalent laws is optional.
- **1.4 Outcome.**
 - Amended to provide clarity.
- **1.5 Documentation.**
 - Updated to reflect procedures and records generated for each element.

UPDATES TO APPENDICES AND WORKSHEETS

- Appendix 1.1 Self-Assessment Worksheet.
 - Amended Appendix 1.1 to add new columns including Equivalent, Equivalent in Effect, and not Equivalent.
 - Added 21 CFR 117 Current Good Manufacturing Practice and Hazard Analysis and Risk Based Preventative Controls for Human Food.
 - Removal of the sections of the Code of Federal Regulations (CFRs) and Food Drug and Cosmetic Act listed in Appendix 1 that reference tobacco and tobacco products.

STANDARD TWO

NEWLY DEFINED TERMS

- Contact Hours
- Current Experienced Staff
- Evaluations
- Joint Field Training Inspections
- Newly Experienced Staff
- Qualified Field Inspection Trainer
- Qualified Date
- Start Date

NEW SECTIONS AND APPENDICES

- Section 2.3.1 Training Plan and Training Records
 - This is a new section in the Program Elements that moves the requirement for a written training plan out of the Requirement Summary and down into the elements.
- Section 2.3.2.3.2 under Field Training is new and is specific to inspectors who inspect non high risk food warehouses.
- Section 2.3.3.3 Experienced Inspectors
 - This is a new section that addresses how experienced staff may complete the training plan. The basis for this section was adapted from the 2013 Interpretation Document.
- Section 2.3.5 Coursework sources. Sources of where coursework may be obtained for basic, advanced, and continuing education where added.
- Appendix 2.1 – *Self Assessment Worksheet*
 - Appendix 2.1 is a self-assessment of the program elements in the Standard.
 - The 2013 Appendix 2.1 Self-Assessment Worksheet was renumbered in 2016 as Appendix 2.2.
- Appendix 2.4 - *Curriculum Example for Basic Food Inspector Training*
 - This new Appendix has been provided as an example curriculum consisting of available online courses which would meet the Basic Food Inspection Training Course Curriculum in 2.3.2.2.

UPDATES MADE TO THE STANDARD

- **2.1 Purpose.**
 - No change.
- **2.2 Requirement Summary.**
 - Amended to provide clarity and remove any program element requirements and place them within the Program Elements section.
- **2.3 Program Elements.**
 - A set time for completing Basic Field Training has been replaced with the requirement that an inspector complete Basic Field Training prior to conducting independent inspections. (2.3.2.3.4)
 - Added the option for state programs who wish to subdivide their basic course curriculum for inspectors who only inspect low risk warehouses. (2.3.2.3.2)

Manufactured Food Regulatory Program Standards – October 2016

- Advanced Food Inspection Training Coursework. The courses Traceback Investigations and Foodborne Illness Investigations are not subject to Advanced Field Training requirements. (2.3.3.1)
- Advanced Food Inspection Training Field Training. Two passing evaluations prior to independent inspections was modified to one passing evaluation prior to independent inspections and a second passing evaluation within one year. (2.3.3.2)
- Continuing education section was greatly expanded to parallel what was in the Voluntary National Food Regulatory Program Standards. (2.3.4)
- The requirement for two joint inspections as part of Continuing Education was removed.
- **2.4 Outcome.**
 - Amended to provide clarity.
- **2.5 Documentation.**
 - Updated to reflect procedures and records generated in each element.

UPDATES TO APPENDICES AND WORKSHEETS

- Appendix 2.2 *State Training Record Summary Worksheet* and Appendix 2.3 *Inspector Training Record* were updated to reflect changes within the program elements.

STANDARD THREE

NEWLY DEFINED TERMS

- Consumer Complaint
- Industry Complaint
- Recall Audit Checks
- Sampling Program

NEW SECTIONS AND APPENDICES

- 3.3.3 Inspection Report
 - Added a new section to Standard 3 that outlines what must be included in a written procedure for writing inspection reports. This section now aligns with Appendix 4.6 *Inspection Report Audit Form*.
- 3.3.7 Sampling Procedure
 - This is a new section to Standard 3 that outlines what must be included in a written sampling procedure. The elements included in this section were based on the Partnership for Food Protection's Food/Feed Testing Laboratories Best Practices Manual.
- 3.3.8 Records Retention
 - This is a new section which describes specific record requirements for Standard 3.
- No new appendices added.

UPDATES MADE TO THE STANDARD

- **3.1 Purpose.**
 - Amended to include the term “manufacturing.”
- **3.2 Requirement Summary.**
 - Amended to provide clarity and remove any program element requirements and place them within the Program Elements section.
- **3.3 Program Elements.**
 - Added the option for a state to use a FSMA based risk factor and classification criteria or to develop their own risk factor and classification criteria. (3.3.1.2)
 - Amended the language in section 3.3.2 Inspection Procedure to remove FDA specific terminology and include information on verification of equipment.
 - Reformatted section 3.3.4 and provided a reference to the PFP *Best Practices for Improving FDA and State Communication during Recalls* as a resource.
 - Renamed section 3.3.6 from “Food Industry Inspection Complaints” to “Complaints Resulting from State Program Inspection Activities” to reflect the intent of this section.
- **3.4 Outcome.**
 - Amended to provide clarity.
- **3.5 Documentation.**
 - Updated to reflect procedures and records generated for each element.

Manufactured Food Regulatory Program Standards – October 2016

UPDATES TO APPENDICES AND WORKSHEETS

- Modified Appendix 3.2- *Risk Classification Criteria for Food Plants* to reflect updated elements associated with risk factor and classification criteria and removed specific FDA terminology.

STANDARD FOUR

NEWLY DEFINED TERMS

- Field Inspection Audit
- Qualified Field Inspection Auditor
- Verification Audit Inspection

NEW SECTIONS AND APPENDICES

- No new sections added.
- Appendix 4.1 – *Self Assessment Worksheet*
 - The 2013 Appendix 4.1 *Self-Assessment Worksheet* was removed.
 - A new Appendix 4.1 – *Self Assessment Worksheet* was developed.

UPDATES MADE TO THE STANDARD

- **4.1 Purpose.**
 - Amended to provide clarity.
- **4.2 Requirement Summary.**
 - Amended to provide clarity and remove any program element requirements and place them within the Program Elements section.
- **4.3 Program Elements.**
 - Amended to list out separately the individual Program Element requirements.
 - Clarified that a written quality assurance protocol is required. (4.3.1)
 - Amended the Field Inspection Audit Program Element requirements to allow for use of Appendix 4.5 or a State audit form that meets the program elements in Standard 3, Program Element 3.3.2. (4.3.2)
 - The minimum number of Inspection Reports to be audited is now a scale based on the total number of inspections conducted in 12 months. (4.3.3)
 - The minimum number of Sample Reports to be audited is now a scale based on the total number of samples collected in 12 months. (4.3.4)
 - The criteria for when corrective action must be taken was clarified. (4.3.5)
- **4.4 Outcome.**
 - No change.
- **4.5 Documentation.**
 - Updated to reflect procedures and records generated in each element.

UPDATES TO APPENDICES AND WORKSHEETS

- Amended Appendix 4.6 *Inspection Report Audit Form* to align with State program inspection reports and match the requirements in Standard 3, section 3.3.3.
- Amended Appendix 4.7 *Sample Report Audit Form* to match the requirements in Standard 3, section 3.3.7.

STANDARD FIVE

NEWLY DEFINED TERMS

- Environmental Assessment
- Food Related Incidents
- Hazards
- Traceback
- Traceforward

NEW SECTIONS AND APPENDICES

- No new sections added.
- No new appendices added.

UPDATES MADE TO THE STANDARD

- **5.1 Purpose.**
 - Amended to provide clarity.
- **5.2 Requirement Summary.**
 - Amended to provide clarity and remove any program element requirements and place them within the Program Elements section.
 - Amended language to emphasize documented food emergency response procedures for surveillance, investigation, control and post-response in collaboration with other agencies and jurisdictions.
- **5.3 Program Elements.**
 - Amended to list separately food emergency response elements into the following areas: 1) coordination with other authorities, 2) surveillance, 3) investigation/environmental assessment, 4) control measures and 5) post response.
 - Amended MOU criteria have been updated to be in alignment with elements in section 5.3. (5.3.1.1)
 - Removed references to foodborne illness investigation “contracts and contractual agreements” and “service support agreements.” (5.3.1.2)
 - Expanded program elements to address coordination in all food-related incidents beyond foodborne illness and intentional tampering.
 - Added maintaining notification of food-related incidents in complaint log(s) or database(s). (5.3.2.2)
 - Amended language to emphasize collection of environmental versus epidemiological data during investigations. (5.3.3.2)
 - Tracebacks and traceforwards have been expanded from food implicated in a foodborne illness to foods containing a hazard. (5.3.3.3)
 - Amended to expand laboratory support for investigations from foodborne illness to all food-related incidents. (5.3.3.4)
 - Amended correlation and analysis of investigation data language to focus on environmental assessment data. Added antecedent to the identification of contributing factors in the investigation of foodborne illness, injury or outbreaks. (5.3.3.5)

Manufactured Food Regulatory Program Standards – October 2016

- Added industry education to enforcement and public notification as a strategy for control measures. Amended to expand the need for control measures from foodborne illness to all hazards. (5.3.4.1)
- Added language to focus on maintenance of environmental assessment findings and reports. (5.3.5.1)
- Added language to focus on sharing of environmental assessment investigation findings and reports with authorities responsible for reporting foodborne illness investigation contributing factors and antecedents to CDC. (5.3.5.2)
- Amended language to emphasize the distribution of recommendations from environmental assessments and investigation reports, when made, with stakeholders for prevention. (5.3.5.3)
- **5.4 Outcome.**
 - Amended to provide clarity.
- **5.5 Documentation.**
 - Updated to reflect procedures and records generated for each element.

UPDATES TO APPENDICES AND WORKSHEETS

- Appendix 5.1- *Self-Assessment Summary Report* has been updated to reflect updated elements in new format.
- Appendix 5.2 – *Sample MOU* has been removed.

STANDARD SIX

NEWLY DEFINED TERMS

- Critical Violations

NEW SECTIONS AND APPENDICES

- No new sections added.
- Appendix 6.1 – *Self Assessment Worksheet*
 - The 2016 Appendix 6.1 was redesigned into a self-assessment worksheet. Any required elements that were in the 2013 Appendix 6.1 were moved into the body of Standard 6.

UPDATES MADE TO THE STANDARD

- **6.1 Purpose.**
 - No change.
- **6.2 Requirement Summary.**
 - Amended to provide clarity and remove any program element requirements and place them within the Program Elements section.
- **6.3 Program Elements.**
 - Amended to provide a clear requirement for a written compliance and enforcement program. (6.3.1)
 - Removed the requirement to monitor “critical violators”.
 - Amended language throughout to provide clarification.
- **6.4 Outcome.**
 - Amended to remove “timeframes.”
- **6.5 Documentation.**
 - Updated to reflect procedures and records generated in each element.

UPDATES TO APPENDICES AND WORKSHEETS

- Appendix 6.2 *Calculation of the Level of Conformance to Compliance Procedures*, instead of a worksheet.
- Worksheet 6.2a *Performance Review of Enforcement Actions* is now a worksheet and not an Appendix.

STANDARD SEVEN

NEWLY DEFINED TERMS

- Outreach Activity Event

NEW SECTIONS AND APPENDICES

- No new sections added.
- Appendix 7.1 – *Self-Assessment Worksheet*
 - This is a new self-assessment worksheet.

UPDATES MADE TO THE STANDARD

- **7.1 Purpose.**
 - Amended to include the term “outreach activity event.”
- **7.2 Requirement Summary.**
 - Amended to provide clarity and remove any program element requirements and place them within the Program Elements section.
- **7.3 Program Elements.**
 - Amended to add a written procedure of methods that will be used for communication with the food industry stakeholders and consumers. (7.3.1)
 - Amended to add the requirement to document and evaluate Outreach Activity Events using Appendix 7.2 or equivalent form.
- **7.4 Outcome.**
 - Amended to include the term “outreach activity event.”
- **7.5 Documentation.**
 - Updated to reflect procedures and records generated in each element.

UPDATES TO APPENDICES AND WORKSHEETS

- The 2013 Appendix 7.1 was renumbered as 7.2.

STANDARD EIGHT

NEWLY DEFINED TERMS

- There are no new terms defined for this section.

NEW SECTIONS AND APPENDICES

- No new sections added.
- Appendix 8.1a – *Self Assessment Worksheet Instructions*
 - This new appendix was created provide clarity to Appendix 8.1.

UPDATES MADE TO THE STANDARD

- **8.1 Purpose.**
 - No change.
- **8.2 Requirement Summary.**
 - Amended to provide clarity and remove any program element requirements and place them within the Program Elements section.
- **8.3 Program Elements.**
 - Amended to condense and clarify 8.1 into three: Program Assessment, Staffing, and Equipment.
 - Amended language throughout to provide clarification and simplify.
- **8.4 Outcome.**
 - No change.
- **8.5 Documentation.**
 - Updated to reflect procedures and records generated in each element.

UPDATES TO APPENDICES AND WORKSHEETS

- Appendix 8.3 – *Inspection Equipment*
 - Added an additional column to indicate if equipment is expected to be verified. This is cross referenced with Standard 3, element 3.3.2.2.

STANDARD NINE

NEWLY DEFINED TERMS

- Assessments
- Conformance
- Current and Fit-for-Use
- Document Control
- Implementation
- Strategic Improvement Plan

NEW SECTIONS AND APPENDICES

- No new sections added.
- No new appendices added.

UPDATES MADE TO THE STANDARD

- **9.1 Purpose.**
 - Amended to provide clarity.
- **9.2 Requirement Summary.**
 - Amended to provide clarity and remove any program element requirements and place them within the Program Elements section.
- **9.3 Program Elements.**
 - Amended to include a written document control procedure. (9.3.2.1)
 - Removed the three-year record retention requirement from Standard 3 to Standard 9 and expended it to include previous version of standard operating procedures. (9.3.2.2)
 - Amended to include new language to clarify that a state’s record retention laws or specific language in another Standard may supersede the 3-year requirement. (9.3.2.2)
 - Amended to include new requirements for the strategic plan including: personnel responsible and date completed. (9.3.3.4 and 9.3.3.5).
 - Amended to include an annual review and update to appendices and strategic improvement plan. (9.3.4)
 - Amended to change the term “FDA Assessments” to “FDA Program Assessment Validation Audit” and “comprehensive program audit.” (9.3.5)
 - Removed the audit procedure and the 18, 36 and 60 month PAVA and audit timeframes. (9.3.5)
 - Added a requirement to address FDA assessment observations and to add corrective actions to the strategic plan, if necessary. (9.3.5)
- **9.4 Outcome.**
 - No change.
- **9.5 Documentation.**
 - Updated to reflect procedures and records generated in each element including: strategic plans, document control procedures, record retention rules, policies and procedures and FDA assessment reports.

Manufactured Food Regulatory Program Standards – October 2016

- Added new language to clarify that documents may be maintained either manually or electronically.
- Moved the term “Completed self-assessment appendices” and “Documents, records and supporting documents” from Standard 9 to the respective standards.

UPDATES TO APPENDICES AND WORKSHEETS

- Appendix 9.1- *Self-Assessment Summary Report*
 - No change.

STANDARD TEN

NEWLY DEFINED TERMS

- Primary Servicing Laboratory

NEW SECTIONS AND APPENDICES

- 10.3.2 Non-ISO Accredited Laboratories.
 - This is a new addition to the Program Elements that describes requirements for labs that do not have an ISO Accreditation.
- No new appendices added.

UPDATES MADE TO THE STANDARD

- **10.1 Purpose.**
 - No change.
- **10.2 Requirement Summary.**
 - Amended to provide clarity and remove any program element requirements and place them within the Program Elements section.
- **10.3 Program Elements.**
 - Amended to include the requirement to outline what should be in a contract or written agreement with a primary servicing laboratory. (10.3.1.3)
 - Added the requirement for documentation from non-primary servicing laboratories and what a list of constitutes adequate documentation. (10.3.1.3)
 - Added the requirement for state food programs that use laboratories holding ISO/IEC 17025:2005 or current version to be accredited by a body that is full signatory to the ILAC Mutual Recognition Arrangement (MFA). (10.3.2)
 - Added a list of procedures is now included in which the servicing laboratory will need to meet, for state food programs that do not use laboratories holding ISO/IEC 17025:2005 or current version. (10.3.3)
- **8.4 Outcome.**
 - No change.
- **10.5 Documentation.**
 - Updated to reflect procedures and records generated in each element.

UPDATES TO APPENDICES AND WORKSHEETS

- Appendix 10.1 *Self-Assessment Worksheet*.
 - All changes made in in 10.3 Program Elements are reflected in Appendix 10.1 *Self-Assessment Worksheet*.