

Manufactured Food Regulatory Program Standards

September 2022

Summary of Changes



The collection of information has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 and has been assigned OMB control number 0910-0601.

A copy of the standards is available on the [MFRPS site](#).

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SUMMARY OF CHANGES

This summary provides a synopsis of the changes made to the 2022 Manufactured Food Regulatory Program Standards (MFRPS). The primary intent of this summary document is to provide a broad overview of substantive changes found in the 2022 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. Refer to the 2022 MFRPS for detailed change information.

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

The 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 MFRPS. Changes may be proposed by the 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 the FDA to consider.

CHANGES MADE THROUGHOUT THE MFRPS

There were several updates and changes made to the 2022 MFRPS to improve program effectiveness, understanding, and clarity which are highlighted. Changes voted and approved by the MFRPA may be accessed on the [MFRPS Index of Shared Documents and Best Practices](#) by clicking the appropriate workgroup “Button” at the top of the page. Changes throughout this document are italicized and shown in blue. Numerous edits for uniformity and clarity were made to the 2022 MFRPS that are not included in this summary of changes document. For example, the term “manufactured food firm” is now used consistently throughout the document rather than “food firms” or “establishments”.

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DEFINITIONS

- **New Definitions**

- **NO AUTHORITY**: responsibility for enforcing a specific section of the federal statutes and/or regulations lies with another program or agency and not the state program. There is such a state law, but it does not apply to the state's program.
- **CORRECTION**: action to eliminate a detected non-CONFORMITY.
- **CORRECTIVE ACTION(S)**: action to eliminate the cause of a non-CONFORMITY and to prevent recurrence.

- **Revised Definitions**

- **EVALUATION**: This definition was modified to say, "Evaluations are required for *basic* and each *advanced (specialized) inspection type*". In addition, the evaluation should assess an inspector's ability to "Assess *advanced (specialized) inspection types* (as applicable)". Other required elements during an evaluation remain the same. References to use of the Appendix 4.5 Field Audit Form have been changed to the *Appendix 4.3 Field Inspection* Audit Form.
- **FIELD INSPECTION AUDIT**: The definition was modified to say an inspector is accompanied by a QUALIFIED *FIELD INSPECTION AUDITOR*, rather by a QUALIFIED AUDITOR.
- **NOT EQUIVALENT**: The definition was modified to remove "there is such a state law but it does not apply to the State's food plan or manufacturing establishment program". The modified definition has been revised to the following:
 - 1) there is no state law EQUIVALENT to the relevant federal law or regulation, or 2) the federal and state laws address the same matter but are inconsistent and do not have the same regulatory effect.
- **QUALIFIED FIELD INSPECTION AUDITOR**: This definition was modified to include reference to advanced food inspection training coursework and field training to include low-acid *canned* foods.
- **QUALIFIED FIELD INSPECTION TRAINER**: This definition was modified to include reference to advanced food inspection training coursework and field training to include low-acid *canned* foods.
- **TRACEBACK**: This is an existing term in the definitions. However, the definition has been revised to the following:
 - *traceback begins at the end of the supply chain at the point of purchase or point of service (e.g., grocery stores and restaurants) and follows the food product back through the points of distribution, processing, and production to determine the source of the product and its ingredients.*

- **TRACEFORWARD:** This is an existing term in the definitions. However, the definition has been revised to the following:
 - *traceforward follows the movement of a food in the opposite direction, from the source (e.g., a farm or manufacturer) forward to the retail shelf, to determine the scope of a potential recall and the impact of the contaminated product on the public health.*
- **VERIFICATION AUDIT INSPECTION:** This definition was modified to say it is an inspection in which an FDA or state **QUALIFIED FIELD INSPECTION AUDITOR** observes a state **QUALIFIED FIELD INSPECTION AUDITOR** performing an audit of a state inspector conducting an inspection.
- **START DATE:** This definition was modified to say it is the date *an employee is hired or assigned to* the manufactured food program *as the beginning date for training timelines.*
- **Removed Definitions**
 - **HIGHLY SUSCEPTIBLE POPULATION:** This term was removed as it was only referenced via the previous appendix 3.2 which is now a *job aid.*

STANDARD 1 – REGULATORY FOUNDATION

DEFINITIONS

- **New Definitions**
 - **NO AUTHORITY**
- **Revised Definitions**
 - **NOT EQUIVALENT**

UPDATES MADE TO THE STANDARD

- **1.1 – Purpose:** No Changes
- **1.2 – Requirement Summary:** No Changes
- **1.3 – Program Elements:**
 - 1.3.2, “REGULATORY FOUNDATION Assessment” has been revised as follows:
 - The state program must complete Appendix 1.2 or equivalent form. The state program conducts a baseline self-assessment to determine if they are EQUIVALENT, EQUIVALENT IN EFFECT, NOT EQUIVALENT *or have NO AUTHORITY* to sections of the current Federal Food, Drug, and Cosmetic Act (FD&C Act) and Code of Federal Regulations (CFR) Title 21 specified in Appendix 1.2.
 - The following statement was removed from section 1.3.2: “If the State program has not adopted the current version of a CFR provision the State must provide the revision date of the CFR that was adopted for each regulation”.

- **1.4 – Outcome:** No changes
- **1.5 – Documentation:** No changes

APPENDICES

- **New Appendices:** None
- **Revised Appendices:**
 - Appendix 1.1, “Self-Assessment Worksheet”, was revised to remove “Revision date of the CFR that was adopted for each regulation if the State Program has not adopted the current version of a CFR provision”, under 1.3.2.
 - Appendix 1.2, “Regulatory Foundation Worksheet”, was previously titled, “Statutes and Regulations Worksheet”. Additional revisions include the following:
 - The addition of drop-down options added for documenting whether state laws and regulations are EQUIVALENT, EQUIVALENT IN EFFECT, NOT EQUIVALENT *or NO AUTHORITY* to sections of the current Federal Food, Drug, and Cosmetic Act (FD&C Act) and Code of Federal Regulations (CFR) Title 21.
 - The addition of *21 CFR 1*; Foreign Supplier Verification Program (Subpart L §1.500 – 1.514).
 - The addition of *21 CFR 121*, Mitigation Strategies to Protect Food From Intentional Adulteration.
- **Removed Appendices:** None

STANDARD 2 – TRAINING PROGRAM

DEFINITIONS

- **New Definitions:** None
- **Revised Definitions**
 - **EVALUATION**
 - **FIELD INSPECTION AUDIT**
 - **QUALIFIED FIELD INSPECTION AUDITOR**
 - **QUALIFIED FIELD INSPECTION TRAINER**
 - **START DATE**

UPDATES MADE TO THE STANDARD

- **2.1 – Purpose:** No Changes
- **2.2 – Requirement Summary:** No Changes
- **2.3 – Program Elements:**
 - 2.3.2, “Basic Food Inspection Training”, has been revised as follows:
 - 2.3.2.2.10, “Food defense”
 - The words “awareness training” have been removed.
 - 2.3.3, “Advanced Food Inspection Training”, coursework requirements have been revised as follows:

- 2.3.3.1.7, “*Preventive Controls for Human Food*”, has been added.
 - 2.3.4, “Experienced Inspectors” requirements for CURRENT EXPERIENCED STAFF have been revised as follows:
 - 2.3.4.1.2, “Basic *food inspections* course work”, was previously titled, “Basic Course Work”.
 - 2.3.4.1.3, “Specialized food inspection course work certificates”, has been revised as follows:
 - “Documentation in the Employee Training File” will now include “Statement or affidavit explaining the date and location that they have successfully completed the specialized *food inspection* training *course work*”.
- **2.4 – Outcome:** No changes
- **2.5 – Documentation:** No changes

APPENDICES

- **New Appendices:** None
- **Revised Appendices:** None
- **Removed Appendices:**
 - Appendix 2.4, “Curriculum Example Basic Food Inspector Training”, has been reclassified as a *job aid*.

STANDARD 3 – INSPECTION PROGRAM

DEFINITIONS

- No changes

UPDATES MADE TO THE STANDARD

- **3.1 – Purpose:** No changes
- **3.2 – Requirement Summary:** No changes
- **3.3 – Program Elements:**
 - 3.3.2, “Inspection Procedure”, has been revised as follows:
 - 3.3.2.14, “*Properly evaluate good manufacturing practice requirements (21 CFR 117, Subparts A, B, and F (for training records only) or equivalent state regulation)*”.
 - 3.3.2.15, “*When appropriate, verify the manufactured food firm has a written food safety plan which includes a written HAZARD analysis that appropriately addresses HAZARDS, and when appropriate, addresses preventive controls (process controls, allergen controls, sanitation controls, supply-chain controls, other controls) and a recall plan*”.
 - 3.3.2.16, “*When appropriate, review the manufactured food firm’s written procedures, monitoring, verification, correction, and corrective action records for process, allergen, sanitation, supply-chain controls, and other controls which are identified in their food safety plan*”.
 - 3.3.2.17, “*When appropriate, verify the manufactured food firm is in compliance with the modified requirements that apply to a*

- *described in section 9.3.2*".
- 4.3.2, "FIELD INSPECTION AUDIT", has been revised as follows:
 - 4.3.2.3, "*State programs may use the current Form FDA 3610 in lieu of Appendix 4.3*".
- 4.3.5, "*CORRECTIVE ACTION*", was previously titled "Corrective Action Plan". This section was revised as follows: "The state program *shall initiate CORRECTIVE ACTIONS as described in 9.3.2 when the FIELD INSPECTION AUDIT, inspection report audit, or sample report audit meets one or more of the conditions below...*". Additional revisions include the following:
 - 4.3.5.2, "A single performance factor for the program falls below 80%, *or four or more 'needs improvement' ratings are identified in a single performance factor. Note that if fewer than four audits are conducted, a performance deficiency may be considered for a single performance factor that 'needs improvement'*".
- **4.4 – Outcome:** No changes
- **4.5 – Documentation:** No changes

APPENDICES

- **New Appendices:** None
- **Revised Appendices:**
 - Appendix 4.1, "Self-Assessment Worksheet", has been revised as follows:
 - 4.3.1, "Quality Assurance", was revised to include the requirement for initiating CORRECTIVE ACTION(S) to be documented on the STRATEGIC IMPROVEMENT PLAN as described in 9.3.2.
 - 4.3.5, "CORRECTIVE ACTIONS", was revised to included updated performance factor requirements.
 - Appendix 4.2, "*Instructions for Performance Ratings of Audit Findings*", is a combination of the prior Appendix documents (4.2a, 4.3a, and 4.4a) for the summary of audit findings for field inspection audits, inspection reports, and sample reports. The prior Appendix documents 4.2a, 4.3a, and 4.4a have been removed.
 - Appendix 4.3, "*Field Inspection Audit Form*", was previously identified as Appendix 4.5. This Appendix has additionally been revised to include inspectional elements related to inspections conducted under 21 CFR 117, as well as for the evaluation of sanitary transportation practices and food defense plans, as appropriate.
 - Appendix 4.3a, "*Summary of Field Inspection Audit Findings*", was previously identified as Appendix 4.2, "Performance Rating for the Field Inspection Audits".
 - Appendix 4.4, "Inspection Report Audit Form", was previously identified as the Appendix 4.6.
 - Appendix 4.4a, "*Summary of Inspection Report Audit Findings*", was previously identified as the Appendix 4.3, "Performance Rating for Inspection Report Audits".
 - Appendix 4.5, "Sample Report Audit Form", was previously identified as

the Appendix 4.7. Additional revisions include the following:

- 1.1, “Method of collection *and equipment* was appropriate”.
- Appendix 4.5a, “*Summary of Sample Report Audit Findings*”, was previously identified as the Appendix 4.4, “Performance Rating for the Sample Report Audits”.
- **Removed Appendices:**
 - The prior Appendix 4.5a, “Guidance for Completing the Contract Audit Form (FORM FDA 3610)”, has been reclassified as a *job aid*.
 - The prior Appendix 4.8, “Corrective Action Plan”, has been removed.

STANDARD 5 – FOOD RELATED ILLNESS, OUTBREAK AND HAZARDS RESPONSE

DEFINITIONS

- **New Definitions:** None
- **Revised Definitions:**
 - TRACEBACK
 - TRACEFORWARD

UPDATES MADE TO THE STANDARD

- **5.1 – Purpose:** No changes
- **5.2 – Requirement Summary:** No changes
- **5.3 – Program Elements:** No changes
- **5.4 – Outcome:** No changes
- **5.5 – Documentation:** No changes

APPENDICES

- No changes

STANDARD 6 – COMPLIANCE AND ENFORCEMENT PROGRAM

DEFINITIONS

- No changes

UPDATES MADE TO THE STANDARD

- **6.1 – Purpose:** No changes
- **6.2 – Requirement Summary:** No changes
- **6.3 – Program Elements:**
 - 6.3.1, “Compliance and Enforcement Program”, has been revised to remove the requirement for having “a system to communicate policy and guidance to managerial and non-managerial staff”.
 - 6.3.2, “Performance Review”, has been revised as follows:
 - 6.3.2.4, “Require a CORRECTIVE ACTION if performance ratings fall below 80%, *which will be documented on the STRATEGIC*”

IMPROVEMENT PLAN as described in 9.3.2".

- **6.4 – Outcome:** No changes
- **6.5 – Documentation:** No changes

APPENDICES

- No changes

STANDARD 7 – INDUSTRY AND COMMUNITY RELATIONS

DEFINITIONS

- No changes

UPDATES MADE TO THE STANDARD

- **7.1 – Purpose:** No changes
- **7.2 – Requirement Summary:** No changes
- **7.3 – Program Elements:** No changes
- **7.4 – Outcome:** No changes
- **7.5 – Documentation:** No changes

APPENDICES

- No changes

STANDARD 8 – PROGRAM RESOURCES

DEFINITIONS

- No changes

UPDATES MADE TO THE STANDARD

- **8.1 – Purpose:** No changes
- **8.2 – Requirement Summary:** No changes
- **8.3 – Program Elements:**
 - 8.3.1, "Program Assessment", has been revised to say the "state program completes the *Resource Summary Report* to assess staffing, funding, and equipment using the Appendix *8.2* or equivalent form".
 - 8.3.2, "Staffing", has been revised to say, "The state program conducts *and documents the* calculation for determining *the* required number of inspectors *to inspect manufactured food firms in its manufactured food firm* inventory at a frequency that is based on the *manufactured food firm's* risk classification and the necessary inspection and travel time".
- **8.4 – Outcome:** No changes
- **8.5 – Documentation:**
 - 8.5.3, "*Documentation of the calculation of number of inspectors*"
 - 8.5.4, "*List of equipment used for inspections and sample collections*".

APPENDICES

- **New Appendices:**
 - Appendix *8.1*, "Self-Assessment Worksheet", has been created to serve as

a true self-assessment worksheet.

- **Revised Appendices:**
 - Appendix 8.2, “*Resource Summary Report*”, was previously identified as Appendix 8.1, “Self-Assessment Worksheet”.
 - Appendix 8.2a, “*Resource Summary Report Instructions*”, was previously identified as Appendix 8.1a, “Self-Assessment Worksheet Instructions”.
- **Removed Appendices:**
 - The prior Appendix 8.2, “Calculation for Determining a Number of Inspectors”, has been reclassified as a **job aid**. The information in this document has been modified to include the risk classification criteria described in the FD&C Act, Section 421(a)(1).
 - The prior Appendix 8.3, “Inspection Equipment”, has been renamed the “List of equipment used for inspections and sample collections”. This document has also been reclassified as a **job aid**.

STANDARD 9 – PROGRAM ASSESSMENT

DEFINITIONS

- **New Definitions:**
 - **CORRECTION**
 - **CORRECTIVE ACTION(S)**
- **Revised Definitions:** None

UPDATES MADE TO THE STANDARD

- **9.1 – Purpose:** No changes
- **9.2 – Requirement Summary:**
 - 9.2, “Requirement Summary”, has been revised as follows: “Subsequent self-assessments *and FDA ASSESSMENTS* are used to track progress toward meeting and maintaining CONFORMANCE with the program standards *or identifying any non-CONFORMANCE when the program was previously in CONFORMANCE with the standards*”.
- **9.3 – Program Elements:**
 - 9.3.2 STRATEGIC IMPROVEMENT PLAN requirements have been revised as follows: “If the state program fails to meet any of the program elements and documentation requirements of a standard, *whether identified through self-assessment or FDA ASSESSMENTS, the program shall develop or update a* written STRATEGIC IMPROVEMENT PLAN that includes the following information (as applicable)”. Additional revisions include the following:
 - 9.3.2.2, “Improvement *or CORRECTIONS* needed to meet the program element or documentation requirement of the standard”.
 - 9.3.2.3, “*The cause for any non-CONFORMANCE requiring CORRECTION when the program was previously in CONFORMANCE with the individual element or documentation requirement of a standard*”.
 - 9.3.2.4, “*The CORRECTIVE ACTION taken to prevent future*

similar non-CONFORMANCE when the program was previously in CONFORMANCE with the individual element or documentation requirement of the standard that was corrected”.

- **9.4 – Outcome:** No changes
- **9.5 – Documentation:** No changes

APPENDICES

- **New Appendices:**
 - Appendix **9.1**, “Self-Assessment Worksheet”, has been created to serve as a true self-assessment worksheet.
- **Revised Appendices:**
 - Appendix **9.2**, “Self-Assessment Summary Report”, was previously identified as Appendix 9.1.
- **Removed Appendices:** None

STANDARD 10 – LABORATORY SUPPORT

DEFINITIONS

- No changes

UPDATES MADE TO THE STANDARD

- **10.1 – Purpose:** No changes
- **10.2 – Requirement Summary:** No changes
- **10.3 – Program Elements:**
 - 10.3.2, “ISO Accredited Laboratories”, has been revised to identify laboratory accreditation as “ISO/IEC 17025:2017 *(or current version)*”.
 - 10.3.3, “Non-ISO Accredited Laboratories”, has been revised to clarify laboratories not holding “ISO/IEC 17025:2017 *(or current version)*” accreditation.
- **10.4 – Outcome:** No changes
- **10.5 – Documentation:**
 - 10.5.5 has been revised as follows: “ISO Accredited Laboratory: ISO/IEC 17025:2017 *(or current version)* Certificate and Scope of Accreditation”. Reference to accreditation to the ISO/IEC 17025:2005 standards has been removed.

APPENDICES

- No changes