# Manufactured Food Regulatory Program Standards

# September 2019

---

# Summary of Changes

---

**U.S. Department of Health and Human Services**
**Food and Drug Administration**
**Office of Regulatory Affairs**

**OMB Control No. 0910-0601**
**Expiration Date: 09-30-2022**

## SUMMARY OF CHANGES

This summary provides a synopsis of the changes made to the 2019 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 2019 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

There were no extensive and/or significant changes made throughout the 2019 MFRPS Standard. However, there were several changes made to improve understanding and clarity which are highlighted below. Please refer to the MFRPA documented changes approved by vote on April 10, 2019 for full and detailed list of changes. The MFRPA approved changes document 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: http://mfrpaindex.afdo.org/fppp/

## CHANGES MADE TO DEFINITIONS

12. Evaluation:  In the last paragraph of the definition, the following sentence was removed. "*Two successful evaluations must be completed prior to conducting independent inspection*".

## STANDARD ONE – REGULATORY FOUNDATION

**NEWLY DEFINED TERMS**
- None

**NEW SECTIONS AND APPENDICES**
- None.
- New appendices added (1.1) and renumbered (1.2).
    - Amended and updated Appendix 1.1 As a true Self-Assessment Worksheet.
    - Amended and updated the title/number of the previous Appendix 1 Worksheet to the new Appendix 1.2. The Appendix remained the same.

**UPDATES MADE TO THE STANDARD**
- **1.1 Purpose.**
    - No change
- **1.2 Requirement Summary**.
    - No change
- **1.3 Program Elements**.
    - Amended 1.3.2.1 to include accurate reference from the previous Appendix 1 to the new Appendix 1.2.
    - Amended 1.3.2.2 to include and update the reference from the previous Appendix 1 to the new Appendix 1.2

- **1.4 Outcome.**
    - No change

- **1.5 Documentation.**
    - Amended and added 1.5.4 Appendix 1.1 the new Self-Assessment Worksheet.
    - Amended and added 1.5.5 Appendix 1.2 Statutes and Regulations Worksheet or equivalent form.
    - Amended and added 1.5.6 number, statement remained the same.

**UPDATES TO APPENDICES AND WORKSHEETS**
- Amended and updated Appendix 1.1 As a true Self-Assessment Worksheet.
- Amended and updated the title/number of the previous Appendix 1 Worksheet to the new Appendix 1.2. The Appendix remained the same.

## STANDARD TWO - Training Program

**NEWLY DEFINED TERMS**

- None

**NEW SECTIONS AND APPENDICES**

- None

**UPDATES MADE TO THE STANDARD**

- **2.1 Purpose.**
    - No change
- **2.2 Requirement Summary**.
    - No change
- **2.3 Program Elements**.
    - No change
- **2.4 Outcome.**
    - No change
- **2.5 Documentation.**
    - Amended to include 2.5.9, a "*Written Training Plan*".

**UPDATES TO APPENDICES AND WORKSHEETS**

- No change

## STANDARD THREE – Inspection Program

**NEWLY DEFINED TERMS**

- None

**NEW SECTIONS AND APPENDICES**

- New Section: None
- Amended Appendix 3.1 for additional clarity for sampling elements.
    - Appendix 3.1 was amended, specifically section 3.3.7 to include an expanded list of sampling criteria as referenced in the Standard.

**UPDATES MADE TO THE STANDARD**

- **3.1 Purpose.**
    - No change
- **3.2 Requirement Summary**.

- o No change
- **3.3 Program Elements**.
  - o Amended 3.3.1 to remove the words "safety or defense" and add the word *RELATED to the term "Food Related Incident"*. The term *Food Related Incident* remains a defined term in the definition section.
  - o Amended 3.3.7.2 to remove the words "unless specified by" and add the words "*elements when applicable to*".
- **3.4 Outcome.**
  - o No change
- **3.5 Documentation.**
  - o No change

**UPDATES TO APPENDICES AND WORKSHEETS**
- Appendix 3.1 was amended, specifically section 3.3.7 to include an expanded list of sampling criteria as referenced in the Standard.

## STANDARD FOUR - Inspection Audit Program

**NEWLY DEFINED TERMS**
- None

**NEW SECTIONS AND APPENDICES**
- New Section: None
- Amended Appendix 4.6 (Inspection Report Audit Form) #4 to add clarity to the procedures an inspector uses during an audit.
  - o Amend Appendix 4.6 (Inspection Report Audit Form) #4 to add clarity to the procedures an inspector uses during an audit. New language is "*The inspector followed all current and applicable state report writing and inspectional documentation procedures*".

**UPDATES MADE TO THE STANDARD**
- **4.1 Purpose.**
  - o No change
- **4.2 Requirement Summary**.
  - o No change
- **4.3 Program Elements**.
  - o No change
- **4.4 Outcome.**
  - o No change

- **4.5 Documentation.**
  - o No change

## UPDATES TO APPENDICES AND WORKSHEETS
  - o Amended Appendix 4.6 (Inspection Report Audit Form) #4 to add clarity to the procedures an inspector uses during an audit. New language is "*The inspector followed all current and applicable state report writing and inspectional documentation procedures*".

## STANDARD FIVE – Food Related Illness, Outbreak and Hazards Response

- There were no changes to Standard Five.

## STANDARD SIX – Compliance and Enforcement Program

- There were no changes to Standard Six.

## STANDARD SEVEN – Industry and Community Relations

- There were no changes to Standard Seven.

## STANDARD EIGHT – Program Resources

- There were no changes to Standard Eight.

## STANDARD NINE – Program Assessment

## NEWLY DEFINED TERMS
- None

## NEW SECTIONS AND APPENDICES
- New Sections: None
- Appendices: No new Appendix, however there were recommended changes to the Appendix 9.1 Instruction document regarding the self-assessment "calculation of hours used" section, which are not a part of the Standard.
  - o Appendices: No new Appendix, however there were proposed changes to the Appendix 9.1 Instruction document regarding the self-assessment "calculation of hours used" section, which are not a part of the Standard. Examples were provided in the Appendix 9.1 instruction document to help programs better

understand how to calculate the "hours used" section. *Note: This proposed change was made to the instruction document not to the Standard.*

**UPDATES MADE TO THE STANDARD**

- **9.1 Purpose.**
  - No change
- **9.2 Requirement Summary**.
  - No change
- **9.3 Program Elements**.
  - Amend 9.3.2.1 to provide greater clarity on what is required for Document Control.
- **9.4 Outcome.**
  - No change
- **9.5 Documentation.**
  - No change

**UPDATES TO APPENDICES AND WORKSHEETS**

- Appendices: No new Appendix, however there were proposed changes to the Appendix 9.1 Instruction document regarding the self-assessment "calculation of hours used" section, which are not a part of the Standard. Examples were provided in the Appendix 9.1 instruction document to help programs better understand how to calculate the "hours used" section. *Note: This proposed change was made to the instruction document not to the Standard.*

## STANDARD TEN – Laboratory Support

**NEWLY DEFINED TERMS**

- None

**NEW SECTIONS AND APPENDICES**

- New Sections: None
- Appendices: Appendix 10.1 was amended to include clarifying information regarding ISO/IEC 17025 (2005 version) accreditation and the movement towards ISO/IEC 17025 (2017 version). Changes clarify that a program can be ISO accredited by the 2005 or the 2017 versions for now.
  - Appendix 10.1
    - Amend 10.3.2 to include use of either ISO/IEC 17025 (2005 or 2017) versions.
    - Amend 10.3.3 to include use of either ISO/IEC 17025 (2005 or 2017) versions.

- Amend 10.3.3 #1 to remove the term "Quality Manual".
- Amend 10.3.3 #2 to remove the terms "documented process" and replace with the term "Procedure".

## UPDATES MADE TO THE STANDARD

- **10.1 Purpose.**
  - No change
- **10.2 Requirement Summary**.
  - No change
- **10.3 Program Elements**.
  - Amended 10.3.2 to add clarity to include both ISO/IEC 17025 accrediting versions (2005 and 2017) would be acceptable.
  - Amended the area below 10.3.2 to add a "Note" was added to inform the reader that ISO/IEC 17025 (2005 version), will be invalid after November 30, 2020 per ILAC.
  - Amended 10.3.3 to include language updates to provide clarity in the terms and statements of laboratory quality systems.

- **10.4 Outcome.**
  - No change

- **10.5 Documentation.**
  - Amended 10.5.6 to include clarity and allow for the use of ISO/IEC 17025 (2005 or 2017 versions) for accreditation.
  - Amended 10.5.6.1 to remove the term "Quality Manual" and replaced with the term "Documented Quality System"
  - Amended 10.5.6.5 to remove "Process for References" and replacing the language with "Process for Ensuring Validity of Results (including but not limited to Reference materials and or Proficiency Testing)".
  - Amended 10.5.6.6 to remove "Process for Proficiency Testing Activities".

## UPDATES TO APPENDICES AND WORKSHEETS

- Appendices: No new Appendix, however there were changes to the Appendix 10.1.
  - Appendix 10.1
    - Amend 10.3.2 to include use of either ISO/IEC 17025 (2005 or 2017) versions.
    - Amend 10.3.3 to include use of either ISO/IEC 17025 (2005 or 2017) versions.
    - Amend 10.3.3 #1 to remove the term "Quality Manual".
    - Amend 10.3.3 #2 to remove the terms "documented process" and replace with the term "Procedure".