

**Minnesota Department of Agriculture  
Food and Feed Safety Division**

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Title: <b>Document Development and Control</b>	

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**1. PURPOSE**

This document describes the procedure for developing, implementing, and controlling all documents developed by Manufactured Food Program, Retail Food Program, Compliance Unit, Response, Training, and Outreach Unit, Business and Quality Management Unit, Administrative Support Unit, and the Food and Feed Safety Division (FFSD).

**2. SCOPE**

This procedure applies to all official documents and related documents produced by the Manufactured Food Program, Retail Food Program, Compliance Unit, Response, Training, and Outreach Unit, Business and Quality Management Unit, and the Food and Feed Safety Division. This procedure does not apply to documents created for the Feed Program. Refer to *FEED.9.01 – Document Development and Control SOP* for feed specific procedures. **Standard Operating Procedures developed using this procedure will superseded any existing division General or Policy memos. These General or Policy memos are considered null and void unless specifically accepted in writing by the Division Director.**

**3. BACKGROUND**

FFSD develops numerous official documents including Policies, Standard Operating Procedures (SOPs), Work Instructions, and related documents such as forms, guidance, appendices, and references. As described in *FFSD.POLICY.90.06 – Document Development and Control Policy*, FFSD uses parent documents as the main document to control and the related documents are attached to the parent documents.

Consistent document development and control is critical to the foundation of the programs and units. Standard operating procedures are written to describe processes in sufficient detail as to ensure the quality and integrity of the work completed and to serve the following functions:

- a) Document established procedures that lead to quality and consistent work;
- b) Provide staff with references for specific tasks;
- c) Construct checklists and quality controls for inspections and audits;
- d) Help management evaluate the adequacy of the procedures;

To achieve these functions, SOP's must be written by an individual experienced in the process to be described; the completed SOP's then must be reviewed and approved by peer reviewers and appropriate management prior to the use of the SOP. A defined format in styling, information

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required, and a numbering system is needed, as well as a periodic review process to ensure that the procedure is up-to-date.

The division is enrolled in three sets of standards: the Manufactured Food Regulatory Program Standards (MFRPS), Retail Food Regulatory Program Standards (RFRPS), and Animal Feed Regulatory Program Standards (AFRPS). The standards create the base for documents required to be created. The division also creates documents for other process in division that fall outside the requirements of the standards such as administrative tasks and program management.

#### 4. **RESPONSIBILITY**

**Approving Authority:** The Approving Authority will review all submitted parent documents, conduct a review of the document and contact the document manager with concerns or questions, sign and date the document, and approve the documents in SharePoint. The approving authority is defined by the division based on the purpose and scope of the document.

**Division Director:** The Division Director will approve procedures and oversee the implementation of procedures related to the entire division, multiple units and programs, or when the program manager is the author of the document. The Division Director will also support the division in resources and training required to maintain controlled documents for all of FFSD.

**Document Coordinator:** The Document Coordinator will contact the Document Manager when a draft document or update to an approved document is needed, identify content requirements based on Program needs and standard requirements, identify workgroup members (Document Developers) to assist with content development, verify workgroup members are utilizing the identified working controlled document during development, and communicate progress to the Document Manager.

**Document Developer:** The Document Developer will participate in workgroup meetings as requested, provide expertise related to the content of the document, complete document development tasks by agreed upon timeframes, utilize the identified working controlled document to during development, and conduct reviews of working and final documents.

**Document Manager:** The Document Manager will manage all draft, approved, and rescinded (archived) documents in SharePoint. The Document Manager will help document developers and coordinators create controlled documents using approved templates, compare document content to standard requirements, provide support and feedback throughout document development, create final document set for final review by Quality Manager and Approving Authority, submit final version of document to approving authority, and notify the Training Coordinator and Training and Standards Analyst that the document is ready for training.

**FFSD Staff:** FFSD staff will use the most current versions of documents located on SharePoint, complete assigned training on documents by the due date, and discard any saved or printed documents that have been achieved or rescinded.

**Retail Food and Manufactured Food Program Managers:** The Food Program Managers will review program specific procedures, act as the approving authority for program specific documents (not authored by the program manager), and oversee the implementation and training of program staff.

**Quality Manager:** The Quality Manager will verify documents follow document development and control procedures and policies, could be followed by someone with the assigned responsibilities, and meet Standard requirements and use standard language as possible. The

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Quality Manager will also identify any inconsistencies or issues in the documents (especially if there is overlap with other procedures).

**Supervisors:** Each Supervisor will ensure all staff in their respective program areas are trained in changes to documentation policies and act as the approving authority for unit specific procedures.

**Training Coordinator (TA) and Training and Standards Analyst (TSA):** The TC/TSA will create training for all newly approved PARENT DOCUMENTS, follow-up with staff that have not completed training in the assigned time.

## 5. DEFINITIONS

**Attachments/ Appendices:** are an extension to a PARENT DOCUMENT. That provide further detail and directions for specific sections of the parent document. They may also be diagrams or charts.

**Required Approver (Approving Authority):** is the employee within the division with the most senior position authority based on the scope of the procedure. The approving authority may not be the Document Coordinator (main author).

**Current and Fit-for-Use:** “current” indicates that documentation is signed and dated in accordance with division policies and procedures that meet criteria in the most current standards. “Fit-for-Use” is a quality term used to indicate that a product or service fits the customer’s defined purpose for that product or service. Documentation will be electronic.

**Document control:** established process whereby documents are reviewed for adequacy, approved for release by authorized personnel and distributed to and used at the location where the prescribed activity is performed.

**Draft Documents:** unapproved version of official documents marked by large draft watermarks and stored in a location with limited access to only developers, reviewers, and approvers.

**Effective Date:** the date established by the Approving Authority for distribution and implementation of a document.

**External Documents:** is a document created and managed outside of FFSD but are used by FFSD. If there is a web source for the document available, the link is used to make sure the most current external document is available. If a link is not used, the version of the document should be updated if needed when the parent document is reviewed.

**Guidance Document:** is a supporting document that is used when there are not specific tasks or action required by the division but general boundaries for the work. Specifically, a guidance document can be used when tasks or actions are encouraged or supported by the division but not specifically required. Guidance should have limited use only when the information cannot be contained in a Policy, SOP, or WI. Guidance documents are also used to capture audit examples since audits may vary.

**Internal Documents:** is a documents that is created within FFSD which provides further technical information or outreach material used for industry, consumers, and/or regulatory. These may be handouts, checklists, diagrams, pictures, etc. that support the process defined in the parent document.

**Joint Document:** is a document that is created and managed jointly with another division within MDA or another department within the state. Joint Resources are stored and managed by all affiliated divisions and agencies. For example, a joint document could be a Memorandum of

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Understanding, Sample Acceptance Criteria, FERP, etc. These documents are approved by the division director and have a version date.

**Major Revision:** a significant content or conceptual change to a parent or related document.

**Master List:** A list of all approved and implemented PARENT DOCUMENTS associated with the division and each program.

**Minor Revision:** a change that does not significantly change the concept of the document. This includes but is not limited to grammar corrections, the addition or deletion of specific procedures under Section 6.x, or changes in personnel titles or definitions.

**Parent Document:** the official document controlled by the division. A parent document is a Policy, Standard Operating Procedure, or Work Instruction.

**Policy:** A written body of information that describes the interpretation and application of specific rules, regulations and functions of the programs within the Food and Feed Safety Division.

**Procedure:** A written body of information having a specified format that provides a stand-alone description of a process as part of a system.

**Record:** A written body of information that provides chronological objective evidence that related activities have been conducted according to a procedure, test method, or instruction. Documentation becomes a record when information from a procedure is entered.

**Related Document:** A document that provides supplementary information to a procedure, policy, method, or inspection document. Attachments/ Appendices may be examples of computer screenshots, other documents, or information capable of standing alone, such as a flow chart and are included at the end of the SOP or policy or in the Related Documents section.

**Revisions:** Those changes which affect the content or quality of the action being prescribed in the document, such as updated technology resulting in change of procedure or multiple changes within the document. Those changes that do not affect the content or quality of the action being prescribed in the document, such as typographical or grammatical changes, may be corrected without a change in revision number.

**Standard Operating Procedure (SOP):** a set of written directions that describes processes in sufficient detail as to ensure the quality and integrity of the work completed.

**Templates:** is a document created for template letters, inspection reports, etc. that are used as a base document for completion of processes outlined in the parent document. Templates are stored within the main document management system or the electronic inspection system.

**Work Instruction (WI):** a set of written instructions that specifically describes, in sufficient detail, instructions for completing a single activity or task.

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## 6. PROCEDURES

### 6.1. Document Development and Initial Review

#### Standards Coordinator, Standard Lead, and Program Manager

- 6.1.1. Identify procedures and processes to define and support the work of the division, program, and/or unit.
- 6.1.2. Review the relevant standards (MFRPS, RFRPS, and/or AFRPS) for required procedures or processes.
- 6.1.3. Assign a Document Coordinator for each parent document and a deadline for completion based on program/division need and contractual agreement such as cooperative agreements from the FDA.

#### Document Coordinator

- 6.1.4. Assess the procedure required to decide on the best process for development. Document work groups are used many times for documents that need the process further defined or when there are multiple programs or units affected. Another option is for individual development.

#### Document Coordinator and Document Developer(s)

- 6.1.5. Draft the document within a workgroup or individually.
- 6.1.6. Identify reviewers through consultation with leadership and Standards Coordinator.
- 6.1.7. Submit document for review or work with the Standards Coordinator to submit the document for initial review.
- 6.1.8. Update the document based on feedback. A meeting (or more than one) may be required to work through questions or concerns.
- 6.1.9. Notify the appropriate Document Manager when the document is ready for review.

#### Document Manager

- 6.1.10. Review the draft documents for the following:
  - 6.1.10.1. Meets appropriate standard requirements,
  - 6.1.10.2. Procedure is able to be followed,
  - 6.1.10.3. Document does not contradict or duplicate other currently approved documents,
  - 6.1.10.4. Correct format is used, and
  - 6.1.10.5. All related documents are present and referenced in the document.
- 6.1.11. If possible issues are identified, contact the Document Coordinator regarding the issues via email or set-up a meeting to review.
- 6.1.12. Conduct a final review of the document once all updates are complete.
- 6.1.13. Notify the Quality Manager when the document is ready for the quality review.

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Quality Manager

- 6.1.14. Conduct a quality review of the document within five (5) business days of the request.
- 6.1.15. Verify the following:
  - 6.1.15.1. Applicable Standards are met,
  - 6.1.15.2. Document is complete and meet current document format requirements, and
  - 6.1.15.3. Document could be followed by someone with the assigned responsibilities.
- 6.1.16. Notify the Document Manager if updates are required, further discussion is needed, or if the document is ready for final review and approval.

**6.2. Document Content and Formatting – Document Coordinator**

- 6.2.1. Use the most current template of the Policy, SOP, and WI documents located with this document.
- 6.2.2. Request for the Document Manager to create a draft folder in the Master Word documents for revisions or Draft document set for new documents in SharePoint.
- 6.2.3. Complete all sections and header information in the document template. Refer to the following for specific document directions:
  - 6.2.3.1. *Appendix 2: Policy Sections and Content*
  - 6.2.3.2. *Appendix 3: Standard Operating Procedure Sections and Content*
  - 6.2.3.3. *Appendix 4: Work Instruction Sections and Content*

**6.3. Document Identification and Header Information – Document Manager**

- 6.3.1. Assign a unique document number for each PARENT DOCUMENT in the appropriate header location.
- 6.3.2. Use the document numbering system described in *Appendix 1: Document Numbering System*.
- 6.3.3. Document the version number based on the following:
  - 6.3.3.1. Create all initial versions of documents as version 1.0.
  - 6.3.3.2. Increase the version by a whole integer (e.g. from 1 to 2) when MAJOR REVISIONS are made to the document.
  - 6.3.3.3. Increase the version by decimal points (e.g. 1.0 to 1.1) when MINOR REVISIONS are made to the document.

**6.4. Document Review and Approval – Document Manager and Approving Authority**

Document Manager

- 6.4.1. Identify the appropriate Approving Authority based on purpose and scope of the procedure, author of the procedure, availability of approvers and consultation with leadership and Quality Manager.

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- 6.4.2. Submit PARENT DOCUMENTS through Docusign for signature.
- 6.4.3. Submit the document sets including all related documents through SharePoint for approval.

Approving Authority

- 6.4.4. Review all documents submitted thoroughly.
- 6.4.5. If issues or questions are identified, contact the Document Manager.
- 6.4.6. Update the EFFECTIVE DATE on all parent documents.
- 6.4.7. Sign and date documents via Docusign and approve document in SharePoint once document meets the required standards and requirements.

**6.5. Distribution and Training – Document Manager and Training Coordinator (TC)/Training and Standards Analyst (TSA)**

Document Manager

- 6.5.1. Notify the TC/TSA that a document has been approved.
- 6.5.2. Identify the required staff for distribution and training, major changes, and proposed due date for training.

TC/TSA

- 6.5.3. Create an online course in Absorb for each newly approved version of the PARENT DOCUMENT. Course in Absorb are considered the official distribution of the document.
- 6.5.4. In consultation with the Approving Authority, Document Manager, Agricultural Consultants (if applicable), and other personnel, identify the best mode of training. Options include but are not limited to:
  - 6.5.4.1. Read and Review
  - 6.5.4.2. Read and Review with an assessment
  - 6.5.4.3. Read and Review with additional training via WebEx
  - 6.5.4.4. Read and Review with additional training in person
- 6.5.5. Assign the appropriate staff training in Absorb within five (5) business days of the request.
- 6.5.6. Continue to verify completions and extend due dates based on conversation with supervisors.

**6.6. Document Revisions and Cancellations –Document Manager**

- 6.6.1. Review all document revisions or cancellation requests from any FFSD staff.
- 6.6.2. Confer with appropriate leadership, required approvers, document coordinator, and other staff if changes to documents and processes are proposed and identify if a workgroup is required.
- 6.6.3. If typographical, printing, or any errors that do not affect the scope or procedures, correct the errors immediately.

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6.6.3.1. Do not generate a new revision number for these types of errors.

6.6.3.2. Create a note in the change panel with reasoning for update and the absence of a new revision number.

6.6.3.3. Submit the updated document for approval.

6.6.3.4. Do not re-distribute the document since the version number did not change and the change did not substantiate a change in scope or procedure only a clarification.

6.6.4. If updates to a document are required immediately, additions can be made to document via clarification or addendum.

6.6.4.1. Add attached clarifications or addenda to the PARENT DOCUMENT set.

6.6.4.2. Distribute the clarification or addendum through the learning management system.

6.6.4.3. Update the document when resources are available, biennial review is required, or based on program need.

6.6.5. Rescind (archive) an SOP when it is no longer applicable.

6.6.5.1. Send the request to rescind a document to the approving authority.

6.6.5.2. Capture the reason for the document being rescinded and the replacement document in the comments on SharePoint.

6.6.5.3. Notify the TC/TSA to create a rescinded document assignment in Absorb to notify staff that the document is no longer current and fit for use.

**6.7. Storage – Document Manager**

6.7.1. Maintain a CURRENT AND FIT-FOR-USE electronic version of each document on the SharePoint SOP Site to provide easy access to documents and assure the most current versions are available to all personnel.

**6.8. Document Use – All FFSD**

6.8.1. Use only the most current version of all documents located on SharePoint.

6.8.2. Complete all assigned document training and distribution tasks by the due date.

6.8.3. If documents are printed or saved outside of SharePoint, ensure that all rescinded (archived) documents are discarded when new versions are released, as notified through Absorb.

**6.9. Archiving Previous Versions and Obsolete Documents – Document Manager**

6.9.1. Retain previous version of all internal PARENT DOCUMENTS and related documents that provide specific direction on SharePoint per *FFSD.POLICY.90.07 – Records Management and Data Practices Policy*.



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**6.10. Master Lists – Document Manager**

6.10.1. Maintain a master list of all PARENT DOCUMENTS using the FFSD Document SharePoint site.

**6.11. Periodic Document Review – Document Manager and Document Coordinator**

6.11.1. Review all parent documents and related documents at least every 22 months, after an approval date, in order to maintain their relevancy.

6.11.2. Update or reapprove documents at least every 24 months.

**7. RELATED DOCUMENTS (includes References, Attachments)**

FFSD.POLICY.90.07 – Record Management and Data Practices Policy

FFSD Policy Template

FFSD SOP Template

FFSD Work Instruction Template

**8. EQUIPMENT/MATERIALS NEEDED**

SharePoint

**9. SAFETY**

N/A

**10. CIRCULATION**

This policy will be circulated to all FFSD staff. The current version will be stored electronically on the FFSD document control site.

**11. APPROVAL/DOCUMENT HISTORY**

Document History		
Version #	Status (I, R)	Change History
1	I	Initial Policy
1.1	R	Revised to address previously existing general and policy memos and add more specificity to major and minor revisions.
2	R	Revised to make the procedure more specific, action oriented, and describe the current document control and management procedures used by the FFSD.
DocuSigned by: 		1/19/2017
Approved By: [Name]		Date
Approved By:		Date

I = Initial document; R = Revised document

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**APPENDIX 1: FFSD Document Numbering Requirements**

Each parent document assigned a prefix and a unique number. The prefix corresponds to the Program in which the document pertains.

The prefix is followed by a period (.) and then the unique document number. For example: ADMIN.XX.

**Established Numbering Systems for Program Areas are as follows:**

**Prefix Selection:**

1. Policy
  - a. FFSD.POLICY.XX.XX – Policies that apply to the entire division
  - b. FOOD.POLICY.XX.XX – Policies that apply to one or both of the food programs (and associated units)
  - c. RESP.POLICY.XX.XX – Response policies that apply to the entire division
2. SOP
  - a. FFSD.SOP.XX.XX – SOPs that apply to the entire division
  - b. FOOD.XX.XX – SOPs that apply to one or both of the food programs (and associated units)
  - c. RESP.XX.XX – SOPs that apply to the entire division related to response activities
3. WI
  - a. FFSD.WI.XX.XX – WIs that apply to the entire division
  - b. FOOD.WI.XX.XX – WIs that apply to one or both food programs (and associated units)
  - c. RESP.WI.XX.XX – WIs that apply to the entire division related to response activities

**Classification Selection:**

**Index of Classification Categories**

Classification Categories:	Food Program topic:
10	Regulatory Foundation
20	Training
30	Inspections
40	Audits
50	Response
60	Compliance
70	Outreach
80	Program Resources
90	Administrative Procedures

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**APPENDIX 2: Policy Sections and Content**

1. Purpose – Explain the reason for the policy or the expectation of the process.
2. Scope – Describes the application of the policy and in some cases, to what the policy does not apply. Exclusionary statements can provide clarity.
3. Policy – Describes the interpretation and application of specific rules, regulations and functions of the programs within the Food and Feed Safety Division.
4. Responsibility – Responsibilities are identified by a position title (example: Inspector) or as a role (example: Document Manager) assigned by leadership. If a position is vacant, the supervisor of the previous role or position will identify a substitute until the position is filled. Leadership may also reassign responsibilities if there are limited resources, position is on leave, or there is an emergency.
5. Related Documents – Documents referenced within the policy and defined as RELATED DOCUMENTS. Related documents should only include documents that are specifically referenced in the policy.
6. Circulation — List of personnel to whom the policy is distributed and storage location.
7. Approval/Document History – Contains the signatures and titles of the approving authority, version number and change history. The Change History section summarizes the revised content of the current version. Signatures apply only to the current version. Historical signatures are maintained in files of archived documents.

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**APPENDIX 3: Standard Operating Procedure Sections and Content**

1. Purpose – Explains the reason for the procedure or the expectations of the process.
2. Scope – Describes the application of the procedure and in some cases, to what the procedure does not apply. Exclusionary statements can provide clarity.
3. Background – Provides information relevant to the SOP or policy that may assist the reader in properly applying the SOP or policy. This may include why the procedure or process was created, related standards, and applicable regulations, laws, statutes, and/or rules.
4. Responsibility – Responsibility are identified by a position title (example: Inspector) or as a role (example: Document Manager) assigned by leadership. If a position is vacant, the supervisor of the previous role or position will identify a substitute until the position is filled. Leadership may also reassign responsibilities if there are limited resources, position is on leave, or there is an emergency.
5. Definitions – Those terms that are unique to the procedure or terms that have distinct meaning in the context of the procedure.
6. Procedures – Provides the details of the process and tasks including responsible party, timelines, and chronological steps. All items in the procedures section should be written using present tense verbs and an active voice. Use sequential numbers and letters in this section starting at 6.1. Format of numbers and letters may vary slightly based on format of procedure section.
7. Related Documents – Documents referenced within the SOP and defined as RELATED DOCUMENTS. Related documents should only include documents that are specifically referenced in the policy.
8. Equipment/Materials Needed – Where relevant for the procedure, this section lists the equipment or other items necessary to perform the work described.
9. Safety – Where relevant for the procedure, this section lists the safety precautions necessary to protect personnel during operations.
10. Circulation — List of personnel to whom the policy is distributed and storage location.
11. Approval/Document History – Contains the signatures and titles of the approving authority, version number, and change history. The Change History section summarizes the revised content of the current version. Signatures apply only to the current version. Historical signatures are maintained in files of archived documents.

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**APPENDIX 4: Work Instructions Sections and Content**

1. Purpose – Explains the reason for the work instruction or the expectations of the process.
2. Frequency – Describes the instances when the work instruction should be utilized.
3. Responsibility – Responsibility are identified by a position title (example: Inspector) or as a role (example: Document Manager) assigned by leadership. If a position is vacant, the supervisor of the previous role or position will identify a substitute until the position is filled. Leadership may also reassign responsibilities if there are limited resources, position is on leave, or there is an emergency.
4. References – Documents referenced within the WI and defined as RELATED DOCUMENTS. Related documents should only include documents that are specifically referenced in the WI.
5. Supplies – Where relevant for the work instruction, this section lists the equipment or other items necessary to perform the work described.
6. Procedure – Provides the specific details of the activities addressed in the Purpose and Frequency of the WI. All items in the procedures section should be written using present tense verbs and an active voice. Use sequential numbers and letters in this section starting at 1. Format of numbers and letters may vary slightly based on format of procedure section.
7. Approval/Document History – Contains the signatures and titles of the approving authority, version number, and change history. The Change History section summarizes the revised content of the current version. Signatures apply only to the current version. Historical signatures are maintained in files of archived documents.