Key Components of Effective Coordination of the Manufactured Food Regulatory Program Standards

Developed for Coordinators, by Coordinators
Version 1: 2020
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The contributing PSC Editors that authored and edited chapters in this manual are as follows:

- Cassie Mueller, Minnesota Department of Agriculture
- Jennifer Bonsky, Michigan Department of Agriculture and Rural Development
- Amber Grisamore, Kansas Department of Agriculture
- Skya Murphy, Wisconsin Department of Agriculture, Trade and Consumer Protection
- Jennifer Pierquet, Iowa Department of Inspections and Appeals

The PSC Editors would like to extend special gratitude to FDA DSI advisor and reviewer, Angela Kohls, who assisted the group throughout the process, provided great insight, and kept the group motivated.

OVERVIEW OF THE MANUAL

PURPOSE OF THE MANUAL
This manual is designed to capture and document information that the authors and fellow Coordinators would like to have known when newly assigned to the position and which the group continues to find valuable. The manual also includes areas targeted towards continued improvement of the Standards. This document may be used as a quick start guide for new Coordinators and as a resource for program improvement for all Coordinators. All Coordinators, through discussion with their management, are encouraged to complete formal training on project management, facilitation, quality systems and leadership to further understand and apply concepts introduced in this document. This manual may be useful to program managers and other Standards staff, as training material for new Coordinators, for developing position descriptions prior to recruitment, and as a guide for creating a professional development plan for the current Coordinator.

BACKGROUND INFORMATION
Why was the manual created?
This manual was initiated as a way for state programs receiving cooperative agreement funding to share best practices between states.

Who was involved in the development of the manual?
The State of Kansas had the original concept for this type of manual and proposed the idea as a group project at a Regional Program Standards Coordinators (PSC) Meeting in 2016. At that time, the group heartily endorsed the concept. Minnesota and Kansas lead while other attending states committed to contribute. The group quickly began to identify and develop topics that would be included in the manual. At the first national PSC workshop at the 2016 Manufactured Food Regulatory Program Alliance (MFRPA) meeting, the project leads presented the concept and were encouraged by the PSC feedback. The group continued to work on the manual. At the next two Regional PSC Meetings, Minnesota and Kansas shared progress and the group conducted editing sessions.
What is the scope of the manual?

The manual was written to be compatible with MFRPS, but it may be useful to Coordinators of other sets of standards, for example, information in this manual could be used as an outline for a Coordinator that works with the AFRPS or VNRFRPS. The complexities of each set of standards did not allow for specific information to be discussed for all sets of standards.

**HOW TO USE THE MANUAL**

This manual is designed so that users may go straight to topics of interest. The glossary includes definitions for terms used within the manual but not defined in the MFRPS, where possible, definitions are excerpted from FDA source material, grants, cooperative agreements, etc. The chapters are comprised of major topics that the editors have sought previous guidance on. If a user or reader would like to propose a topic for inclusion, feel free to contact one of the editors. Success of this manual would be its increased use, improvement, and expansion over time. Each chapter begins with “Key Questions Discussed in this Chapter”, is followed by answers and discussion surrounding those questions, and ends with “Key Takeaways”.

**REVISIONS TO THE MANUAL**

The editorial group proposes to review and revise this manual in coordination with each subsequent release of the MFRPS to keep information current. If other coordinators are interested in assisting with future versions, they may contact editorial group members or their DSI representative.

Disclaimer: This manual is meant to outline the general duties of the Coordinator and does not cover every situation or job task that a Coordinator may encounter.
### GLOSSARY OF TERMS

#### KEY TERMS USED IN THIS MANUAL, WHICH ARE NOT DEFINED IN THE MFRPS:

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
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<tbody>
<tr>
<td><strong>After Action Review (AAR)</strong></td>
<td>A learning tool intended for the evaluation of an incident (investigation, event, etc.) in order to improve performance by sustaining strengths and correcting weaknesses. The written After-Action Report also provides investigation and response partners a final summary of the incident, including issues raised during the After-Action Review process. (Source: RRT Best Practices Manual).</td>
</tr>
<tr>
<td><strong>Continuous Improvement</strong></td>
<td>Ongoing effort to make incremental improvements to products, services or processes over time.</td>
</tr>
<tr>
<td><strong>Contract</strong></td>
<td>A funding instrument used when the U.S. Federal government acquires (i.e. purchases or procures) goods or services from a non-federal entity, to directly benefit the government in fulfilling public duties. Also see Grant and Cooperative Agreement.</td>
</tr>
<tr>
<td><strong>Cooperative Agreement</strong></td>
<td>A financial assistance support mechanism used when there will be substantial federal programmatic involvement, meaning grant-making program staff will collaborate or participate in project or program activities as specified in the Notice of Grant Award.</td>
</tr>
<tr>
<td><strong>Coordination</strong></td>
<td>The process of organizing people or groups to work together properly and well; the harmonious functioning of parts for effective results.</td>
</tr>
<tr>
<td><strong>Division of Standards Implementation (DSI) Office of Partnerships (OP)</strong></td>
<td>Technical advisors to state programs enrolled in Regulatory Program Standards and their standards development bodies (i.e. MFRPS Alliance and AAFCO).</td>
</tr>
<tr>
<td><strong>Facilitator</strong></td>
<td>An individual who enables groups and organizations to work more effectively; to collaborate and achieve synergy.</td>
</tr>
<tr>
<td><strong>Grant</strong></td>
<td>A financial assistance support mechanism providing money, property or other direct assistance in lieu of money, or both, to an eligible entity to carry out an approved project or activity in support of a public purpose and not the direct benefit of the government. A grant is used whenever the funding organization anticipates no substantial programmatic involvement with the recipient during performance of the financially assisted activities. The term “grant” is used to mean both grants and cooperative agreements in this manual unless specified.</td>
</tr>
<tr>
<td><strong>Maintenance</strong></td>
<td>Activities required or undertaken to conserve as nearly, and as long, as possible the original condition of an asset or resource.</td>
</tr>
<tr>
<td><strong>Monitor</strong></td>
<td>Conduct a planned sequence of observations or measurements to assess whether procedures are operating as intended (adapted from 21 CFR part 117); to check the progress or quality of something over a period; keep under systematic review. Grant monitoring is a process in which a grant’s programmatic performance and business management performance are assessed by reviewing information gathered from various required reports, audits, site visits, and other sources (HHS 2007).</td>
</tr>
<tr>
<td><strong>Notice of Grant Award (NOA or NGA)</strong></td>
<td>The official, legally binding document, signed (or the electronic equivalent of signature) by a Grants Management Officer that notifies the recipient of the award of a grant; contains or references all the terms and conditions of the grant and federal funding limits and obligations; and, provides the documentary basis for recording the obligation of federal funds in the accounting system. This document also contains the grant award number which will be used in future communications with FDA. The Notice of Grant Award, should be filed with other important MFRPS documents.</td>
</tr>
<tr>
<td><strong>Office of Acquisition and Grants Services (OAGS)</strong></td>
<td>The organization within the FDA that holds the authority for awarding contracts, grants, and interagency agreements.</td>
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<tr>
<td><strong>Principle Investigator</strong></td>
<td>Individual designated by applicant organization to have the appropriate level of expertise, authority, and responsibility to direct the project or program being supported by an award.</td>
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<tr>
<td><strong>Progress Report</strong></td>
<td>A grant deliverable consisting of information submitted by the grantee and used by the funding organization and the awardee alike to assess progress toward meeting grant milestones. Midterm and year-end reports are used by funding organizations to determine whether to provide funding for the subsequent budget period; this report may also be called the non-competing continuation progress report.</td>
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<tr>
<td><strong>Quality Assurance Program</strong></td>
<td>Written procedures which require a program to correct performance deficiencies detected during an audit or review.</td>
</tr>
<tr>
<td><strong>Quality Improvement Program</strong></td>
<td>Written procedures which require a program to enhance quality over time, and to correct performance deficiencies detected during an audit or review.</td>
</tr>
<tr>
<td><strong>Rapid Response Team</strong></td>
<td>The group of state and federal partners associated with each State’s Rapid Response Team, as well as the group of individuals who conduct specific investigation activities and coordinate the RRT’s response to an incident (adapted from RRT Best Practices Manual).</td>
</tr>
<tr>
<td><strong>Regulatory Program Standards (RPS)</strong></td>
<td>The RPS establish a uniform foundation for the design and management of state, local, tribal, and territorial programs that have the responsibility for regulating human and animal food.</td>
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<tr>
<td><strong>Request for Applications (RFA)</strong></td>
<td>A formal statement that solicits grant or cooperative agreement applications in a well-defined scientific area to accomplish specific program objectives. An RFA indicates the estimated amount of funds set aside for the competition, the estimated number of awards to be made, whether cost sharing is required, and the application submission date(s). For cooperative agreements, the RFA will describe the responsibilities and obligations of NIH and awardees as well as joint responsibilities and obligations.</td>
</tr>
<tr>
<td><strong>State Liaison</strong></td>
<td>Interacts with state and local officials to help promote uniform policies and activities in food and drug matters and serves as the liaison for information transfer between FDA and state, territorial, tribal and local agencies. Represents the FDA District and Program Division to the state and locals and represents state and locals to the Human and Animal Food (HAF) Division. Facilitates implementation of Integrated Food Safety system within state agencies with food &amp; feed regulatory responsibilities.</td>
</tr>
<tr>
<td><strong>Strategic Planning</strong></td>
<td>Setting goals and mapping out how to achieve them within a targeted timeframe. Involving cycles of planning, implementation and assessment. Means to formulate and implement Strategic Improvement Plan as defined in the MFRPS.</td>
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**ADDITIONAL TERMS USED IN THIS MANUAL, WHICH ARE DEFINED IN THE MFRPS DEFINITION SECTION:**

Assessment  
Conformance  
Equivalent  
Equivalent in Effect  
Implementation  
Strategic Improvement Plan
<table>
<thead>
<tr>
<th>ACRONYMS</th>
<th>EXPLANATION</th>
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<tbody>
<tr>
<td>20.88</td>
<td>Agreements pertaining to communications with state and local government officials</td>
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<tr>
<td>AAR</td>
<td>After Action Review</td>
</tr>
<tr>
<td>AFRPS</td>
<td>Animal Feed Regulatory Program Standards</td>
</tr>
<tr>
<td>CFR</td>
<td>Code of Federal Regulations</td>
</tr>
<tr>
<td>CIFOR</td>
<td>Council to Improve Foodborne Outbreak Response</td>
</tr>
<tr>
<td>ERA Commons RPPR</td>
<td>Electronic Research Administrations</td>
</tr>
<tr>
<td></td>
<td>Research Performance Progress Report</td>
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<tr>
<td>FDA</td>
<td>United States Food and Drug Administration</td>
</tr>
<tr>
<td></td>
<td>DSI-Division of Standards Implementation</td>
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<tr>
<td></td>
<td>OIG-Office of Inspector General</td>
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<td></td>
<td>OP-Office of Partnerships</td>
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<td></td>
<td>ORA-Office of Regulatory Affairs</td>
</tr>
<tr>
<td>FD&amp;C</td>
<td>Federal Food, Drug, and Cosmetic Act</td>
</tr>
<tr>
<td>FMD-76</td>
<td>FDA Field Management Directive, State Contracts-Evaluations of Inspection Performance</td>
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<td>GMP</td>
<td>Good manufacturing practices</td>
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<tr>
<td>IAFP</td>
<td>International Association for Food Protection</td>
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<td>ISO</td>
<td>International Organization for Standardization</td>
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<td>MFRPS</td>
<td>Manufactured Food Regulatory Program Standards</td>
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<td>MFRPA</td>
<td>Manufactured Food Regulatory Program Alliance</td>
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<tr>
<td>NGA</td>
<td>Notice of Grant Award</td>
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<td>NOA</td>
<td>Notice of Award</td>
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<td>PSC</td>
<td>Program Standards Coordinators</td>
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<td>QAP</td>
<td>Quality Assurance Program</td>
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<tr>
<td>RFA</td>
<td>Request for Application</td>
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<tr>
<td>RAC</td>
<td>Recall Audit Check</td>
</tr>
<tr>
<td>SIP</td>
<td>Strategic Improvement Plan</td>
</tr>
<tr>
<td>SOPS</td>
<td>Standard Operating Procedures</td>
</tr>
<tr>
<td>SOW</td>
<td>Statement of Work for the FDA Food Contract</td>
</tr>
<tr>
<td>SME</td>
<td>Subject Matter Expert</td>
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<tr>
<td>VNRFRPS/VRFRPS</td>
<td>Voluntary National Retail Food Regulatory Program Standards</td>
</tr>
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CHAPTER 1: PREPARE FOR SUCCESS

Scope:
This chapter focuses on building awareness of the food regulatory program and the Coordinator’s role within the program.

Key Questions Discussed in this Chapter:

- What is coordination?
- Where does the requirement for a Coordinator come from?
- How is the program organized to meet the standards?
- How are the roles and responsibilities related to the Standards work defined in the program?
- How can the Standards Coordinator obtain support from program management and staff?

What is Coordination?
Coordination is defined as “the process of organizing people or groups so that they work together properly and well, and the harmonious functioning of parts for effective results” by the Merriam-Webster Dictionary. In simple terms, this means leading a group of people to accomplish a task, likely without direct supervisory authority over the group. Coordination is not easy and requires skills such as leadership, excellent verbal and written communication, peer mentoring, teambuilding, project management, and the ability to manage negotiations, conflicts, meetings, and time.

Coordinator Requirement
Each grantee that receives funding under the FDA Manufactured Food Regulatory Program Standards cooperative agreement (now part of the Flexible Funding Model) is required to assign a Project Coordinator “with the overall responsibility for implementation of the strategic plan” per the Notice of Grant Award. This does not mean the Project Coordinator is responsible for completing all the work towards meeting the Standards, but that this person is responsible for ensuring that the work needed to meet the goals of the Standards program is planned, scoped, completed, and documented. Different schemes for how a program may be structured (and therefore how work may be delegated) to meet the standards will be discussed in this chapter. This Project Coordinator likely has a slightly different working title depending on the program for which they work. The terms ‘Program Standards Coordinator’ (PSC), ‘Standards Coordinator’ or ‘Coordinator’ are used interchangeably when referring to this position throughout the manual.

Determination of the Program Organizational Scheme
One of the first challenges for a new Standards Coordinator is to determine how the State food regulatory program is organized to meet the Standards. Understanding who is involved in Standards work, and what their responsibilities are, is an important first step. This includes visualizing the organizational structure and determining who the key individuals responsible for deliverables are. While becoming familiar with the State program and key individuals, ask questions about the program’s current conformance status and if resources are adequate to fully implement,
conform to, and maintain the Standards. The organizational structures of food regulatory programs and agencies can vary greatly, as can the program’s relationships with other divisions.

For some Standards Coordinators, a majority of the work to meet the Standards may be their responsibility, but for others, there may be an entire team involved in Standards work in some capacity. Below are some example schematics of how a program may be organized to meet the Standards:

**Figure 1: Organizational Structure Schema Examples**

Note the presence of FDA’s Division of Standards Implementation Staff (DSI) in each organizational schemes above. A DSI representative is assigned to each program and traditionally serve a group of states. The DSI representative is a
crucial reference for answering technical questions and issues related to the Standards. DSI conduct yearly meetings with each program to monitor progress towards conformance with the Standards.

**Budgets and Finance Role Consideration**

Not all Coordinators may have a direct role or responsibility for budget management of the grant or cooperative agreement. However, if responsible for ensuring that training takes place or that equipment is purchased, then consider inquiring from management how these tasks are completed and what the spending authority is. Some Coordinators are responsible for overseeing the budget and working closely with finance to track expenditures, while others work through program managers or liaisons responsible for this work. Consider discussing the following items with the program manager and/or finance office:

- How are expenditures tracked and shared?
- How is staff time tracked?
- Who purchases equipment and materials?
- Who approves travel for training or conferences?
- How does the program subcontract with other agencies?

**Review Regulatory Authority**

In addition to differences in programmatic organizational structure to meet the Standards, there are also differences in regulatory authority. One program may conduct inspections under FDA authority provided through a commissioning process, while another program may have state authority to conduct inspections through state statutes and regulations. Determining the regulatory authority of the food program will assist in coordinating the efforts to meet program elements in all 10 Manufactured Food Regulatory Program Standards and other sets of standards as well.

**Get Support from Key Individuals**

After determining how the food program is structured to meet the Standards and reviewing the regulatory authority, it will be important to assess the general feeling or attitude of the staff involved in Standards work. Support or “buy-in” can be described as actively believing that the work being performed is important and necessary. For programs that have been enrolled and actively working towards meeting the Standards for many years, staff acceptance likely exists. Standards Program staff with many years of experience may already ask the following questions when changes to the State Program occur:

- *how does this new process or procedure align with the Standards?*
- *will this new procedure affect how a certain program element is met?*

Actively asking these types of questions and soliciting solutions is an indicator that the staff and program have confidence in working with the standards. On the contrary, if the State Program does not support the Standards, adopt best practices, and internalize quality management principles, the PSC may be pushed into a difficult role, even when conformance is being maintained.
If State support for MFRPS is limited, then the Program may struggle to meet the Standards or even see value in them. In this case, the Coordinator must find ways to overcome this. Open and candid discussions about why the program has struggled in the past or the possibility of future struggles, is a good first step to determine best ways to move forward. A theme that may emerge from these discussions is change. Change can be hard, especially for a program operating the same way for years now being required to meet new requirements. After initial discussions, hold brainstorming sessions with key individuals to actively address barriers and concerns and prepare an action plan. In general, people are more likely to accept new ideas if they are provided opportunities to be an active part of the discussion and the decision-making process. Based on a column by Bruna Martinuzzi, Columnist with Clarion Enterprises Ltd., the following actions will help others' willingness to change:

1. **Communicate Change as a Conversation**: have a real dialogue with people and remember that emotions are involved. Give just enough information, be genuine, be relevant, and be clear about the message.

2. **Address Emotions in the Room**: it is key to actively prepare for the discussion and determine ahead of time how each person may react to the information provided.

3. **Repeat the Message**: most people need to hear information 3-5 times before they believe the message.

4. **Use Different Communication Methods**: take discussions outside the large group meeting when feasible. Utilize other methods of communication such as one-to-one talks with hard to reach staff. Send follow-up emails with notes about what was discussed during each group meeting so people can refer to the information if necessary.

5. **Use Stories, Examples, and Analogies**: facts alone are less likely to influence staff that are resistant to change. Include examples of what the change means for them. Think about questions they may be asking themselves: ‘What’s in it for me?’ “What’s the public health concern?” “How does this help provide better customer service?” and provide relevant answers.

6. **Develop a ‘Pitch’**: prepare dialogue to sell the change. Include the following: ‘here’s what our changes are about...’, ‘it’s important to do this because...’, ‘here’s what success will look like, especially for you...’, ‘here’s what we need from you...’. Focus on the public health message.

7. **Walk the Talk**: to maintain credibility, those delivering the message need to put it into practice.

8. **Provide Resources**: staff may benefit from resources regarding change management, including facilitation, business writing, project management, or other training to help staff who will be actively involved in the work.

9. **Know Who to Include**: some staff will support and encourage while others may interrupt progress and slowdown success. One person alone will not be able to implement the Standards, it will take diligence on many levels of the organization to ensure the changes can move forward without barrier.

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Figure 2: Buy-in Strategies
Key Takeaways:

- Determining how the program is set-up to meet the Standards will help the PSC understand who is involved in the Standards work, determine the current conformance status of the State program and whether more resources may be needed to fully implement, conform to, and maintain the Standards.
- Obtain support from the key individuals working on the Standards and those affected by the Standards to help build and maintain momentum towards conformance.
CHAPTER 2: VALUABLE SKILLS–INSIDE THE COORDINATOR’S TOOLBOX

Scope:

This chapter includes straightforward skills that may help the Standards Coordinator successfully manage job duties.

Key Questions Discussed in this Chapter:

• What is the Strategic Improvement Plan?
• What is strategic planning and what are some best practices?
• How do project management and facilitation fit into the role of the Standards Coordinator?

Before the Standards Coordinator even begins working the role, the hiring manager and others involved in the interview process determined that the Coordinator already has the potential to complete the duties of the job. As mentioned in Chapter 1 of this manual, coordination requires many skills such as leadership, mentoring, teamwork, and the ability to manage negotiation, conflicts, meetings, projects, planning, and time. In this chapter, some of these skills including strategic planning, project management, and facilitation will be further discussed. Professional development opportunities may be available to some Coordinators as well depending upon their program’s set up and resources.

Time management skills are critical for Coordinator success. The Standards Coordinator should review the Notice of Award (NOA) for important due dates, such as cooperative agreement starting and ending dates, mid-year and end of year reporting timeframes, FDA assessments, or Division of Standards Implementation visits and plan or schedule accordingly. Understand where the food program is in terms of reporting and requesting multiple years of funding. Consider using a calendar to plot these dates to determine when the best time to complete yearly assessments might be. This will help assure the program maintains funding and influence workload planning over the course of the year.

Strategic Improvement Plan

The Strategic Improvement Plan is a required document in Manufactured Food Regulatory Program Standard 9– Program Assessment. After a program conducts a baseline or yearly self-assessment against the Program Standards, the results are used to develop the Strategic Improvement Plan for the State food program. The current version of the MFRPS defines what the Strategic Improvement Plan is and what it must contain. Essentially, the Strategic Improvement Plan is a project plan which guides the work of the State program towards meeting requirements of the Standards not yet met. The plan may also include tasks related to maintenance and continuous improvement of standards in full conformance.
Strategic Planning

In an article titled The Top 10 Strategic Planning Best Practices, author Kim Perkins (2015) provides the following 10 best practices that may be useful to the Standards Coordinator and other program staff that may be involved with Standards work:

1. Assemble a diverse, appropriate team.
2. Allow time for big picture thinking.
3. Get full commitment from key individuals.
4. Allow for open and free discussion.
5. Think about execution before you start.
6. Use a facilitator if budget allows.
7. Make the plan actionable.
8. Do not write the plan in stone.
9. Clearly articulate next steps.
10. Make strategy a habit.

• Diversity leads to better strategy, include members from different areas of the agency or program.
• Having an appropriate amount of time to ‘think big’ is key. Trying to have strategic planning discussions in between putting out fires leads to less productivity.
• It cannot be done alone, getting buy-in from management and the team is key to success.
• This is regardless of each person’s position with the work. Hire an outside facilitator if needed to help alleviate the concern of staff ‘being led down a path’.
• If the plan cannot be executed, it is not a good plan.
• An impartial third party can concentrate on the process instead of the end result.
• Clearly articulate goals, action steps, responsibilities, and deadlines.
• Good strategic plans are fluid, not rigid and unbending, this allows for change when needed.
• Before closing a strategic planning session, explain what comes next and who is responsible for what and by when.
• Review the strategic plan for performance achievement on a regular basis (weekly, monthly, and quarterly). Focus on accountability for results.

Figure 3: Top 10 Planning Strategies

Project Management

Once the Strategic Improvement Plan has been created and agreed upon by key individuals (including those who will be actively involved in completing the work), the Standards Coordinator’s role will likely shift into project manager mode. A successful Coordinator will have to utilize both technical and interpersonal skills to move a project from initiation to completion. Having technical skills does not mean that the Coordinator knows how to complete every task needed to accomplish the end goal. Instead, a
Coordinator should have a general understanding of the work that needs to be done and ask the right questions throughout the project lifecycle to determine if the project team has the expertise to complete the work. The Coordinator must use their interpersonal skills to motivate and manage the team and ensure that key individuals work well together.

In addition to project management, it is also important that the Standards Coordinator have facilitation skills. Meetings are a constant in the life of a Coordinator and if not run in an organized fashion, attendees may be confused about the actual purpose of the meeting, what is proposed to be accomplished, and/or what follow-up or action items need to be addressed and by whom. Facilitators make it easy for groups to succeed. The Institute of Cultural Affairs in the U.S.A. has created a facilitation training method titled ‘Technology of Participation-Effective Tools for Participation from the Institute of Cultural Affairs’ or ToP for short. This facilitation training highlights the following skills for a successful facilitator:

![Figure 4: ToP Facilitator Skills](image)

The Standards Coordinator may be responsible for organizing and facilitating many meetings as the program works towards conformance with the MFRPS. Effective preparation ahead of any meeting will help the Coordinator and the meeting attendees accomplish whatever task the group is setting out to do.

Preparation should include determining the:

- focus of the meeting (i.e. talking about a procedure or a process that is being drafted into a procedure),
- type of meeting it will be (i.e. status update, informational, decision-making, etc.),
- role each attendee will play during the meeting (i.e. facilitator, note taker, decision-maker, etc.), and
- method of follow-up communication that will occur after the meeting ends.

Consider setting up recurring meetings to allow for better attendance, since group members know the set day and time for each meeting. Prior to each meeting, provide an agenda discussing the above items to help ensure that all may be adequately prepared. Organization and follow-through are key components to ensuring that work accomplished during a meeting is translated into task completion so that the program continues to move forward with Standards work.

**Key Takeaways:**

- The Strategic Improvement Plan is an important document to manage the work of the Standards (think of it as the project plan driving the work of the Standards).
- Build up project management and facilitation skills to set up for success in the role of Standards Coordinator.
CHAPTER 3: CONDUCTING SELF-ASSESSMENTS

Scope:

This chapter describes self-assessments and their purpose and provides information for completing the self-assessments within each Standard.

Key Questions Discussed in this Chapter:

- What is a self-assessment?
- What is the purpose of the self-assessments?
- How can the self-assessments be used to improve the State food program?
- Who completes the self-assessments?
- What can be with the results?

What is a Self-Assessment?

A self-assessment could be described as a systematic evaluation to determine where a program is and reveal gaps between the current state of the program and full conformance with the performance elements of the MFRPS. The Standards Coordinator is likely the lead for conducting and updating self-assessments required by the Standards. To be successful, the self-assessments must reflect an accurate representation of the program and aim to correct any deficiencies identified. Answering no on a self-assessment does not necessarily mean lack of full conformance. For example, the standard element may not be the responsibility of the program, so answer no and describe why. It is best to answer these questions honestly and accurately. If it is unclear whether yes or no is the right answer, have discussions with the appropriate personnel to determine the most accurate conclusion. Consider providing an explanation or details, even when yes is recorded for a self-assessment element, for example, including the relevant policy or procedure reference in the “comments” section on the self-assessment appendix helps tremendously when it comes time for re-assessing the Standards and for the on-site audits.

Purpose of a Self-Assessment

The Coordinator conducts a self-assessment to identify the strengths and areas of improvement for the program based on the requirements in each Standard. One strategy is to examine existing evidence of implementation and conformance and prepare a draft self-assessment based on these policies, procedures, and records. Consider meeting with key individuals and MFRPS drivers to validate the self-assessment and identify root causes of any deficiencies. The gaps revealed through assessments are used to develop the Strategic Improvement Plan and to establish timeframes for making improvements. Updating self-assessments shows progress towards meeting Standard elements over time. Looking at the self-assessments from a different perspective each year can help keep from misinterpreting Standard requirements. This can be done by re-examining...
supporting documentation within each self-assessment to ensure it is current and fit-for-use, because even small changes to a document can change whether it meets the Standard.

**Value of Conducting Self-Assessments and Improving the Program**

The MFRPS provide a self-assessment and a series of supporting worksheets that help guide the program through the self-assessment process and to assist in achieving and sustaining conformance. Self-assessments are an invaluable tool for establishing a program baseline, evaluating and making program improvements, and ensuring that the food program is prepared for the next FDA audit. Below outlines the self-assessment for each standard and describes tips and examples to guide the process.

**Standard 1 Self-Assessment:** The self-assessment worksheet, Appendix 1.1, includes an element to conduct a baseline self-assessment utilizing Appendix 1.2 (or equivalent). Appendix 1.2 identifies how each state’s laws and regulations compare to federal statutes and regulations and ensures the protection of manufactured foods within each state. These comparisons will be valuable during work planning meetings between states and FDA.

**Standard 2 Self-Assessment:** This assessment highlights training activity and record keeping that fails to fulfill the Standard. When completed regularly, the value of this assessment is found by eliminating questions of the state training program conforming to the training plan and training record, basic food inspection training, advanced food inspection training, and experienced inspector training requirements. This ensures that only properly trained inspectors are conducting manufactured food inspections.

**Standard 3 Self-Assessment:** Each aspect of the inspection program is evaluated to determine whether it meets the Standard elements. These elements can be used as a checklist to ensure procedures are in place for a risk-based inspection program, field inspections, inspection reports, food recalls, consumer complaints, industry complaints about inspections, sampling, and record retention.

**Standard 4 Self-Assessment:** This Standard assessment verifies a written Quality Assurance Program (QAP) is in place with program elements to conduct and analyze field inspection audits, inspection report audits, sample report audits, and corrective action. This assessment is a valuable tool to help write the QAP and document how each element is being met, such as stating the method used to achieve random selection.

**Standard 5 Self-Assessment:** Overall program coordination with other authorities, surveillance, investigation or environmental assessment, control measures, and post response are reviewed. This can help identify where written procedures and pertinent information are housed. Creating a supplemental table to show the role each agency or program fulfills regarding prevention, detection, and intervention actions required by the Standard can be useful to further highlight areas needing improvement and in communicating with auditors during an onsite assessment.

**Standard 6 Self-Assessment:** The self-assessment verifies that a written compliance and enforcement program is in place and that performance reviews are being conducted. This can be valuable when writing the compliance and enforcement program procedures. It is also a reminder to keep standard 6 compliance reviews on track and make any necessary improvements.

**Standard 7 Self-Assessment:** Outreach methods are reviewed and documented. This tool can be used to identify documents applicable to each element.
Standard 8 Self-Assessment: Meeting this standard means that the program can accurately assess the resources needed to support implementation and conformance with the Standards. It does not indicate that the program is fully staffed and funded, instead, experience suggests that this is rarely the case. Rather, inadequate resources demonstrated through this assessment can support resource acquisition or mobilization. It is a useful summary resultant from a thorough evaluation of the program’s resources and description of future needs. A best practice is to evaluate this throughout the year. Any results showing a lack of funds, staff, and equipment should be used to obtain these needed resources. If these resources are not available, it will be difficult to meet the requirements of the standards. For example, a lack of staffing can make it difficult to meet the desired inspection frequencies defined by the program, based on need.

Standard 9 Self-Assessment: The completion of each Standard’s self-assessments is verified under “program assessment”. This assessment is a high-level summary of the program’s implementation of each standard. Improvement needed to address deficiencies identified during assessments should be addressed in the strategic improvement plan and completed to gain or demonstrate full conformance. The standard 9 self-assessment can refer to the SIP where elements of a standard are not yet met. Document control practices are also assessed in this standard.

Standard 10 Self-Assessment: Completing this assessment will provide an opportunity to talk to the program’s primary servicing laboratory about progress towards meeting Standard 10 requirements. The lab may be working to achieve and maintain International Organization for Standardization (ISO) Accreditation. Make sure the food program is working cooperatively with the lab to create a mutually beneficial sampling plan. Encourage the lab to review the results of the self-assessment and to provide updates. The Coordinator must understand the lab’s answers to the self-assessment questions. If the lab used is not an ISO Accredited Laboratory, this tool outlines the analogous requirements needed in order for this lab to be utilized.

As a best practice, self-assessments can be reviewed throughout the year and updated to reflect necessary changes, remember to update the SIP to reflect assessment findings. This can help the program maintain focus and make improvements as needed and can include program-specific elements or other additions to the self-assessments. It is important to distinguish between elements that are required by the Standards and elements that are not required or realistic for the food program. Consider expanding upon the assessments to satisfy the State’s needs by providing additional details to help meet the requirements of the Standards and other goals set by the program.

Roles and Responsibilities When Conducting Self-Assessments

As stated earlier in this manual, managing the Standards is not done alone. It may be within the Coordinator’s role to conduct the self-assessments; however, not to validate the results. In this case, policies and supporting documentation should lead to agreement between the PSC’s assessment and the subject matter experts’ (SME) assessment of the program area. In some instances, the subject matter expert will be the Standards Coordinator and they will need to persuade management and other stakeholders to act based on the results of the self-assessments. It is important to identify Standard SME(s) and the
decision makers if program personnel disagree with self-assessment findings. Bear in mind that FDA audit staff are the ultimate arbiters of conformance, regardless of what the self-assessment says.

Another likely responsibility for the Coordinator is updating necessary self-assessments and the SIP to reflect the most recent assessment findings. When approaching an SME for self-assessment information, be prepared. It is important to know what information is necessary for completing each self-assessment. For example, before assessing the sampling procedures in Standard 3, a helpful practice may be to set up a meeting with the sampling SME and request the current sampling procedures, along with any pending changes, then hold a meeting to review the results of the assessment. In order to be more efficient and effective, consider evaluating all the elements within each self-assessment before discussing them with the SME. Simply asking the SME if the sampling program meets the list of requirements can lead to frustration, uncertainty, and ultimately an incorrect evaluation of the program.

**Self-Assessment Results**

All gaps or deficiencies discovered during self-assessments must be addressed in the strategic improvement plan. Prioritizing these gaps are an essential step toward meeting the end goal. Focus on gaps that contribute to the highest public health severity issues. For example, if guidelines are not met in Standard 3 for selecting appropriate high-risk product or process for the inspection, then this is considered more of a public health concern and should be addressed prior to addressing gaps related to document control.

The self-assessments findings should be shared with the individuals assigned to the affected standard, program management, and occasionally inspection staff. These results can be used when proposing updates to state laws and regulations, addressing training needs, updating inspection procedures, writing a QAP, enhancing communication procedures, improving compliance and enforcement, implementing outreach, obtaining necessary resources, and making needed updates within the laboratory to meet the Standard requirements. Assessment findings can also be used to help inspection staff understand the reasoning behind guidelines or procedures. Fundamentally, these self-assessments are there to help evaluate, monitor, and improve the program.

**Key Takeaways:**

- Accurate and honest completion of the self-assessments will help to identify strengths and opportunities for improving the program, outlined by each Standard.
- Answering no on a self-assessment does not necessarily indicate non-conformance with the Standard.
- Use the results of the self-assessments to identify gaps make recommendations for program improvements.
CHAPTER 4: BUILDING QUALITY CONFORMANCE AND CONTINUOUS IMPROVEMENT

Scope:

This chapter describes quality assurance and provides information for implementing quality assurance concepts using MFRPS Standard 4 as a template.

Key questions:

- What is Quality Assurance?
- What are some of the challenges to implementing standard 4 and standard 6 quality assurance?
- What are the roles a PSC might play in auditing and managing audit data?
- How can quality assurance become quality improvement?
- How does providing feedback fit into the quality assurance system in the State food program?
- How have some states made quality assurance works for the program?

What is Quality Assurance?

Quality assurance can be defined as a part of quality management focused on providing confidence that quality elements will be fulfilled. For example, finding and fixing deficiencies, enhancing performance, and documenting processes. MFPRS is a mechanism that Coordinators can use to achieve and enhance basic quality assurance for the program. In fact, most state programs that participate, comply, or conform with MFRPS report improvements in the overall State program. The Coordinator can also use the MFRPS Self-Assessments and the Strategic Improvement Plan to track progress, accomplishments, and completion dates of improvement actions.

Challenges to Implementing a Quality Assurance Program

Despite the benefits of implementing a quality assurance program, Standards 4 and 6 remain the most challenging for many programs. Participants at the 2017 Program Standards Coordinators Workshop reported several challenges to Standard 4 implementation or conformance.

- finding time to complete audits amid staff turnover,
- figuring out the best time to complete audits (monthly, quarterly, etc.),
- finding pre-audit time to train to procedures,
- completing post-audit corrective action training,
- consistency between auditors,
- making feedback to individuals positive, and
- new Coordinators becoming familiar with Standard 4 elements.

The following sections aim to provide guidance for overcoming these challenges by sharing best practices compiled by Standards Coordinators.
Quality Assurance Roles and Responsibilities

Not all Coordinators will have the same roles or responsibilities pertaining to implementing or enhancing a quality assurance program. Since every program will approach quality assurance differently, the Coordinator may want to consider discussing the following with the key program personnel:

- Who is responsible for audits?
- What is the audit process flow for the program?
- Who tracks audit data?
- Who provides audit feedback?
- How is audit feedback tracked?
- How do audit findings influence updates to policies, training, and other program elements or metrics?

Getting Started with Quality Assurance

When developing a quality assurance program, Coordinators may find it helpful to use Standard 4 as a framework for establishing quality elements for the State’s quality program. One approach the Coordinator may take is to first ensure that written policies and procedures are in place that detail requirements for conducting inspections, writing inspection reports, and documenting sample collection. The Coordinator then ensures that the staff responsible for completing those tasks are properly trained and that the training is documented in accordance with the State program and MFRPS. Finally, audits are completed to verify conformance with requirements established by the program. Another approach may be that the Coordinator chooses to audit current systems before developing procedures to determine what is taking place. In both cases, the program needs to write procedures that have clear measures and expectations; the next chapter of this manual provides additional information to accomplish this.

The program must also prioritize workload to allow time for auditors to prepare, conduct the audit, draft the audit report, and convey feedback. This may mean other assigned duties are reassigned temporarily. Program assessments, documentation, and auditing are steps that allow the program to measure success in conforming to the MFRPS and strategically plan greater program improvements beyond the minimum requirements of the standards.

Selecting Auditors

Most Coordinators have to ensure that the proper number of audits are completed in accordance with MFRPS and program procedures. Some PSCs may even be involved in assigning or completing audits. When selecting field inspection auditors, the Coordinator should work with program management to make sure proposed auditors meet the MFRPS definition of a Qualified Field Inspection Auditor. The PSC should also strive to ensure that auditors are independent, objective, and do not have a direct interest in the results of the audit. If Supervisors are assigned to audit, consider having them audit outside of their supervisory group when possible. If peers evaluate peers, then the program must allow for comfortable evaluation of colleagues. Furthermore, for auditor feedback to be viewed as credible, the auditors must have the respect and esteem of inspection staff and appropriate training.

Similarly, inspection and sample report auditors should be experienced in report writing and review, sample collection, and the established procedures. However, if report writing and sample collection instructions are clear, the auditor need not be assigned the responsibility of writing reports to be effective and provide feedback. The

MFRPS auditors that also audit FDA contract inspections must be qualified per the current FDA Field Management Directive, “State Contracts—Evaluation of Inspectional Performance” (FMD 76).
The Standards Coordinator Manual

The auditor can determine whether instructions were followed and provide feedback that rephrases the instructions, for example, “list the records reviewed per the instructions for documenting the establishment records reviewed during an inspection.”

Making Quality Assurance Work for the State

Audit Forms and Audit Elements

Through Standard 4 and its associated appendices, MFRPS provides a framework for creating a quality assurance program. Some programs may find that the MFRPS Inspection Report Audit Form or the Sample Report Audit Form are not applicable to the program as-is. Even though an equivalent form must be utilized, the PSC may consider substituting, consolidating, or augmenting quality measures or performance elements, so that they are more meaningful to the food program.

Field inspection audits should be a comprehensive analysis of the food program. To help accomplish this, include all types of manufactured inspections the State conducts and all staff that complete those inspections in the list used to assign audits. If the field inspection audit form is used for FDA contract audits, then use the same form and follow FMD 76 for MFRPS field inspection audits too.

For any form, the Coordinator may rearrange the order of the performance elements to match the arrangement the state reports and sample collection reports. If the elements provided in the appendices of the standard are enough to measure quality in the food program, use them as-is. However, if more specifics or metrics of quality are desired by management, then add those criteria. The more quality assurance aspects measured for the program, the more valuable the results will be.

Audit Instructions

The Coordinator may consider providing instructions to all auditors as to what constitutes “needs improvement” or “acceptable” for each performance element, and how to interpret each element in the program. For example, during non-contract audits, State programs may interpret the “establish FDA jurisdiction” as “verify state license.” Consider discussing what each performance element means to key individuals and come to a consensus on what constitutes quality. Standardize the observations and thresholds for “acceptable” among the auditors for each element and repeat as needed. Draft, pilot, and update audit instructions before they are implemented.

The Coordinator will need to make sure that the food program is auditing all the required MFRPS performance elements, and if not, then document that the element is not required by the food program and score that element as “acceptable” for all scoring or calculations.

Policies and Procedures that Meet Audit Needs

Once the elements of quality and procedures for achieving them are clear, quality assurance SOP development is set to begin. Document each step of the procedure for auditing, including instructions for how to locate reports, select...
the sample to audit, tabulate and analyze audit data, report results to management, carry out and document corrective action plans, and report results to FDA. Include instructions for phrasing effective feedback, and a plan for communicating feedback to inspection staff, individually and as a group.

Before extensive auditing begins, the Coordinator should make sure that policies and procedures for conducting quality inspections, report writing, and documenting sample collection can lead to a successful audit. This means, that every audit element is covered by the procedures, and that auditees who follows those procedures can achieve an “acceptable” audit score. Policies and procedures must be clear, specific, accessible, and contain the performance elements of quality. If policies and procedures are inadequate, then it is unreasonable to expect uniform quality or even successful audit scores. If procedures are clearly written, explained, and trained on, then the program can audit the degree to which those procedures are followed by Inspection staff.

**Individual Audit Feedback**

Feedback should be balanced, specific, and measurable. Coordinators and key personnel will likely have to figure out the style and manner of feedback that will be most effective for the program, and may want to consider discussing the following feedback items for inclusion into the quality audit procedures:

- **Types of feedback.** MFPRS identifies “needs improvement” and “acceptable” for audit results, but the program may want to identify excellent work that exceeds an “acceptable” rating. These items can be incorporated into best practices and may be shared with others.
- **Strategies for providing effective feedback.** The program may pair positive feedback with “needs improvement” items, by instructing auditors and assessors to call out at least one detail to praise via positive feedback to increase the effectiveness of “needs improvement” feedback. Alternatively, feedback may be kept more neutral, like “fill in the applicable instructions you are given” or “inspector followed job instructions.”
- **Who is best positioned to provide feedback?** Audit feedback can be provided in various ways, but it is likely most effective, when conveyed by the individual’s supervisor, or by the auditor with the supervisor present.
- **Details to be included with the feedback.** These details will be used to draft corrective action plans and ultimately improve the program, so specifics should be phrased to point out exactly the what, why, and how the performance element was scored.

**Programmatic Audit Feedback**

The Coordinator will likely be one of the first to recognize the importance of providing feedback and building a quality assurance culture where there is always room for improvement. Coordinators may have to convince key personnel that if audits and self-assessments don’t reveal room for improvement, then the program is not poised to make improvements. A program that does not generate needs improvement feedback may be assuring a steady level of quality, but without a communicated need for change, future improvements are not assured.
**Process Flow for Audits**

Each Coordinator must understand how the audits will be conducted, documented, and analyzed within the program. This audit flow will also likely include items related to corrective action, training, and policy update. Each state may have different flows and different personnel in charge of each step in the audit cycle, but here is one example.

![Diagram](image)

Figure 7: Example Audit and Corrective Action Flow

**Use of Data and Corrective Actions/Creating New Metrics**

The Coordinator and key program personnel may determine that the metrics described in the Standards aren’t specific enough for the program. Therefore, the program may identify areas, outside the scope of the Standards, where additional measurements are needed to ensure the program is functioning properly. There will be opportunities for improvement revealed by the Coordinator. Beyond meeting MFRPS, quality assurance and quality improvement systems can identify areas outside the purview of Standards where the food program would like to improve or enhance the program activities. If this is the case, then consider the following:

- **Define the measure of success.** There must be thresholds for each area which are clear to the auditors, auditees, and the program.
- **Measure existing and new data in comparable ways.** If new areas to measure are created, use the terms and measurements consistent with MFRPS, such as “acceptable” and “needs improvement” to determine the scores or percentages.
### Quality Assurance Systematic and Holistic Policy

MFRPS provides systematic ways to implement quality assurance of inspections, associated records, and compliance actions. There will be opportunities for improvement purposefully or incidentally revealed by the Coordinator. Beyond meeting MFRPS, quality assurance and quality improvement systems can identify areas outside the purview of Standards where the food program would like to improve to enhance conformance. While not required, a holistic, system-wide policy for quality assurance can be applied beyond the Standards. Such a system will empower and reference the quality assurance and improvement mandated for Standards 4 and 6, and the SOPs used to conduct them, while also making room for future quality assurance efforts that are more wide ranging.

An example holistic and systematic statement for quality assurance is: “All aspects of our regulatory program are subject to ongoing evaluation, which is undertaken to maintain conformance with federal standards, ensure that internal quality standards are maintained, and detect opportunities for improvement. Evaluations are handled in a systematic fashion via sampling and/or an all-inclusive review, at least annually or as required by the Standard.”

This policy enables review of training records, consumer complaints, or actions taken during response, which contains a list of the SOPs used for each type of quality review. Quality assurance provides a methodical way to provide feedback for improvement, and an enabling policy sets expectations of communicating the results of quality assurance efforts:

“Results of evaluations and annual reviews are shared with management, FDA, supervisors and the staff they supervise, so that they may recognize and reinforce outstanding work and make any necessary improvements via training with measurable objectives.”

### Key Takeaways:

- A quality assurance program that meets MFRPS and is successfully adapted to a State program’s needs will result in increased quality activities performed by the program.
- Change is part of the any continuous improvement culture.
- Quality Assurance is a never-ending process, there will always be opportunities for improvement.
- Providing and responding to feedback is necessary for all programs involved in the Standards and Quality Assurance.
CHAPTER 5: PROCEDURE DEVELOPMENT AND DOCUMENT CONTROL

Scope:

This chapter focuses on creating and maintaining policies, procedures, documents and records in order to meet the document control requirement in MFRPS.

Key Questions Discussed in this Chapter:

- What is Document Control and what is the requirement in MFRPS?
- Which documents are controlled for MFRPS?
- Who should write the documents?
- How should documents be written?
- What does the process for reviewing, updating, and approving documents look like?
- What does the organization, dissemination, and access to documents look like?

**Document Control:**

As a MFRPS Coordinator, the program may have a well-established system of document control or a more haphazard arrangement. Regardless of where the program is in its development, it will need to have effective document management methods to maintain all current and archived files related to MFRPS, both programmatically and fiscally. This will include documents subject to Standard 9 document control as well as grant applications, notice of awards, progress reports, historical self-assessments, historical strategic plans, etc. This section intends to point out strategies that will help PSC understand and meet both sets of requirements.

Document Control is defined in the Standards and can be furthermore broadly described as coordination and control of the flow (storage, retrieval, processing, printing, routing, and distribution) of electronic and paper documents and records in a secure and efficient manner, to ensure that they are complete, accurate and accessible to authorized personnel as and when required. As per MFRPS, the purpose of document control is to ensure that 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. This promotes public health by ensuring the most current policies and procedures are followed.

Document Control is required by MFRPS Standard 9 Program Assessment and will affect all the standards. MFRPS requires that the State program has a written document control procedure that ensures the information contained in the appendices and supporting documents for program elements are current and fit-for-use. However, MFRPS does not prescribe how this must be achieved. This chapter will describe a compilation of best practices that may help State programs meet the requirement for document control.
Identify the Documents the Manufactured Food Program Utilizes:

The PSC should consider cataloging documents utilized by the agency to support the manufactured food program and associated performance elements for regulatory foundation, training, inspections, sampling, complaint, audits, emergency response, enforcement, outreach, and laboratory activities, such as:

- Current MFRPS Standards, appendices, and documentation required in each standard
- Laws and Regulations
- Policies and Standard Operating Procedures
- Guidance Documents, Toolkits, or Job Aids
- Other

Documents relied upon by the program that come from external sources and which thus need not be reviewed, approved, or officially “controlled” by the agency still need to be included in the food program document control procedures. This ensures that they will be identified, included in the document control system for reference, and maintained to ensure end users have access to the correct version. Typical examples of this type of document are those documents which are relied upon by the State, and controlled by the FDA, such as the Field Management Directive 76 for Field Inspection Audits.

Although it’s not specifically required in MFRPS, one option used to identify State program documents is to compile them in a Master List containing the title, version, approval status, location, and other pertinent information for each controlled document, as in the example below:

<table>
<thead>
<tr>
<th>Document Name</th>
<th>Distribution</th>
<th>Internal</th>
<th>Revised OR Reviewed By</th>
<th># of Revision</th>
<th>Archival Last Revision</th>
</tr>
</thead>
<tbody>
<tr>
<td>Michigan Food Law</td>
<td>External</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2009 Michigan Modified Food Code</td>
<td>External</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Department of Agriculture Act 13 of 1921</td>
<td>External</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Administrative Procedures Act 306 of 1969</td>
<td>External</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smoked Fish Regulation NO. 559</td>
<td>External</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Food Field Guide</td>
<td>Internal</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Food Policy</td>
<td>Internal</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Figure 8: Documents Required in MFRPS Standard 9

Figure 9: Example Master List
Determine Who Writes Documents for the Agency:

Identify individuals that will be responsible for writing documents for inclusion into the State program. MFRPS allows flexibility for this so each state can identify what will work best, therefore, some agencies identify a single person to write all documents while others identify various groups that can submit documents based on content and application. As an example, document writers may include:

- MFPRS Coordinator
- Program Planner
- Food Program Manager
- Policy Specialist
- Subject Matter or Specialist Groups
- Field Staff or other end users

Describe the Process for Reviewing, Updating, and Approving Documents:

Identify individuals responsible for reviewing, updating, and approving documents for inclusion into the State program. Every program will look different and likely include document writers and additional groups. One example showing a possible flow for who might update a Recall Policy is provided below:

```
Review
• Emergency Management Seniors and RRT review current Recall Policy

Update
• Policy Specialist or PSC incorporates changes
• Supervisors review

Approval
• Food Program Manager approves
```

Figure 11: Example Document Review-Flow-Expanded

After identifying who is responsible for writing, reviewing, updating, and approving documents, the program may want to consider establishing document workflow process or routing in written procedures. This may include step by step processes along with established timeframes for each phase. The example below builds on the Recall Policy Update Example by including some workflow process details that could be captured in the workflow process:

```
Review
• Review of current Recall Policy conducted by RRT and Emergency Management Seniors biennially.
• Proposed changes are submitted to the Policy Specialist via email using the policy submittal form as needed.

Update
• Policy Specialist reviews submittal form and presents update to Supervisors for further review at the next policy meeting.
• Supervisors approve or decline changes within 5 business days.
• Once Supervisor consensus is achieved, Policy Specialist submits the updates to Food Program Manager.

Approval
• The Food Program Manager reviews the updates and approves (or denies) the final updated version of the new Recall Policy within 10 business days.
• The Food Program Manager notifies the Policy Specialist which initiates the next phase of document control.
```

Figure 10: Example Document Review Flow

Figure 11: Example Document Review-Flow-Expanded
Determine How Documents Will Be Written:

There are a variety of documents that will need to be written throughout the MFRPS process. This section will provide some guidance on writing Standard Operating Procedures (SOP). SOPs outline procedures which must be followed to ensure compliance with rules and regulations, policies, MFRPS, or other agency standards. The purpose of an SOP is not to in any way replace or preclude the requirements of statues and rules. Rather, the purpose is to provide detailed instructions on how to carry out a task which is not prescribed precisely in rule so that it is done correctly, that is, in line with the current management directive, each time. SOPs should be used during training but cannot replace proper training. The process for writing SOPs can vary, but the basic steps are described in the following sections:

Outline and Format SOPs

When writing standard operating procedures, authors can choose multiple ways to organize and format them. If the procedures have many steps, then consider using bullets, flow charts, graphics, visuals, or a decision tree to convey the information. SOPs may contain some or all the following components:

- Cover Page
- Title
- SOP identification number
- Revision number
- Header with document control information
- Footer
- Page numbers
- Purpose and Scope
- Defined roles & responsibilities
- Procedures Section
- Table of contents
- Related Documents
- Definitions
- References
- History of changes
- Tables, figures, appendices, and etc....
The PSC may want to consider using an SOP template to ensure consistent content, tone, numbering, and formatting. The template would also be subject to document control. This helps make document control procedures easier to follow and verify. For example,

![Standard Operating Procedure Template](image)

Figure 13: Example SOP Template

**Write SOPs and Follow Them**

Well-written procedures provide direction, improve communication, reduce training time, and improve consistency. To help create SOPs that work well for the program, consider the following steps for drafts or updates:

- Conduct a gap analysis: review requirements of each standard against current written procedures to identify deficiencies and need for new or updated procedures.
- Identify the purpose of the SOP: determine the purpose and the intended audience of the SOP to help ensure the procedure is properly written and includes the appropriate level of detail.
- Describe the process: the goal is to create a document that is easy for the reader to understand and helpful for the task that must be completed. Procedures must be written in a concise, step-by-step, easy-to-read format. SOPs should be unambiguous, not overly complicated, and provide enough detail so someone with basic knowledge can complete the task described. Consider making a rough flowchart of the entire process to help identify procedural task and use an action word to begin each step description. Procedures should address the who, what, where, when, why and how of each task; however, use position title(s) instead of individual names.
• Collaborate: SOP development should be an inclusive process that considers the input of those with an interest in the procedure’s success. SOP writers must have a clear understanding of the steps involved in the process, so consider collaborating with users who will be (or already are) responsible for the tasks described in the procedure. Working together allows for more expertise incorporation into the SOP, provides a sense of ownership, and leads to better SOPs.

**Ensure Success and Accuracy:**

Test the procedure by having several staff with varied knowledge levels review or test the Standard Operating Procedure and give feedback. Different individuals will have different perspectives. They may provide feedback on instructions being easy and logical to follow, are any steps left out, or where more detail is needed. Once the team approves the content of the SOP, begin the agency approval phase. Policies should be clear and concise and wording should be selected carefully. For example, “may” or “should” implies choice, where “shall” does not.

There are many options for documenting workflow process. Some states manage this manually while others use sophisticated document control software with built in workflow processes. Some examples include using Excel Spreadsheets, FoodSHIELD, SharePoint, MasterControl, Qualtracks, and others. Note: the authors of this document do not endorse or recommend the methods named in this section, they are provided as examples only. Consider discussing document control with associated laboratory to explore opportunities to sharing software or programs.

Self-assessments and the Strategic Improvement Plan must be reviewed and updated at least annually. Beyond that, MFRPS does not require set timeframes for reviewing documents. States may consider adding review timeframes to the written procedures. For example, policies and procedures will be reviewed biennially and updated as necessary. If this is determined to be a best practice for the program and included in procedures, then it must be followed, so be realistic and include tracking mechanisms.

**Describe the Organization, Dissemination, and Access to Documents:**

Describe procedures for distributing documents to ensure that staff only utilize the most current released or approved version and archived or rescinded files are withdrawn from circulation and retained in accordance with MFRPS and agency record retention policy, or RDA (record disposition authority). The written document control policy may also consider procedures for training and ensuring new information gets to end users. The procedures ensure that users have access to the necessary documents when and where they need them. In this example,
SharePoint is used along with individualized permissions to assure access is granted and appropriate distribution to end users is achieved:

There are multiple ways to train and share new updates with end users, but for any system, ensure that the delivery can be tracked and that the records can be maintained for verification purposes. Documentation of training on modified procedures could include:

- Email notifications of the new policy with read and delivery receipts
- Enrollment in a training course which covers the new policy with completion records
- Use of an automated document control system with tracking
- Group meetings with agendas and sign-in lists
- New Inspector training

Ultimately, the degree to which staff are found by auditors to be following the correct and current procedures is the measurement of successful SOPs and training on those SOPs. Plan on embracing feedback about how SOPs could be improved based on the results of field inspection audits, inspection report, sample collection record, and compliance action audits.

**Key Takeaways:**

- Well-written, comprehensive SOPs will make a Coordinator’s job easier and will benefit the State food program. Include SME input in SOP review, get approval and buy-in, and train to the SOP.
- Written procedures for document control may benefit from including a process for rescinding obsolete versions of documents and ensuring old copies are not available. Consider including a statement such as: “Printed copies are considered uncontrolled and must be verified against the copy in Document Control prior to use” on documents. States may want to capture history of changes for each document and may also consider keeping a running list of possible updates for consideration between review periods.
CHAPTER 6: AUDIT PREPARATION AND EXECUTION

Scope:

This chapter focuses on preparing for an FDA onsite assessment (audit) of state implementation and conformance to the Program Standards.

Key Questions Discussed in this Chapter:

- Why have an assessment?
- Should the Coordinator conduct a document review?
- What documents and records should be on hand?
- What are the steps of an assessment?

Purpose of an Assessment (Audit)

Assessment and audit are used interchangeably in this chapter, and assessment is defined by the MFRPS. An assessment of the State program can help identify areas for improvement and maintain quality standards. The outside perspective during the audit and examination of the State policies and procedures help determine the differences between the State program activities and the intent of the Standards.

Document Review

The Coordinator may know that the program meets all the standards, but this will need to be demonstrated to the FDA during the assessment. The PSC needs to know each document that proves implementation and conformance with each standard, and where to find them. It is not ideal to have to search through lengthy documents in front of auditors that are waiting for the Program to demonstrate implementation. Therefore, before the assessment, consider reviewing each element in the self-assessments and note where each element’s supporting documentation can be found. This can be accomplished by making a linked document connected to the source documents for each element or having notes that include sections or page numbers where the element can be found. The Coordinator may also want to review each document listed in the audit staff checklist and address any previous FDA DSI comments. It may be helpful to use the “Comments” column of the self-assessments to note where the element is documented. Prepare other key personnel that may be joining the audit, so they are familiar with each of their documents. Not every document needed to demonstrate conformance is listed in the self-assessments, so do not rely on them exclusively. For instance, the program will need a mechanism comparable to a Master List to demonstrate conformance with document control requirements, and to assist in the document control requirements review that goes with the review of conformance to each standard.

Available Records

Now that the Coordinator knows what documents are needed and where to find them, the PSC will need to make sure that records that demonstrate the program’s adherence to program elements are readily accessible during the assessment. It may be helpful to select several examples ahead, as some records demonstrating conformance may seldom occur. For example, a consumer complaint against a manufacturer which triggers a recall and compliance
actions may be a rare occurrence, therefore, if this occurred then gather the records to show the auditors. It will also help program improvement because it will provide an opportunity to identify and correct any deficiency found during the retrieval process. To prepare, review the actions taken, procedures followed, and records that support each action. Pick records that demonstrate trace back/forward across multiple standards (outbreak investigations, complaints, complex compliance cases) or inspections that caused in a reinspection which resulted in a recall or a compliance action. Provide training records for staff that conducted the inspection and audit records show there was two field audits within the last 36 months if applicable.

**Steps Before, During, and After an Assessment**

There are many items that the PSC may consider in order to ensure a successful and efficient FDA MFRPS assessment, the sections below provide some best practices for consideration for different phases of an assessment:

**Before an Assessment**

Key individuals should be available during the assessment. In the program, there will be a lead and sometimes many subject matter experts who are present for the assessment. If the Coordinator will be alone during most of the audit, then define roles and responsibilities beforehand, provide back-ups for personnel, and identify a person(s) that can assist in obtaining documentation. Roles outlined during an assessment may include:

- Who’s navigating the computer?
- Who’s answering questions/is available to answer questions?
- Who’s available to make on-site corrections and route documents for document control?
- Who needs to be on-site during the assessment?
- Who will make decisions about correcting findings?
- Who is contact person for the Audit Staff?

Before the assessment, determine who will explain each aspect of the program to the auditors. Some states may choose to introduce all the Standards leads in the beginning of the audit, and to provide a short PowerPoint orientation to the State program and summary of how it’s meeting, or progressing towards meeting, each standard. The Standards leads can then be released but need to be available upon request during the assessment to respond to specific questions about the Standard when it is discussed. Make sure that all the key personnel are available and aware of their roles. Prepare a slide for each standard lead that will help during the audit, that way the auditors have been introduced to everyone that may participate ahead of time. Improve awareness by inviting the State Liaison and DSI to the beginning and closing of the audit. Accurate self-assessments are the first step to assessment preparation. If the Coordinator is routinely completing and updating self-assessments, there should be no surprises. Before an assessment, it is important to go through the self-assessments thoroughly. Be an auditor and double-check all elements in these self-assessments. If there will be others with joining, then prepare them with questions you know will be asked. Make sure that each self-assessment is signed and dated within the last 12 months.
The audit checklist is also a very important tool to use when preparing for an assessment. Preparing documentation for each item on the most current version of the audit checklist ensures ability to demonstrate that the Program meets all requirements of the standards. It is a recommended practice to note on the checklist which documents (to the page number if appropriate) are relevant to each element, along with a location or link to the documents. Perform traceback or traceforward on agency conformance with the standards. Examining the report from the most recent FDA DSI technical visit will help you outline where any deficiencies may exist. FDA auditors will schedule a pre-assessment call to discuss requested documentation, auditor expectations, and anticipated schedule of the assessment. This can be a good time to ask any questions related to the assessment. Become familiar with previous assessment report findings and assure that these findings have been addressed.

Once ready for the assessment, practice. One of the more popular tools used recently by states is to have a “mock” audit. An outside party, a Coordinator, a program manager within another department, or someone within the program can be the “auditor” and go through a full assessment. It is helpful to make it as realistic as possible. The “auditor” should be instructed to request information, be explained procedures, and look through training plans, audit complaint procedures and records, recall logs, and any other documentation that will be discussed during an actual assessment. When conducting mock audit, schedule it with enough time to correct the deficiencies revealed during the exercise. Allow at least twice the amount of time as the actual assessment for discussion. It is recommended to conduct a mock audit one to two months prior to the assessment.

**During an Assessment**

The assessment is an opportunity to show off the program that the Program has made, so take time and explain the State program to the auditors. View auditor questions during the assessment as an opportunity to explain the program further. Avoid becoming defensive and focus on whether the element is met or not. Some policies or procedures are quite complex, and it may just be difficult to locate the referenced item. During the assessment, be prepared to walk the auditor through different processes. This is when examples can be very helpful. An important idea to keep in mind during the assessment is that the program has 60 days after the assessment to address any findings in the draft report; do not feel that each correction must be implemented before the auditors leave. However, it is a good idea to plan to be able to implement quick fixes for corrections to wording in procedures which do not require extended time to correct.

**After the Assessment**

After the assessment an After-Action Review or “hot wash” can be used to go over the what went well and what can be improved. Conduct the AAR while the material is still fresh in everyone’s minds. A plan should be developed to address any findings during the assessment. Changes made within 60 days after the assessment, if satisfactory, will alter the auditor’s findings. Extensions to this timeframe may also be granted by the audit team. Take the time to make sure the correction can be made meaningfully and successfully rather than hurrying cosmetic conformance which won’t be sustainable. If full conformance is not received after the 60-day window you may want to consider the mid-interval assessment process. Contact the DSI specialist if interested in the option.

**Key Takeaways:**

- Planning the logistics of the audit will make the entire process run smoother.
- Conducting a “mock” audit is a very helpful tool in being prepared for the actual assessment.
- Review any findings soon after the audit, while the information is still fresh in everyone’s minds.
CHAPTER 7: HOW THE FDA CONTRACT ALIGNS WITH THE PROGRAM STANDARDS

Scope:

This chapter focuses on the FDA Food Inspection Contract alignment with the Program Standards.

Key Questions Discussed in this Chapter:

- What are the shared requirements between the Standards and the FDA Contract?
- How can the Standards inform work planning?
- How do the Standards promote mutual reliance between FDA and the States?

Standards and the FDA Contract Requirements

States must have a Food Inspection Contract with FDA as a prerequisite to enrolling in the MFRPS, and the contract is a key part of the standards. The standards require that the contractor have a risk-based inspection system. The current version of the MFRPS state “FDA will use the Program Standards as a tool to continuously improve manufactured food contracts...” A MFRPS Coordinator may or may not be tasked with contract management responsibilities. Whether or not Coordinator responsibilities include the contract on a day-to-day basis, a best practice is to thoroughly understand the role of the contract in the genesis of the Standards. It is necessary to make sure that contract and cooperative agreement monies are kept distinct and separate. A good introduction to the role of the FDA Food Contacts is the 2000 Office of Inspector General (OIG) report, “FDA Oversight of State Food Firm Inspections A Call for Greater Accountability.” In addition to reading the 2000 OIG report, and its 2007, 2010, and 2011 successors, it’s a good idea to learn more about the history of the State’s FDA contract, the inner workings of planning process, the electives in the FDA contract, and what contract auditing phase the State program is in. Each Standard represents best practices for states and FDA. The FDA State Liaison can help with the Standards by meeting the requirements of the Food Contract, for example, by assisting with joint inspections and audits, and sharing the FDA perspective on inspectional and compliance approach. However, don’t mistake the contract as the main piece in the Standards program. Depending on the size of the State food program’s contract, it may cover hundreds of inspections, but the Standards cover all manufactured food work. The Standards are all encompassing, and the contract is one vital piece of the overall State program. It is also wise to consider that the contract is managed via a statement of work (SOW) that changes from year to year. The food program needs to be able to meet the short-term SOW and the long-term MFRPS. Furthermore, the Coordinator and the FDA State Liaison should be on a first name basis. Consider calling the State Liaison for information on joint inspection opportunities, trainings, compliance issues, and audits, to start. MFRPS Coordinators do not need to manage the contract; however, some manage both.

The Standards and Work Planning

If the Coordinator is not involved with the state’s work planning process, consider how to get involved in some way. Before participating, be aware of the confidentiality requirements for FDA-owned information. If the Coordinator doesn’t have direct contract responsibilities, this may mean the Coordinator needs to be under a 20.88 agreement or commissioned by FDA to be authorized to access pertinent information. Check to make sure that the Coordinator has
appropriate authorization to access information as needed. As a commissioned official, one will also benefit from receiving FDA updates on national outbreaks. For more information on confidentiality, credentialing, or commissioning by FDA: https://www.fda.gov/ForFederalStateandLocalOfficials/CommunicationsOutreach/ucm472936.htm.

Remember that contract and cooperative agreement expenditures must remain separate. Therefore, if the Coordinator salary is 100% funded by MFRPS, then the Coordinator’s work cannot also be paid for by the contract. Know what goes into the contract effort estimates and gets billed for in the contract vs. what does not. For example, work planning and coordination, not just for the purposes of the contract, may be an allowed expense under MFRPS, but an auditor being paid by the FDA to audit a contract inspection cannot also be paid by MFRPA cooperative agreement funds.

The FMD 76 describes how contract performance is audited by the FDA using individual audits of state inspectors. State programs are required to follow the FMD-76 when it audits its own inspectors under contract (phases II and III). Following the FMD-76 for all audits, whether of contract or non-contract inspections, is recommended, though where there are discrepancies between the FMD-76 and the MFRPS, the FMD-76 supersedes the MFRPS when it comes to the contract, and the MFRPS supersedes the FMD 76 for audits performed outside of the contract.

The Standards and Mutual Reliance

The following are questions and statements to ask or consider as a MFRPS Coordinator. While working through the standards much of this information will become second nature, but when first stepping into this role one can get overwhelmed quickly. This should provide a roadmap:

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**Standard 1:** While equivalent regulatory authority is not required to meet Standard 1, it is required when being used as the basis for inspections conducted on the FDA’s behalf, under contract. Appendix 1 shows where the state and federal authorities differ for pertinent parts of the CFR. Unless the state’s regulations are at least as strict as the FDA’s for each commodity inspected under contract and its authority to inspect, gather evidence, and prevent adulterated food from entering commerce are equal to the FDA’s, the State must rely on FDA authority via commissioning and credentialing of contract inspection staff, and FDA forms must be used in accordance with the FDA Investigations Operations Manual. Equivalent regulatory authority is a prerequisite to exchanging work product outside of contract as well, via mutual reliance. Consider whether the State is expanding or strengthening its regulatory authority; if not then identify the obstacles.

**Standard 2:** What is the relationship between the contract and the budget for training staff that is included in the state’s cooperative agreement budget? Is there appropriate communication with the State Liaison at the beginning of each contract year about the state’s training needs? The Coordinator must use state program or MFRPS cooperative agreement funds to pay for staff to attend the FDA classroom courses required to inspect establishments under contract, as well as outside of contract. Make sure that the program budgets for all training needs and ensures that there will be enough adequately trained staff to carry out all of the contract inspections and audits. If there will be a shortage of trained individuals, consider whether to propose that the contract be modified. The State Liaison will assist in developing the food program inspectional staff by coordinating joint inspections. Remember to document these for Standard 2.
**Standard 3:** How do the state and FDA inspection systems differ? How can they complement each other? Is there an easy way to share, compare and sync inventories? If the state collects samples, is chain of custody captured? If the state conducts Recall Audit Checks, is the program performing them in a similar way to FDA? Are consumer complaints, both state and FDA, reviewed and covered during the inspections? Can the inspection system accommodate inspections completed by the FDA, to avoid duplicating work?

**Standard 4:** What audit phase of the contract is the state in? How many contract audits are needed per the current version of FMD 76? How does that align with the audit requirement in Standard 4? Are state staff trained to audit or is the responsibility to audit state staff shared with the FDA? If a corrective action plan is needed for the contract, but not because of the standard, who is responsible for capturing that information and how is that fed back into the standards? The State Liaison is responsible for assuring that quality of contract inspection reports is adequate, and requests corrections as needed. How is the feedback from the State Liaison being used to improve the quality of inspection reports?

**Standard 5:** Does the program have a Rapid Response Team? Is the Rapid Response Team coordinating response efforts, including After Action Reports that indicate that outreach is needed under Std. 7? Is the FDA Recall Audit Check form used by the food program? Are training needs identified? Are there skill sets needed to be maintained that could be done under the contract, for example environmental sampling?

**Standard 6:** Is the state tying chronic violations and violators into contract and work planning? Is FDA help needed to deal with the violative firm? Does the state understand the FDA compliance process? Does FDA understand the state’s compliance process? Does the state want to continue to handle the firm without FDA or assist because the firm is not cooperative? Are re-inspections conducted under contract?

**Standard 7:** Is guidance shared on behalf of the contract toward outreach under Std. 7? Can FDA assist with outreach and resources for identified gaps? Is this discussed during work planning? Is there an opportunity for outreach after an outbreak? Does the Coordinator lead or participate on a task force in the state, whether or not it is funded by FDA?

**Standard 8:** Review state resources during work planning so FDA is aware of what resources are present or missing at the state level. How can FDA support current or future state resources?

**Standard 9:** How does FDA and states work together to close gaps identified in the self-assessment? Are documents missing? Are external documents provided by FDA, CDC, CIFOR or the International Association for Food Protection (IAFP) controlled per state policy?

**Standard 10:** Review lab capabilities yearly during work planning so FDA knows when it is acceptable to use State Lab for sampling or compliance and enforcement actions.

The above information provides a lot to consider as a MFRPS Coordinator, so prioritize and don’t take all these questions on at one time. If just beginning Standards implementation, then focus efforts on training. If the program is in full compliance, then auditing and sharing inventory may be more useful. Either way, work through the Standards and think about each of these questions when appropriate. Remember that the FDA State Liaison is an important resource and will provide assistance with Standards and Contract alignment.

**Key Takeaways:**

- Build a relationship with the FDA State Liaison
- Identify ways to be involved in the FDA work planning process
CHAPTER 8: GRANT PROPOSAL DEVELOPMENT, REPORT WRITING, AND MANAGING COOPERATIVE AGREEMENTS

Scope:

This chapter focuses on the different aspects of applying for and managing a cooperative agreement.

Key Questions Discussed in this Chapter:

- What is involved when applying for a cooperative agreement?
- What is the notice of award?
- Who is involved in the management of the cooperative agreement?
- Reporting

Applying for a Grant/Cooperative Agreement

A cooperative agreement application is found and initiated under the Research Performance Progress Report (RPPR) section of eRA Commons and grants.gov where instructions for submitting the application will be provided. There are useful resources available on these pages as well. Some or all tasks related to the application and administration of the Cooperative Agreement may be delegated to the Coordinator. Consider discussing the following items with the program manager or key individuals:

- Who will submit the letter of intent?
- Who will apply for the Cooperative agreement?
- Who will be the principal investor (PI)?
- What is the Data Universal Numbering System (DUNS) number?
- Who has approved log-ins?
- What does the internal process for applying look like and how long does it take?

Submitting the Letter of Intent

Each state program may differ in which staff person is responsible for researching cooperative agreement opportunities, and subsequently identifying the program’s interest in applying. This staff person will likely submit a letter of intent declaring the program’s intention to apply for the funding to ensure inclusion in FDA technical calls for potential applicants. The Funding Opportunity Announcement (FOA) detail the specific requirements for the letter of intent and will vary among each grant or cooperative agreement. If applying, the state program should submit the letter of intent on time; keeping in mind it need not be a lengthy letter and it does not obligate the program to apply for the cooperative agreement.

The terms grant and cooperative agreement may be used interchangeably in this section. See the Glossary of Terms section.
Principal Investigator

If not done so already, the state program will designate a principal investor (PI) for the cooperative agreement. The PI is required to have the level of authority and responsibility to direct the project or program supported by the award. In agencies where some positions are appointed and others are civil service, it may be wise to designate a PI who will not be subject to change with each administration. There may be more than one PI, however, this does not negate the responsibility or accountability of either person.

Applying for the Cooperative Agreement

When applying for a grant or a cooperative agreement, it is important to start and submit early. Identified personnel in the program should make sure the organization’s Dun & Bradstreet’s Data Universal Numbering System (DUNS) number and other log-in accounts are active. Creating a DUNS account can be a time-consuming process. It is also important to determine who has an account and is approved to upload information into each required system (Grants.gov, eRA Commons, etc.). It is also encouraged that identified personnel become familiar with the internal approval process and identify and verify who signs off on the application in addition to the PI, and how much time each approver requires to complete their review. This will allow the program to plan and schedule due dates to adequately accommodate others. The program should also consider the time needed by state program reviewers to review the proposal and make necessary edits. Each added reviewer can provide valuable insights and help to improve the proposal. The agency signing official must submit the application for a cooperative agreement or grant and will usually require that the proposal be reviewed by state financial and legal representatives prior to signing and submitting via eRA Commons. The program should ensure that this person will be available to sign when the proposal needs to be submitted, and that there is a backup person who can submit on behalf of the applicant agency if needed. Agency signing officials and other contacts for grant-related announcements and notifications need to be aware when the application is actively being submitted. Error messages received by the signing official will need to be forwarded to the identified program personnel for correction. Error messages may be viewable before the signing official attempts to submit the application. Unexpected errors and last-minute changes can impact a successful submission process. The organization risks losing any chance of receiving funding if the application is submitted at the last minute. If there are questions during the application submission process, the program is encouraged to contact the Division of Partnership Investment and Agreements (DPIA) Contracts and Grants Office of Partnerships, DSI staff, helpdesk for the appropriate submission program, agency contacts listed on the Funding Opportunity Announcement, or other states or programs. Refer to the FOA for specific contacts for each grant.

Notice of Award

If the cooperative agreement application is successful, a notice of grant award (NGA) will be provided to the PI listed in the application. This should be kept handy and used when managing the cooperative agreement. A typical notice of grant award contains the following sections:
The first page lists the organization’s grant number, Federal Award Identification Number (FAIN), PI, project title, contact information, budget period, project period, and the name of the grant management officer. The budget period refers to the upcoming period while project period refers to the entire period under the cooperative agreement.

**Section I**—This section includes the approved budget information and other fiscal information.

**Section II**—This section includes payment information and forms used by the agency fiscal department. This includes information and instructions for drawing down funds and reporting expenses.

**Section III**—This section includes the terms and conditions for the cooperative agreement. Additional reporting requirements will be outlined here.

**Section IV**—This section includes terms and conditions listed under the agreement. PI rights, PI and FDA responsibilities, funding restrictions, financial and performance reporting, prior approval requirements, and other pertinent information can be found in this section. This should be read carefully to avoid absorbing non-allowable costs. Information regarding mid-year, continuation request, end of year, and end of project reports are outlined in this section. End of project reports outlines project goals and accomplishments made throughout the entire period of the project. “Staff Contacts” can also be found in this section including the grants management officer.

When logged in to the agency eRA Commons account, the notice of award can be found under *institution profile*, then *basic information*, then by viewing *institution contact information*. Additional contact information, primary DUNS number, signing officials, and other organizational information can also be found in this location.

**Management of a Cooperative Agreement**

Once the program receives the NGA, it is important to review the document, specifically *Terms & Conditions*. This section outlines reporting requirements and financial duties. After completing a mid-year report, required under section IV, the next step of this process is to submit a continuation request. This is a request for funding for the following year and includes a revised budget, which may differ from the budget included in the original application. The last step of this process is to submit the year-end report. This step triggers the receipt of the new NGA for the next cycle, making full circle of the award process.

There will be calls discussing the report writing requirements and the PSC should be attended when possible. It is important to double check the NGA for the requirements of the report. If the requirements can’t be found, ask the grant specialist.
Once the NGA has been received, the work of managing the cooperative agreement begins. Management of the cooperative agreement includes accomplishing the work, documentation and reporting, and involves many requirements to adequately track expenses and separate activities funded by distinct cooperative agreements or contracts. It thus requires successful collaboration between several individuals. The FDA grants management office requires that grantees obtain prior approval for certain changes to the planned activities, budget and key personnel changes (as specified in the notice of award), and in all cases keep FDA informed as to planned and completed activities and associated expenses via mid-year and end of year reporting. The grants management office is a great resource for questions with the cooperative agreement. The bottom of the NGA provides the contact information of the Grants Management Specialist, Program Official (FDA Office of Management (OM)) and Program Manager (FDA Office of Partnerships (OP)). Communication with other parties who need to provide report information is key to successful award management.

In order to meet reporting deadlines, work planning is an important tool to use. Place mid-year and year-end reports in the strategic plan. It is a best practice to update the self-assessments, strategic plan, and review financial reports (as needed) before submission. Submit completed report into eRA commons, grants.gov, or directly to the project manager in plenty of time prior to the deadline; for example, one week early or as required by the agency in case changes are needed.

**Key Takeaways:**

- When applying for a grant or a cooperative agreement, start early and submit early.
- Review the NGA as soon as it is received, or when starting the new position if entering into an existing grant cycle, specifically *Terms & Conditions*.
- Get organized from the get-go! Successful work planning is an important tool and may be utilized through the agency strategic plan.
CHAPTER 9: JOB DUTIES OUTSIDE THE STANDARDS

Scope:

This chapter focuses on other job duties that the Program Standards Coordinator may have.

Key Questions Discussed in this Chapter:

- What other duties may a Program Standards Coordinator be responsible for?
- How does a Program Standards Coordinator manage the workload?

Other PSC Responsibilities

Coordinators may have several other job duties in addition to overseeing the Standards. These can range from components within the Standards themselves, to other grants and subject matters entirely. Keeping these responsibilities separate if needed and knowing how to use them to benefit the management of the cooperative agreement can save time and headache.

Training coordination

Training coordination and quality control of training records can be a big part of a Coordinator’s role. Keep in mind that working closely with program management or supervisors to identify training needs for the staff will be important to the success of the training program. Coordinating the documentation of staff training can provide a picture of future trainings needed. It will also help reveal gaps in training and assure that the organization properly plans to secure attendance at courses not always offered by the FDA. Bear in mind that sometimes, learners’ attendance in courses may be outside of the Coordinators control. Work to make sure learners are assigned their curricula especially the FD (food) course prerequisites promptly after hire and that there are alternate individuals that are ready to attend the course if a slot becomes available. Ask the FDA State Liaison or program management about gaining access to FDA’s Pathlore Learning Center system to view, search, and take all relevant food related coursework.

Quality Control

Undertaking quality control practices required under Standards 4 and 6 may be a big part of the Standards Coordinator’s role. The Coordinator may conduct desk audits of field inspections, inspection report writing, sample collection records, and compliance actions. Practice objectivity and rely on written guidelines for completing these audits.

Equipment and Technology

A Coordinator may be responsible for inspection equipment and become a designated technology expert for field computers. If the Coordinator is not familiar with protocols related to equipment troubleshooting, then it is important to have the contact information available to provide answers quickly to inspection staff in the field. Besides equipment, a Coordinator may be involved in the development or maintenance of online databases, inspection, and licensing systems, or websites for the organization. These data management responsibilities may
include other programs, like body art, feed, shellfish, or others, so be aware of all the different online databases the agency may be managing.

**Licensing and Complaints**

Licensing responsibilities may be part of the Program Standards Coordinator’s job description. This can allow for increased familiarize with the program structure and program inventory. Some Coordinators may work to assist the public or current operators with renewing or applying for licenses in the State. Keep in mind not all state agencies license food operations. Similar to licensing, a Coordinator may also be in charge of managing complaints from the general public about food firms or other programs overseen by the organization.

**Workgroups (Committee Work)**

As PSC, opportunities will arise to join and participate in a variety of workgroups for the MFRPS or for a variety of other grant programs, like RRT or the Task Force. Additionally, as time goes by the agency may require participation in work groups or committees, such as, the Association for Food and Drug Officials (AFDO) or the Partnership for Food Protection (PFP) or the International Association for Food Protection. Furthermore, many regional organizations may need help, like regional affiliates for AFDO, IAFP or the National Environmental Health Association (NEHA). As always, work with program management before taking on committee work.

**Grant Writing, Management, and Reporting**

The Coordinator may be called upon to help develop grant proposals to accomplish work outside the MFRPS. It is important to keep funding sources separate and be aware of which funds can be used for what if the Coordinator helps manage multiple cooperative agreements. To help ensure there is no overlap in the deliverables for different cooperative agreements, the PSC should be aware of all the cooperative agreements and grants that the program receives from the FDA. Other types of cooperative agreements may include:

- Rapid Response Team
- Food Safety Taskforce
- Other standards such as the VNFRPS and AFRPS

**Managing the Workload**

There are states that have one Coordinator for both the Voluntary National Retail Food Regulatory Program Standards (VNFRPS) and the MFRPS. Even if the food program has a separate retail Standards Coordinator, it’s a good idea to read them over. The retail standards predate the MFRPS significantly and were the forerunners of the MFRPS. Being able to distinguish between retail and MFRPS requirements will allow for assistance between the standards and identification where both standards can be met using the same documents or system. Depending on the program set-up, feed, dairy, and egg standards may be part of the Program Standards Coordinator’s role.

Program Standards Coordinator responsibilities will feel overwhelming at times, but flexibility and prioritization of daily tasks will help ensure success. Begin each week with a plan, this may be accomplished by reviewing the status of each project and focusing on those with deadlines that are due first. PSC work may be derailed at times, so don’t stress if all tasks are not completed on the desired day, instead remain flexible in planning the work that still needs to be completed. Working overtime is not always a possibility, so scheduling each project and deadline on a calendar ahead of time will be important to achieving project completion. It may also be important to discuss workload management with supervision or key individuals to ensure progress is on track. In addition, feel free to discuss organizational insights, ideas, and tools with other Coordinators.
As a PSC, the responsibilities will be overwhelming at times, but prioritization of daily tasks will help ensure success. Start each week by planning out the work that needs to be done. This can be approached by reviewing the different projects and checking to see what deadlines are due that week or in the next week. As a PSC, derailment will happen. Be prepared to be flexible in planning work to be done within the day or week. Most importantly, do not stress if all the tasks on the list are not completed on the desired day. Flexibility is vital to managing the workload. Always feel free to discuss managing workload with supervisors or other PSCs. Share insights, ideas, and tools on organizing work.

Key Takeaways:

- Other duties may be assigned to the PSC
- Be prepared to manage these responsibilities
- Learn how to leverage non-MFRPS work to advance knowledge, understanding, or tools for MFPRS
### RESOURCES

**Fellow Program Standards Coordinators:**
- Other PSCs may be best resource and can direct questions to get the information that is needed.
- PSC are willing to share documents and processes that they have been developed within the State program. Keep in mind that documents and processes may change between FDA Assessment cycles, so it may be a good idea to ask fellow PSC if the information requested has been audited recently.

**Other Standards (AFRPS, VNRFRPS)**
- Example appendices, documents, templates, etc. that have been developed by states enrolled in the AFRPS and/or the VNRFRPS may be useful to others:
  - AAFCO List Serve (for Appendices) (Association of American Feed Control Officials)
  - FDA Retail Food Specialists (for Appendices)

**MFRP Alliance Portal and FoodSHIELD**
- MFRP Alliance Portal: [http://www.afdo.org/mfrpa](http://www.afdo.org/mfrpa)
  - This portal has procedures from all State programs participating in the standards.
- FoodSHIELD: [https://www.foodshield.org/](https://www.foodshield.org/)
  - The MFRPS workgroup houses the current version of the MFRPS and all the appendices in word format.
  - Emails will be generated from this workgroup that provide information on upcoming webinars and other resources that may be of use to you.
  - Templates to support standards work and cooperative agreement reporting are also available
- Talk to DSI or an AFDO representative (Association of Food & Drug Officials) to get log-in and passwords.

**Food and Drug Administration:**
- DSI Representative
- FDA Audit Staff
- FDA State Liaisons (obtain regular updates to the following resources):
  - Investigations Operations Manual
  - FDA Division enforcement activities (that affect state regulated firms)
  - FMD directives or bulletins
  - Updates to the Code of Federal Regulations
  - FDA Division Workplans
  - Pathlore and Compliance Wire Learning Management Systems
- FDA ORA (Office of Regulatory Affairs) Quality Manuals
- Examples and templates for policies and procedures, particularly document control.

**FDA MFRPA Workgroup Calls**
- Attend FDA workgroup calls for cooperative agreement recipients, especially those talking about report writing requirements
- Join standard specific workgroups to discuss submitted changes to the standards

**State-specific Food Safety and Defense Task Force Websites**
- A good place to find out what other states are doing for outreach per Standard 7

BIBLIOGRAPHY

- The Institute of Cultural Affairs in the U.S.A. (2016). Technology of Participation, ToP Facilitation Methods-Effective Tools for Participation from ICA USA. Chicago, IL: ICA USA.
- Partnership for Food Protection documents have a multitude of best practices
- Manufactured Food Regulatory Program Standards Workgroup
- Manufactured Food Regulatory Program Alliance
- Flexible Funding Model FOA
- Food Contract RFP
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