CHAPTER 2
FEDERAL-STATE COOPERTIVE PROGRAMS

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1.0. PURPOSE

This document is designed to introduce readers to the four areas of the Federal-State Cooperative Programs (the Interstate Milk Shippers Program (IMS), the National Shellfish Sanitation Program (NSSP), the Retail Food Protection Program, and the Radiological Health Program). These programs represent a significant part of state food safety/security programs and should be included in

any response teams, taskforces, or other organizations of that nature. This document is not intended as a guide to the actual incorporation of Cooperative Programs personnel and activities into an integrated food safety system such as a Rapid Response Team (RRT). The development, structure, and function of response teams, taskforces, and other related organizations are topics that must be addressed on an individual basis considering the needs, resources, and limitations of the parties involved. Other chapters of the RRT Best Practices Manual (Working with Other Agencies, Communications, Joint Investigations) provide more specific instructions and examples on the development of these types of organizations (i.e., RRTs). The goal of this chapter is to introduce and detail the roles and responsibilities of the four areas of the Federal-State Cooperative Programs so that they can be included in the development of an integrated food safety response system.

2.0. SCOPE

This document focuses on defining the key activities and responsibilities within each of the Federal-State Cooperative Program areas. This information can be used to determine those areas in which federal, state, and local agencies involved in food emergency response may incorporate Cooperative Programs into their various food safety systems and organizations.

3.0. RESPONSIBILITY

These four programs are monitored by FDA, but regulatory and administrative actions are implemented by the states.

3.1. Agency/Organization Leadership

Representatives from federal, state, local, and all levels of cooperative program areas will jointly approve any customizations made to this template to ensure that procedures developed that are appropriate for state-specific jurisdiction.

3.2. RRT (or investigatory team, in states without an RRT) Leadership

- **Procedure familiarization/training:** RRT leadership is responsible for ensuring that the personnel assigned to respond to a human or animal food incident, involving cooperative programs have been provided with the Incident Command System (ICS) and investigation-related training necessary to implement this chapter.

- **Procedure maintenance:** Ongoing updates and maintenance of procedures would ideally be the duty of combined leadership of the RRT (or in jurisdictions without an RRT, the responsibility of the manager of the appropriate department). In an RRT, this would include representatives such as the FDA Emergency Response Coordinator (ERC), the state RRT program

director or principal investigator, and both state and FDA representation in each of the four cooperative programs.

3.3. RRT Members

- **Procedure Familiarization/awareness:** RRT Members must be familiar (through orientation, training, exercises, etc.) with RRT and Cooperative Program Standard Operating Procedures (SOPs) and their implementation.
- **Skills maintenance:** RRT members are responsible for actively maintaining their subject matter expertise and ability to work effectively in multi-disciplinary and multi-agency response teams.

4.0. DEFINITIONS

The following terms are used frequently in this Chapter: Environmental, Epidemiology, Laboratory, and Food Safety Defense Task Force.

See Manual “Glossary of Key Terms” for definitions.

5.0. BACKGROUND

Overview of Federal-State Cooperative Programs

The Federal-State Cooperative Programs are composed of four separate food safety programs, the IMS, NSSP, the Retail Food Protection Program, and the Radiological Health Program. The authority for these programs is provided in the Public Health Services Act (42 USC 243). Section 311(a) of the Act states in part, “The Secretary shall…assist states and their political subdivision in the prevention and suppression of communicable diseases with respect to public health matters, shall cooperate with and aid states and local authorities in enforcement…health regulations and shall advise the several states on matters relating to preservation and improvement of the public health.” Responsibility for carrying out the provisions of the Act related to food protection was delegated within Public Health Service (PHS) to the Commissioner of Food and Drugs in 1968 (21 CFR 5.1 (a)(2)&(4)). These programs are often cited as a force multiplier and are examples of how a small expenditure of Federal resources may be leveraged to guide a much larger resource investment by state and local governments. The Milk, Shellfish and Retail Food programs each have a governing conference: The National Conference on Interstate Milk Shipments (NCIMS), the Interstate Shellfish Sanitation Conference (ISSC), and the Conference for Food Protection (CFP). The goal of these conferences is to develop and adopt national rules and model regulations that can be implemented by the participating states thereby promoting program uniformity throughout the nation.

5.1. Grade "A" Milk Program

The FDA State Cooperative Milk Safety Program was established under a Memorandum of Understanding (MOU), signed in 1977, between the Commissioner of the FDA and NCIMS. The NCIMS is the mechanism through which the *Grade "A" Pasteurized Milk Ordinance* (PMO) is revised. The PMO is a model regulation for states to adopt which regulates the production of Grade "A" raw milk on the farm; its pickup and transfer from the farm to the dairy plant; and the processing, packaging and handling of Grade "A" milk and milk products in the United States.

5.2. Shellfish Sanitation Program

The NSSP was formed in 1925 when the U.S. Public Health Service responded to requests for assistance from local and state public health officials in controlling disease (primarily typhoid fever) associated with the consumption of raw oysters. Several workshops involving the States and the Federal government were subsequently held to develop program guidelines and address emerging problems pertaining to shellfish (oysters, clams, mussels, and now, whole scallops and scallop adductor muscle meat with attached roe) such as marine biotoxins, heavy metals, pesticides, etc.

The first NSSP Workshop was held in 1954, and subsequent workshops were held in following years. In 1982, a delegation of State shellfish officials from 22 states met in Annapolis, MD and formed the ISSC using the successful NCIMS as a model. FDA has a formal MOU with the ISSC which outlines the responsibilities of each in the sanitary control of shellfish (oysters, clams, and mussels).

5.3. Retail Food Program

FDA's Retail Food Protection Program provides assistance to over 2,200 state and local government agencies that regulate the retail food industry. In 1993, FDA signed a MOU with the CFP, which is an organization that brings together representatives from the food industry, government, academia, and consumer organizations to identify and address emerging problems of food safety and formulate recommendations to be incorporated into public policy and industry practice. The stated purpose of this MOU is to establish a working relationship between CFP and FDA to:

- Place greater emphasis on food safety at the point of sale, and
- Be more successful in promoting food safety, mutual respect and uniformity.

5.4. Radiological Health Program

Regional Radiological Health Representatives (RRHR) are FDA's liaisons to the states for areas of radiological health and radiological emergencies. Radiological emergencies can include malfunctions at nuclear power plants as well as hostile actions to comprise the integrity of a nuclear reactor, or other terrorist

activities involving bombs containing nuclear or radioactive materials. Any of these events could compromise the nation's food supply and allow radioactive materials to enter the ingestion pathway. Additionally, the RRHR is responsible for general oversight of all radiological health program areas and training and considered the Subject Matter Expert (SME) for radiological health.

6.0. SAFETY

N/A

7.0. EQUIPMENT/MATERIALS

N/A

8.0. PROCESS DESCRIPTION

The four cooperative program areas described earlier can play an important part in food safety response. These partners are critical to the Food Safety Defense Task Forces, RRTs, and other Food Safety Response entities. Additional cooperative program partnership and integration best practices can be found in other chapters of the RRT Best Practices Manual including "Working with Other Agencies", "Communications", and "Joint Investigations".

The four programs are described below to familiarize readers with the structure and responsibilities of each.

8.1. Grade "A" Milk Program

The PMO creates a three-tier system consisting of (i) state enforcement, (ii) state rating, and (iii) FDA check rating. State enforcement consists of permitting, inspection, sampling and enforcement activities. State ratings consist of conducting reviews of state enforcement activity to ensure milk supplies and plants are in substantial compliance with the requirements of the PMO before they are listed in the *Interstate Milk Shippers List* (IMS List). Firms on the IMS List are authorized for interstate shipment of Grade "A" products. FDA check rating activity consist of reviewing IMS listed milk supplies and plants in each state to ensure the listed state ratings are valid.

FDA is responsible for the following activities:

- Promoting the adoption, implementation and enforcement of regulatory standards as provided in the model PMO;
- Standardization of FDA and state personnel performing ratings, listings and laboratory certifications;
- Maintaining and publishing the IMS List of milk supplies, dairy plants, and approved laboratories quarterly;

- Providing training to state personnel;
- Conducting check ratings (consisting of a monitoring inspection of a plant and/or farm group and the review of processing, laboratory and regulatory records to evaluate how the State is carrying out their program) and single-service audits for sanitation compliance of listed shippers;
- Issuing interpretations of the PMO; and
- Evaluating and approving milk testing laboratories and evaluation of state milk enforcement and rating programs. *States are responsible for the following:*
- Adopting regulations equivalent to the PMO;
- Issuing permits to Grade "A" dairy farms and Grade "A" plants; inspecting each at required frequencies; collecting milk, milk product and water samples at required frequencies;
- Ensuring all milk is screened for Beta lactam drug residues prior to processing;
- Issuing permits and conducting evaluations of bulk milk haulers and samplers;
- Issuing permits and conducting inspections of milk tank trucks;
- Maintaining FDA certification of state personnel conducting ratings, laboratory certification and sample surveillance; and conducting laboratory certifications at required frequencies;
- Maintaining permit, inspection and sample records for all permit holders;

8.2. Shellfish Sanitation Program

The ISSC membership is comprised of representatives from Federal agencies (FDA, Centers for Communicable Disease Control, US Department of Commerce, National Marine Fisheries Service, and Environmental Protection Agency); State authorities associated with shellfish management and regulation, shellfish industry, academia, and consumer advocacy groups. The ISSC meets biannually to discuss program proposals to address shellfish safety, and to make necessary changes to shellfish program guidelines. The FDA has a MOU with the ISSC that outlines the responsibilities of the States and FDA in the sanitary control of shellfish.

The NSSP Guide for the Control of Molluscan Shellfish, Model Ordinance (MO) section contains the minimum requirements that States must implement and enforce if they wish to ship shellfish in interstate commerce. Firms meeting these requirements are listed on the Interstate Certified Shellfish Shippers List (ICSSL) and therefore are authorized to ship molluscan shellfish in interstate commerce. These requirements are debated and developed by the ISSC members. State shellfish authority delegates vote on proposed or revised requirements (only states vote for final requirements). Following FDA concurrence (proposals may not conflict with existing federal regulation or policy), the new or amended requirements are published in the next revision of the NSSP Guide for the Control of Molluscan Shellfish.

As with all food products, rapid response is needed in dealing with illness outbreaks. Since shellfish are harvested from coastal waters and often consumed

raw, incidents that affect the sanitary quality of coastal waters can have significant public health impacts and require rapid response by public health officials. Such events would include major storm events, major spills (sewage, oil, toxic chemical, radiological) and major blooms of toxic algae. Planning for timely coordination and communication at all levels of public health agencies is critical in these events.

FDA is responsible for the following activities:

- Evaluation of State Shellfish Programs using the guidelines found in NSSP MO and the FDA Molluscan Shellfish Compliance Program (7318.004).
- Providing the ISSC Executive Board with information on any State Shellfish Program not in substantial compliance with NSSP MO guidelines, procedures, and criteria.
- Standardization of State Shellfish Standardization Officers and standardization training for State inspectors.
- Maintaining and publishing an on-line monthly current listing of all shellfish dealers and shippers certified under the NSSP by the States ICSSL.
- Participation in ISSC Task Forces, Committee/Subcommittee/Workgroup meetings, and any other deliberative groups that support the ISSC and the NSSP in the safe production and shipment of molluscan shellfish.
- Coordination with State Shellfish Program Managers, State Health Departments, State Epidemiologists, FDA inspectorate division personnel, FDA Office of Coordinated Outbreak Response, Evaluation, and Emergency Preparedness (OCORE+EP) and Industry in the investigation, recalls, national reporting, and sampling in response to all illnesses/deaths/outbreaks associated with the consumption of raw or undercooked molluscan shellfish.
- Supporting and/or providing shellfish sanitation training, seminars, technical assistance, and scientific research as resources permit. FDA is committed to maintaining a current scientific basis for the shellfish sanitation guidelines and standards.
- Participation in Incident Response; technical assistance, research and training are critical for response to incidents such as illness outbreaks, large sewage spills, oil spills, toxic chemical spills, radiological events, and major storm events. Often, these events have impacts that cross State lines. Therefore, these events require advance planning, communication, and coordination among multiple agencies from the Local, State and Federal levels.
- Promoting and maintaining MOUs or other agreements with participating foreign countries regarding shellfish sanitation programs. There are currently four foreign countries (Australia, Republic of Korea, Japan, and Canada) that have MOUs or other State Department agreements with FDA allowing them to participate in the NSSP; FDA evaluates these programs just as they do the State programs.
- Coordinating Federal interagency affairs on matters concerning shellfish sanitation, including the classification of shellfish growing waters under Federal jurisdiction.

- Maintaining the National Shellfish Consumption-Associated Vibrio Illness Database; all reported Vibrio illnesses are included in this database.

The States are responsible for the following activities:

- Adoption of adequate laws and regulations to provide a legal basis for sanitary control of all phases of State shellfish programs.
- Conducting Sanitary Surveys and implementing proper classification of all shellfish growing waters in the state in accordance with the requirements outlined in the NSSP MO.
- Development of comprehensive Sanitary Survey reports (including shoreline surveys) that identify and evaluate all actual and potential pollution sources, analyze and evaluate bacteriological seawater sample results, and determine proper classification of shellfish growing areas.
- Inspection and certification of each shellfish processor that meets NSSP MO requirements, and submission of the names of certified facilities to FDA for inclusion in the ICSSL.
- Enforcement of classification boundaries, prevention of illegal harvesting, and enforcement of other harvester requirements in all productive shellfish growing areas.
- Supervision of the relaying of shellfish from closed areas to approved areas and subsequent cleansing (depuration) of shellfish.
- Adequate training of State shellfish program personnel to allow proper implementation of the State's shellfish program.
- Utilization of laboratories that reliably perform seawater, shellfish, and biotoxin sample analyses in accordance with the latest approved editions of the American Public Health Association, the Association of Official Analytical chemists, or other methods approved by the ISSC.
- Participation in Incident Response. (e.g., illness outbreaks associated with consumption of shellfish, large sewage spills, oil spills, toxic chemical spills, radiological events, and major storm events.)
- Communicating and coordinating recall information with firms and ensuring recalled product is off the market.

8.3. Retail Food Program

The primary objective of the Retail Food Program is to minimize the incidence of foodborne illness at retail, by directing activities related to the promotion of effective state and local retail food regulatory programs.

These agencies regulate over one million retail food establishments nationally (restaurants, grocery stores, health facilities and nursing homes, schools, correctional facilities, temporary event food service, food vending facilities, etc.). This is highly significant since it's estimated, that the American public now consumes more than 50% of their meals outside the home. Agencies regulating this multi-billion-dollar industry look to the Office of Retail Food Protection (ORFP)

Specialists for training, technical assistance, program evaluation, and to serve as a liaison between FDA, the states, and industry as needed.

FDA is responsible for the following activities:

- Promoting adoption of the *FDA Food Code* and application of science-based food safety principles and methods at the state, local, territorial, and tribal level (SLTT).
- Providing technical assistance on *FDA Model Food Code* requirements and retail food safety issues.
- Providing uniform training on food safety principles and regulations.
- Standardizing state regulatory Retail Food Inspection Officers.
- Promoting national uniformity among retail food regulatory programs by encouraging SLTT in the Voluntary National Retail Food Regulatory Program Standards.
- Conducting Risk Factor Studies.
- Promoting and participating on SLTT food protection task forces.
- Providing risk-based inspection and food defense and surveillance activities/assistance, in conjunction with state and local regulatory authorities, during special security and emergency/disaster response events.
- Conducting Foodborne Illness Risk Factor studies to track the occurrence of behaviors and practices that commonly lead to foodborne illness in various types of retail and foodservice establishments.

8.4. Radiological Health Program

RRHRs are FDA's liaisons to the states for areas of radiological health and radiological emergencies. Radiological emergencies vary in destruction level and can cause detrimental impacts to the nation’s food supply by compromising human health through ingestion of radioactive materials. The RRHRs are FDA’s representatives for The Advisory Team for Environment, Food and Health (Advisory Team), which is a radiological emergency response group tasked with providing protective action recommendations to state and local governments, including Indian Governmental Agencies, on behalf of its member agencies. The permanent membership includes representatives from the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and the U.S. Department of Agriculture (USDA). The permanent members may invite other agencies to participate in Advisory Team activities.

The Advisory Team was incorporated into the Nuclear/Radiological Incident Annex of the National Response Plan (NRP) in December 2005. The NRP has been replaced by the National Response Framework. Program activities performed by RRHRs relative to Emergency Planning and Response Activities are covered under CPGM 7386.009.

Additionally, the RRHR is responsible for general program oversight for the following program areas: The Mammography Quality Standards Act: Inspections of Federal Facilities which provide mammography services, which include Veterans Health Administration facilities as regulated under the VHAMQSA (through an MOU for inspections), Indian Health Services, Department of Defense, and the Federal Bureau of Prisons. Also, RRHRs oversight of the current contracts with state radiological health agencies for annual inspections of mammography facilities, and tracking of audits of all inspectors, FDA and state, to meet the annual joint audit requirement. These activities are covered under CPGM 7385.014.

- Electronic Product Radiation Control (includes suntan beds/booths, bulbs, cabinet x-ray systems, microwaves, therapeutic ultrasound devices, x-ray equipment, lasers, and medical devices utilizing electronically produced radiation) as outlined under CPGM 7386.001.
- Inspection of Domestic and Foreign Manufacturers of Diagnostic X Ray Equipment as outlined under CPGM 7386.003a.
- X-Ray Field Testing as outlined under CPGM 7386.003.
- Compliance assistance as requested by the Centers or Division/Program Offices.

The RRHR is considered the regional SME for all Radiological Issues as regulated by FDA.

9.0. DESIRED OUTCOMES (ACHIEVEMENT LEVELS)

9.1. Achievement Levels

Level	Description
1	Program has little to no knowledge of the roles and responsibilities of the four Federal-State Cooperative Programs[1], how they operate within their jurisdiction (local, state, regional), and how they would be incorporated as part of an integrated food safety system.
2	Program is aware of the roles and responsibilities of the four Federal-State Cooperative Programs and has a basic understanding of how they operate within their SLTT jurisdiction, and how they would be incorporated as part of an integrated food safety system.
3	Program has a strong understanding of the roles and responsibilities of the four Federal-State Cooperative Programs and fully understands how they operate within their SLTT jurisdiction, and how they would be incorporated as part of an integrated food safety system.

[1] There are four Federal-State Cooperative Programs (grade A milk, shellfish, retail, radiological).

Level	Description
4	Program has developed a SOP, MOU or other agreement and/or documentation[2] that describe incorporation of the four Federal-State Cooperative Programs within the RRT and associated capabilities or functional areas.
5	Any SOPs or MOUs include a formal review and update process including how and when they will be exercised.

9.2. Process Overview

Level 1: Little to no knowledge about Federal-State Cooperative Programs operating within jurisdiction (local, state, regional)

- Identify Cooperative Programs operating within the jurisdiction
    - Contact state or local health and agriculture programs to identify what Cooperative Program areas are operating within the jurisdiction
    - Contact appropriate FDA Program office (FDA inspectorate divisions may provide this information) and speak with the ORFP Director.

Level 2: Basic knowledge of Federal-State Cooperative Programs operating within jurisdiction (local, state, regional)

- Obtain contact information for and individuals or organizations responsible for the Cooperative Program areas operating within the jurisdiction
    - Taskforce membership lists
    - Trade organizations
    - Conference Contacts
    - Workgroups
    - Professional Associations
    - State or local regulatory agencies
    - Federal management and Federal subject matter experts- Specialists
- Identify roles, responsibilities, and authorities covered under the specific Cooperative Program area
    - Face-to-face meeting
    - Conference calls
    - Sharing of operational documentation and legal authorities
- Ensure that Cooperative Program personnel have completed required training to be a part of the jurisdiction's integrated food safety response system (i.e., RRT)
    - Provide Cooperative Program directors in FDA and State Agency management with a list of required training (i.e., List of courses required to serve as a member of the response team)
    - Identify means of completing required training
    - Catalog documentation showing completion of required training

[2] Stand-alone documentation not required; the documentation can be part of a larger MOU, SOP or other agreement/documentation.

- Establish role of Cooperative Program personnel as part of the jurisdiction's integrated food safety response system (i.e., RRT)
    - Participation in RRT exercises and other team building events
    - Sharing of resources
        - Purchase of equipment required to fulfill role as part of the response team
        - Equipment and training necessary for communication during response team activation

Level 3: Complete knowledge of Federal-State Cooperative Programs operating within jurisdiction (local, state, regional)

- Document activation, operation, and communication procedures for Cooperative Program personnel involved as member of the jurisdictions integrated food safety response system
    - MOUs – Note FDA MOU with Conferences
    - SOPs

Level 4: SOPs for Cooperative Program integration into the response system have been developed

- A timeframe is established for review of the SOP
    - Is the timeframe between reviews appropriate for the document?
- A procedure has been developed to check the accuracy of contact information included in the SOP
- A schedule has been developed for exercising the SOP
- A procedure exists for incorporating after action reporting and other comments/suggestions into the SOP
- The SOP review includes a process for incorporating and implementing changes to other documents which would impact the Federal-State Cooperative Program areas
    - Communications SOPs
    - Joint Investigations SOPs
    - Training SOPs

Level 5: The SOP includes a formal review and update process including provisions for exercising the procedure.

- Establish personnel responsible for ensuring that review and revision of the SOP is accomplished within the required timeframe

10.0. RELATED DOCUMENTS

- RRT Manual Chapter 1: Working with Other Agencies

11.0. REFERENCES AND OTHER RESOURCES

- National Shellfish Sanitation Program (NSSP) (model ordinance)
- Interstate Certified Shellfish Shippers List – (ICSSL) (Updated monthly on FDA website)
- Grade "A" Pasteurized Milk Ordinance (PMO)
- Interstate Milk Shippers List – (IMSL) (Updated monthly on FDA website)

12.0. ATTACHMENTS

N/A

13.0. DOCUMENT HISTORY

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**Workgroup Lead

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1.1 – Minor editorial revisions to achievement level for clarification purposes.
1.2 – Minor editorial revisions to formatting to align with overall 2017 RRT Manual Edition revision effort.
2.0 – AFDO compilation for 2023 Edition of RRT Manual
3.0 – AFDO compilation for 2025 Edition of RRT manual. Updated FDA program names resulting from the 10/2024 FDA reorganization.