



FDA Office of Partnerships

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FDA-OP Standards Implementation Staff

AFDOSS

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Cooperation & Collaboration: A daily priority for the FDA

*“We will **strengthen our collaborations** with other public health agencies and leverage the expertise and resources of our colleagues at the **international, federal, state, and local levels** to ensure effective solutions for the American people.”*

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs



OP Organizational Structure

- **2 Sections**
 - **Contracts & Grants Staff**
 - **Standards Implementation Staff**
- **Immediate Office**
 - **Quality Management System (QMS)**
 - **Rapid Response Teams (RRTs)**
 - **Senior Federal-State Program Specialist**



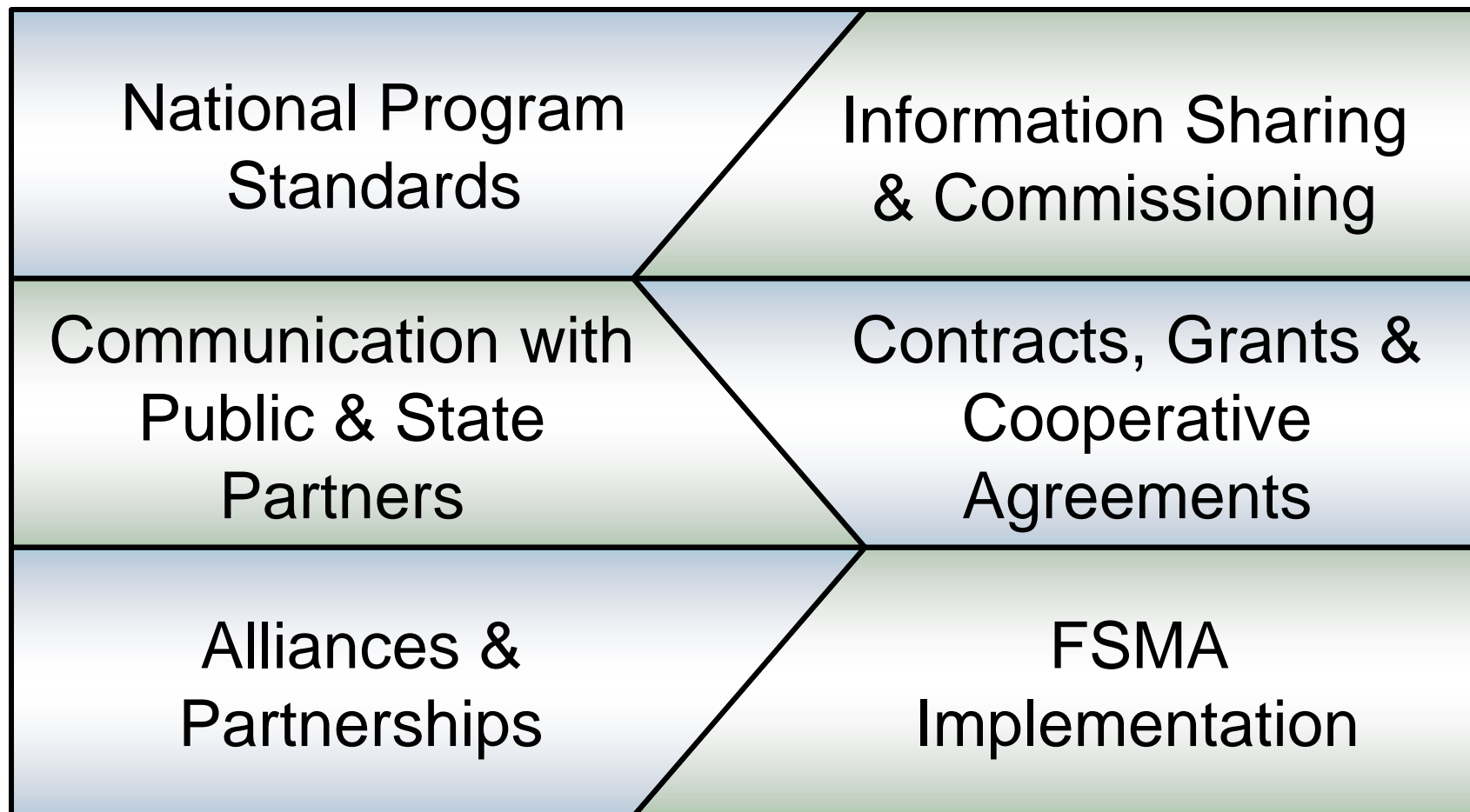
Did You Know

Barbara Cassens is the Acting OP Director

Capt. Wendy Fanaselle is on detail as OP deputy director

OP is part of the Office of Regulatory Affairs (ORA)

OP Initiatives with State Partners



Communication with State Partners



20.88 Confidentiality Agreements

Commissioning & Credentialing

**Directory of State & Local Officials
(DSLO)**

50-State Teleconferences

FDA.gov Website

Broadcast System

eSAF

**FDA-State Communication Field
Management Directive (FMD-50)**

Directory of State & Local Officials

- Hosted through the Association of Food and Drug Officials (AFDO)
 - <http://www.afdo.org/DSLO>
- Searchable
- Contains State and Local regulatory officials
 - Contacts for food, animal feed, animal health, and food defense functions
 - Currently over 1700 contacts





FDA Website

- Links to public documents & information
- OP Accomplishments
- Program Summaries
- Funding Opportunities
- Contact Information

The screenshot shows the FDA website page for Federal, State, Local and Tribal Officials. The page features a dark blue header with the FDA logo and navigation links. Below the header is a main content area with a large image of hands shaking, representing the Office of Partnerships. The page is organized into several sections: a 'Spotlight' section with a list of key events and programs; a 'Recalls & Alerts' section with RSS feeds for press releases, food safety recalls, and consumer updates; a 'Contact FDA' section with phone numbers and an email address; a 'Resources for You' section with links to a directory, grants, and regulatory partners; a 'Search For Federal, State, Local and Tribal Officials' section with a search box; and a 'News and Events' section with a link to a manual on the Rapid Response Team.

U.S. Department of Health & Human Services

U.S. Food and Drug Administration
Protecting and Promoting Your Health

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SEARCH

Most Popular Searches

Home Food Drugs Medical Devices Radiation-Emitting Products Vaccines, Blood & Biologics Animal & Veterinary Cosmetics Tobacco Products

For Federal, State, Local and Tribal Officials

Home > For Federal, State, Local and Tribal Officials

Office of Partnerships
FDA's primary contact for state, local, tribal and territorial officials.

1 2 3

For Federal, State, Local and Tribal Officials Topics

<p>Cooperative Agreements & Grants Competitive grant/cooperative agreement programs related to food safety and human health issues.</p> <p>Partnerships & Contracts State Contracts, and Audit Reports</p> <p>Federal-State Relations Activities Overview of programs, regulations, associations and other initiatives involved in FDA Federal State Relations.</p> <p>Contact Us Contact FDA's Division of Federal-State Relations.</p>	<p>Meeting, Conferences and Events Reports and documents for Major DFRS activities, such as 50-State Meetings, broadcast events, the Partnership for Food Protection, and public meetings.</p> <p>Communication and Outreach Communication and information- dissemination systems between FDA, State, Local and Tribal Officials.</p>
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Resources for You

- [Directory of State and Local Officials \(DSLO\)](#)
- [Grants.gov](#)
- [State, Local and Tribal Regulatory Partners Welcome to ORA!](#)
- [Electronic Laboratory Exchange Network \(eLEXNET\)](#)

Search For Federal, State, Local and Tribal Officials

SEARCH

News and Events

- [The Rapid Response Team \(RRT\) Best Practices Manual Volume 1 is now available upon request!](#)
- [Animal Feed Regulatory Program Standards \(AFRPS\) Overview - April 2012 \(PDF - 17KB\)](#)

Spotlight

- [PFP 2012 50-State Meeting](#)
- [Rapid Response Teams](#)
- [Manufactured Food Regulatory Program Standards \(MFRPS\)](#)
- [State Cooperative Programs](#)
- [Open Funding Opportunities](#)

Recalls & Alerts

- [FDA Press Releases RSS Feed](#)
- [FDA Food Safety Recalls RSS Feed](#)
- [What's New: Animal Veterinary](#)
- [Consumer Updates RSS Feed](#)
- [Recalled Product Photos on Flickr](#)

Contact FDA

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U.S. Food and Drug Administration
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National Program Standards: Manufactured Food Regulatory Program Standards (MFRPS)

- **Uniform foundation for the design and management of state programs responsible for regulating food manufacturers**
- **Institute a comprehensive quality assurance & standardization program**
- **FDA conducts Program Assessment Validation Audits (PAVAs) at 18 and 36; and comprehensive audit at 60 months**



National Program Standards: Animal Feed Regulatory Program Standards (AFRPS)

- **National Standards for feed inspection programs**
- **Joint project of the FDA and Association of American Feed Control Officials (AAFCO)**
- **Committee established in 2011 to develop Standards**
- **Draft document completed in 2012**
- **Final document released in 2014**



National Program Standards: Voluntary National Retail Foods Regulatory Program Standards (VNRFRPS)

- **Standards provide:**
 - A guide to design and management of a retail food program
 - A program foundation
 - A tool to evaluate the effectiveness of food safety interventions
- **546 regulatory jurisdictions enrolled**
- **Additional information available at**
<http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/ProgramStandards/default.htm>



FY13 Grants & Cooperative Agreements

Programs	# of Awards
Food Protection Task Forces	15
Food Emergency Response Network (FERN)	34
Ruminant Feed Ban Support (BSE)	11
Rapid Response Teams	18
Innovative Food Defense	2
Small Science Conference Grants	12
FSMA Emergency Response & Risk Based Inspections	33
Manufactured Food Regulatory Program Standards	37
ISO 17025:2005 Laboratory Accreditation	30
Voluntary Nat'l Retail Food Regulatory Program Standards	35
Integrated Laboratory System	1
Alliances	2
Retail Association	1
Total Funding	\$37.4M



Then & Now: Investment in Federal-State Integration

Programs	FY2009 Funding	FY2012 Funding
Contracts (total)	\$15.5M	\$15.2M
Egg Contract (added FY11)	None	\$320K
Grants (total)	\$17.4M	\$44.3M
MFRPS implementation	None	\$7.1M
ISO	None	\$7.8M
RRT (expanded FY12)	\$4.5M	\$7.4M
FSMA Emergency Response & Risk Based Inspections	None	\$3.5M
Alliances (AFDO and NCSL)	None	\$455K
State Cooperative Programs (total)	\$250K	\$3.4M
Retail Standards Cooperative Agreement	None	\$2.6M
Retail Partnership	\$250K	\$500K
Dairy & Shellfish	None	\$250K
Total Funding	\$33.2M	\$59.5M

Partnership Funds FY14

- **Previous Process:**
 - **Each Region was provided a set dollar amount**
 - **Regions determined use of funds**

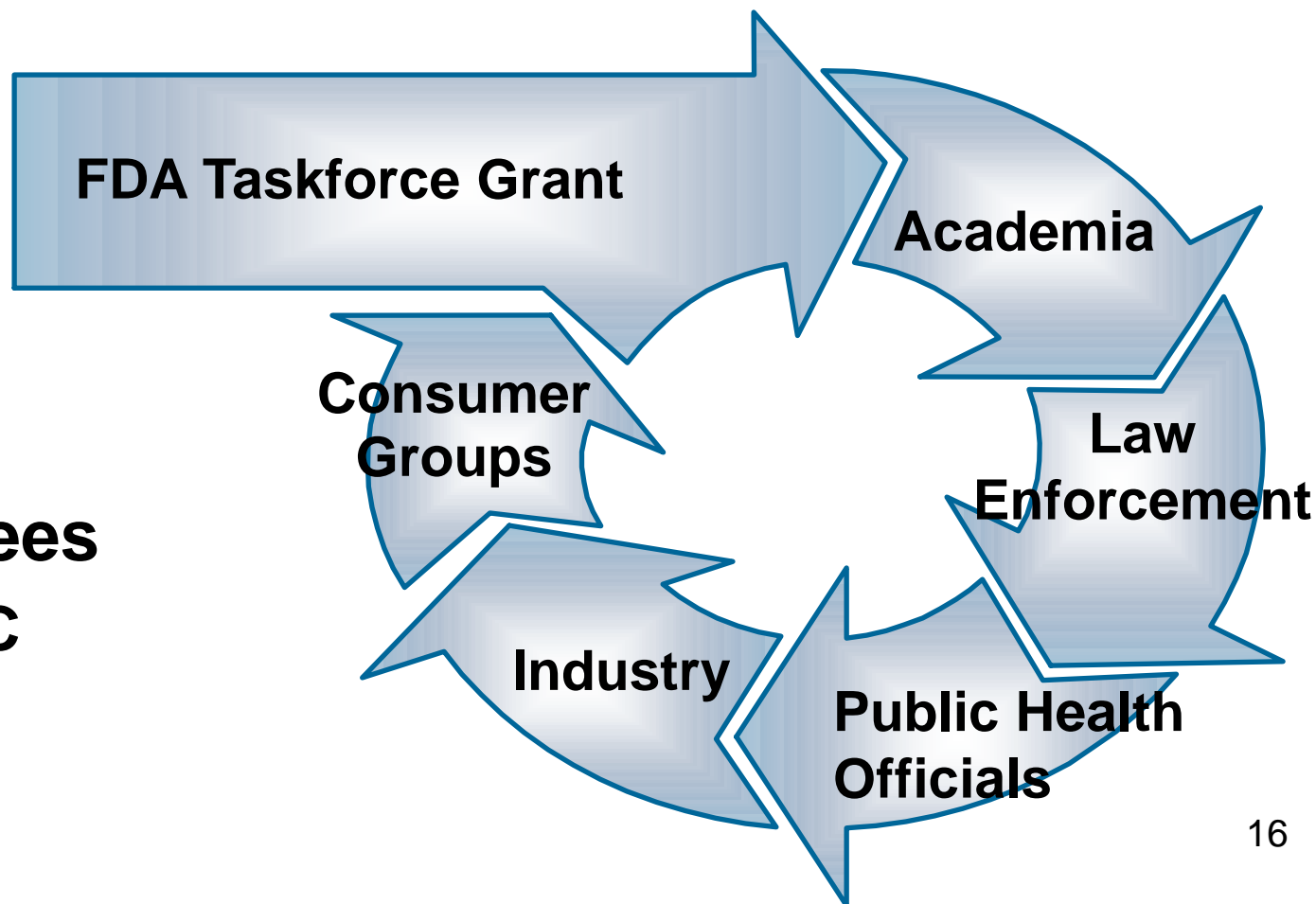
Partnership Funds FY14

- **New Process:**
 - **Regions provide OP with a Proposal for funds (with supporting documentation) for:**
 - **General Partnership funds**
 - **Dairy Cooperative Program**
 - **Shellfish Cooperative Program**
 - **OP reviews all Proposals for adherence to the “Guidance on Field use of Partnership Funds”**
 - **Approved proposals receive a specific accounting code**

Partnership Funds FY14

- **Each Region/District required to report the details of the outcomes of expended funds as compared to the goals and objectives outlined in the original request**
- **OP will provide a reporting tool to each region/district with a due date of January 2015**

Food Protection Task Force Conference Program Grants



Current Grantees

- 22 States & DC

Rapid Response Teams (RRT)

- **Multi-year Cooperative Agreement**
 - Awards range from \$150,000 - \$250,000
 - Awards typically 3 years in length
 - 9 began in 2008/2009
 - 9 added in 2012
- **Why RRTs?**
 - White House & Congressional interest in improving response and food safety
- **Purpose:**
 - Improve response by unifying & coordinating partners
 - Develop effective models for response that can be replicated



Did You Know

9 RRTs are in Public Health Agencies

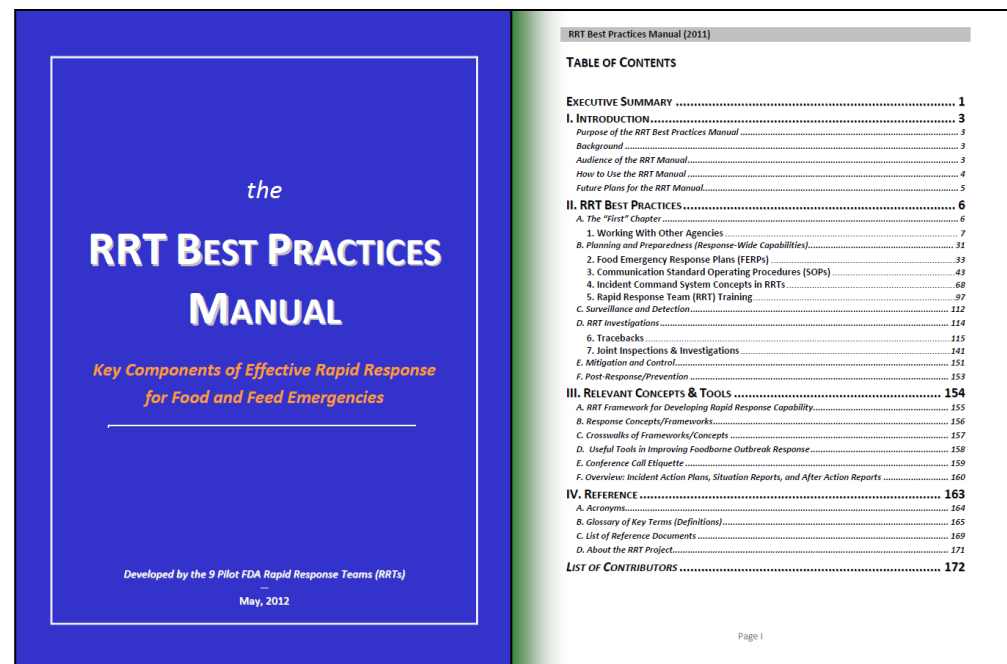
9 RRTs are in Departments of Agriculture

RRT Program Goals & Outcomes

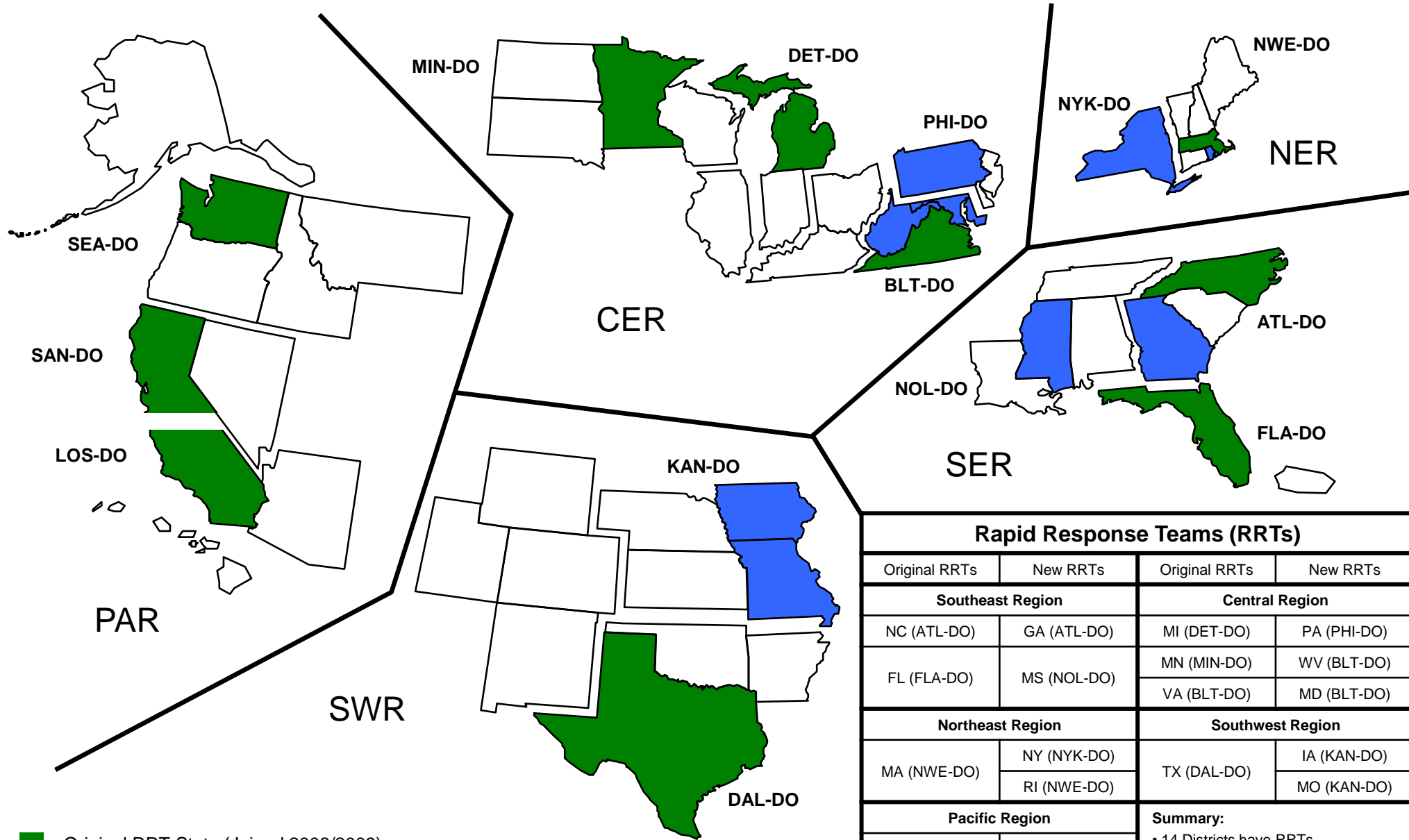
- **New RRTs**
 - **Developing Federal/State/Local Collaboration**
 - **Joint trainings & exercises and joint or coordinated SOPs**
 - **Establishing procedures & processes for rapid response**
 - **Staffing and equipping teams**
 - **Mentorship & Kick-Off Meetings**

RRT Best Practices Manual – 2013 Edition

- The RRT Best Practices Manual is available upon request to OP
 - Send an email to OP-ORA@fda.hhs.gov
- Developed by original 9 RRTs (states and District/Regional partners)
- Reviewed by numerous federal, state and local agencies
- The 2013 Edition includes 7 new chapters, including metrics!
 - 14 chapters total



Rapid Response Teams FY13 (2013-2014 Grant Year)



■ = Original RRT State (Joined 2008/2009)
■ = New RRT State (Joined 2012)

Rapid Response Teams (RRTs)			
Original RRTs	New RRTs	Original RRTs	New RRTs
Southeast Region		Central Region	
NC (ATL-DO)	GA (ATL-DO)	MI (DET-DO)	PA (PHI-DO)
FL (FLA-DO)	MS (NOL-DO)	MN (MIN-DO)	WV (BLT-DO)
		VA (BLT-DO)	MD (BLT-DO)
Northeast Region		Southwest Region	
MA (NWE-DO)	NY (NYK-DO)	TX (DAL-DO)	IA (KAN-DO)
	RI (NWE-DO)		MO (KAN-DO)
Pacific Region		Summary:	
WA (SEA-DO)	N/A	• 14 Districts have RRTs	
CA (LOS-DO & SAN-DO)		• 1 District has 3 RRTs	
		• 3 Districts have 2 RRTs	
		• 10 Districts have 1 RRT	

ISO/IEC 17025:2005 State Laboratory Accreditation

- **Purpose: Microbiological and chemical food analyses performed on behalf of State manufactured food regulatory programs conducted within the scope of an ISO/IEC 17025:2005 accredited laboratory**
- **31 programs participating**
- **Lab programs must:**
 - **Submit a self assessment of laboratory accreditation progress/status, and a cost proposal**
 - **Provide quality management personnel to ensure accreditation success**
 - **Develop an Action Plan**
 - **Develop a Proficiency Testing Plan**
 - **Obtain training necessary to obtain accreditation**
 - **Obtain and maintain accreditation**



ISO-MFRPS Sampling Agreements

- **31 States enrolled in the ISO Cooperative Agreement.**
- **Initiative via the ISO Cooperative Agreement to encourage proactive communication and rational sampling plans that benefit both food safety regulatory and laboratory offices.**
- **Sampling agreements reviewed and approved by FDA.**
- **Sampling is underway!**



FY13 Inspection Contract Programs

Program	# of Awards	Inspections
Food	45	9,823
Feed	36	4,397
Egg	5	45
Tissue Residue	20	335
MQSA*	43	6,917
Medical Device	1	20
Milk Residue	1	Data**
Totals	\$15.2M	23,256

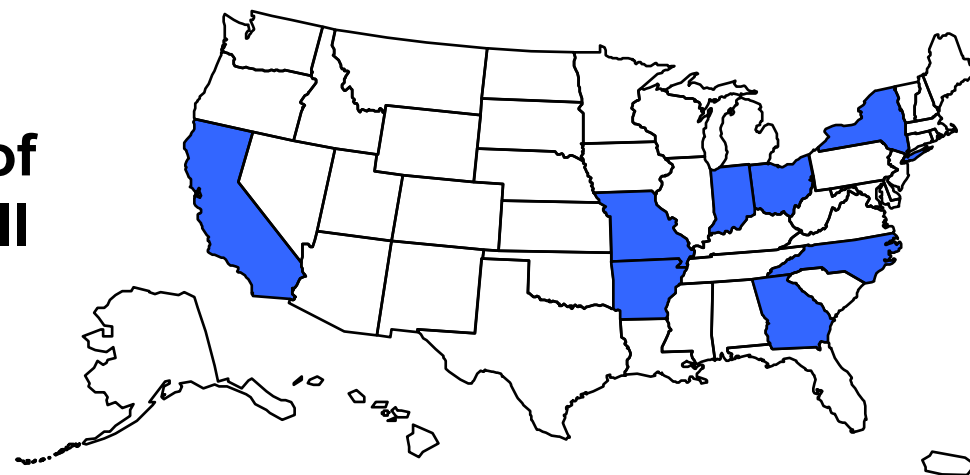
**Mammography Quality Standards Act*

***Analysis of nearly 4 million milk residue samples*

Egg Inspection Contract

- **Purpose: To conduct inspections of egg layer farms to assess compliance with 21 CFR 118**
 - **“The Egg Rule”: Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Transportation and Storage**

- **Awarded to 7 States**
 - **1 year Contracts**
 - **Total Funding: \$245,639**



 = FDA Contract with State

Cooperative Programs

- **Retail Food**
- **Shellfish Sanitation**
- **Dairy**
- **FDA provides:**
 - **Guidance & Technical Assistance**
 - **Training & Certification**
- **Key players**
 - **OP**
 - **CFSAN**
 - **ORA Retail Food, Shellfish & Milk Specialists**
 - **ORA Regional Directors of State Cooperative Programs**



Partnerships & Alliances

- **Sprout Safety Alliance**
- **Produce Safety Alliance**
- **Food Safety Preventive Controls Alliance**
- **Manufactured Food Regulatory Program Alliance**
- **Alliance for Advancing a National Integrated Food Safety System**



A National Integrated Food Safety System (IFSS)

- **Jointly developed and implemented inspection and enforcement programs**
 - **Efficient utilization of resources: workplanning & training**
- **Benefits:**
 - **Increased ability to assess potential risks at domestic food facilities**
 - **More consistent coverage of facilities across entire food supply chain**
 - **Greater food surveillance through integration of food facility inspection information**
 - **Improved rapid response capacity and efficiency**
- **Outcome: Increased public health protection**
- **Emerging focus on international food safety systems initiatives**

Integration Underway

- **Integration Phase I**
 - **Driven by MFRPS, Retail and Feed Standards: Face to Face meetings (State agencies Health and Agriculture and Laboratory/EPI, Federal Agencies (FDA HQ and Districts)).**
 - **National movement underway in 40 States to integrate**
 - **Result: Enhanced communications, dialogue and improved systems understanding**

Integration

- **Integration Phase II**
 - **Progress towards significant conformance with the Standards. Platforms built, communications enhanced, policies and procedures developed, MOU's signed, partnerships forged.**
 - **State programs becoming more robust, more detailed, enhanced national uniformity on a broader scale.**
 - **Process is underway to set the foundation for real integration**

Integration

- **Integration Phase III**
 - **Integration concept becomes more realistic. States reach significant conformance with the Standards and become closer aligned to each other and FDA.**
 - **Contract inspections are becoming more comparable in outcome and align closer with FDA needs.**
 - **Platforms and frameworks are supporting food programs from State and FDA.**
 - **Phase III is reaching real Integration.**

Partnership for Food Protection

- **Bring together regulatory stakeholders to develop an IFSS**
 - **Strengthened inspection, laboratory, and response capacity**
- **2008, 2010, 2012 and 2014 (St. Louis)**
- **50-State Workshops**
- **10 Workgroups**



Food Safety Modernization Act

- **Federal-State Integration Deliverable Groups**
 - **Operational Partnerships**
 - **Sections 201, 209, 210**
 - **Capacity Building**
 - **Sections 205c1, 205c2**
 - **Training**
 - **Section 209**
- **Harmonize with PFP Workgroups**

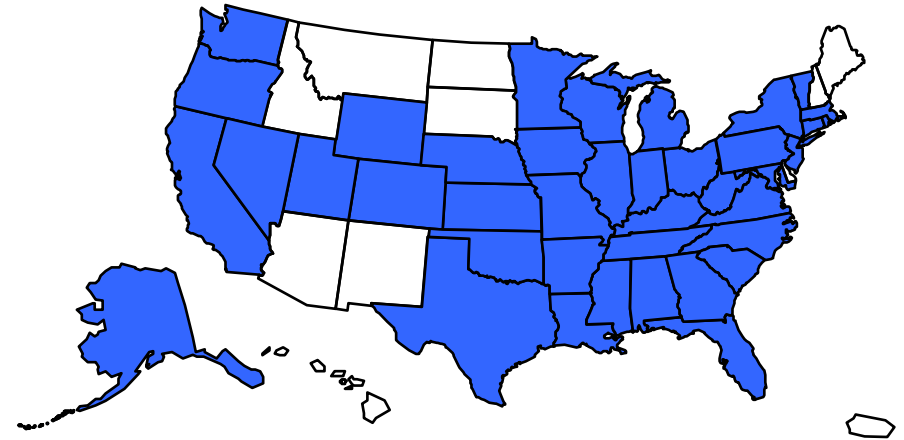


MFRPS

- **Strong Foundation**
- **Positive Movement**
- **Momentum**
- **Progress**

Building a Stronger MFRPS Community

- **40 programs in 39 States**
 - Increased from 28 programs in 2010 to 41 programs in 2013-14
- **FoodSHIELD: Workgroup & Quarterly Webinar**
- **MFRP Alliance**
 - 2nd Annual MFRPS Training conducted in March, 2013, 3rd Annual MFRPS Training held in March, 2014 (Texas). 4th annual proposed for San Diego CA, March 2015.
 - **Strengthen: Community, Collaboration, Resources, and Program Advancement**



MFRPS Status

- **Approximately 30 State programs are in the Implementation phase of the MFRPS. These states have up to 5 years total to reach significant conformance with the Standards.**
- **Other programs such as the 9 State (RRT) programs have been enrolled longer, and are entering in their second of two years to reach significant conformance. Remaining years of the notice of grant award will be based on productivity, Exit Strategy of Sustainment and Standard Enhancement projects.**

MFRPS Phases

- **Implementation Phase**
 - **(Building)**

- **Maintenance Phase**
 - **(Maintaining)**

MFRPS Implementation Phase

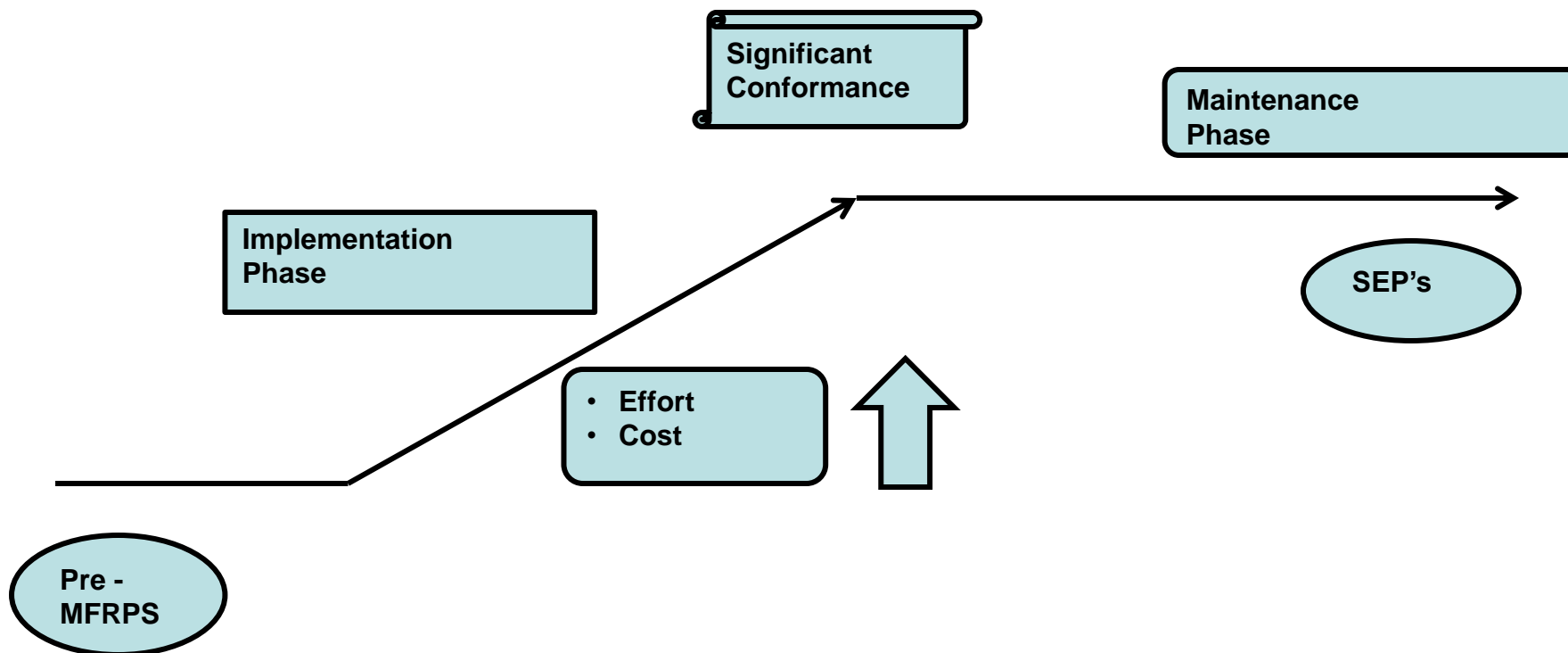
During the Implementation Phase:

- Ongoing work to build the infrastructure for the future.
- Intricate Policies, Procedures and Protocols are considered, drafted, reviewed and implemented.
- Memorandums of Agreement and Understanding outlining crystal clear roles and responsibilities for collective and multi agency response and operations, are drafted and signed by several agencies.
- Establishing documented processes for operations and timelines are forged.

MFRPS Conformance

- In final Implementation phases, States reach significant to full conformance.
- ***Significant Conformance is accomplished if the State regulatory program has policies and procedures in place that meet 80% or more of the individual program elements within each of the ten standards of the MFRPS. Areas not met in this fashion are identified on the Strategic Improvement Plan for completion.....***

MFRPS Maturity



MFRPS Maintenance Phase

- **During the Maintenance Phase, MFRPS States continue to:**
 - **Maintain Significant Conformance with the Standards**
 - **Develop and Submit the Exit Strategy of Sustainment to FDA.**
 - **Develop and work on Standard Enhancement projects.**
 - **Reassess and outline the needs of the State agency to remain in significant to full conformance with the Standards.**
 - **Continue to meet deliverables and dates as outlined in the Notice of Grant Award (NGA)**

Sustainability

- **Sustainability in the MFRPS context, is simply a methodology of a State Program being able to maintain a level of accomplishment that was achieved during a period of growth.**
- **Using as much state recourses as possible, a State Program would continue to maintain (sustain) the level of achievement, that was gained during the MFRPS implementation phase (period of growth).**

Sustainability

- **MFRPS vision includes FDA assistance (funding and support) to States to build infrastructure.**
- **Vision includes State programs maintaining the level of infrastructure that was built (during the implementation phase).**
- **Vision includes State programs using their State resources as much as possible to sustain and maintain the progress.**
- **Total reliance on FDA to fund MFRPS programs at the current level forever - is not a sustainable program.**

Exit Strategy of Sustainment (*ESS*)

- Typically, Grantees are expected to reach significant to full conformance with the Standards by the end of year 5 or year 2 for the RRT states.
- However, Some programs based on progress made, previous enrollment and other factors may be expected to achieve conformance before the 5 years of the cooperative agreement.
- These Grantees, would need to develop their ESS before year 5.

Exit Strategy of Sustainment (ESS)

- ***For those grantees entering the 5th year, they must develop and provide their ESS to FDA before the end of the grant year during which the grantee is required or expects to achieve significant conformance with the MFRPS. This would engage earlier, for those programs referenced on the previous slide.***
- **The ESS will outline the State program's plans to sustain significant conformance and ensure progress continues within their agency to achieve full conformance with the MFRPS.**

ESS

- **The *ESS* must detail:**
 - **Strategy to sustain MFRPS implementation, including identifying personnel/FTE's, current funding sources for these personnel and plans to sustain these personnel using grantee resources to the best of the grantee's ability.**
 - **Identify Data from a 12 month period outlining the number of MF Inspectors, Number of MF firms in inventory, number of routine inspections conducted, number of food related emergency response events investigated, and number of compliance actions.**

ESS

- **The ESS will include whether the grantee wishes to pursue Standard Enhancement Projects (SEP) for any remaining years under the award to further enhance the capacity of the State MFRPS program to protect public health and safety. SEP's may warrant funding as part of the award. Grantees must describe the SEP to be pursued, estimate the funding to be required to support the SEP, and identify specific outcomes/deliverables that will be shared with other state programs.**

MFRPS Deliverable Due Dates

- **First Quarter Report (SCS):** **October 31, 2014**
- **Mid Year Report for all and
(2nd quarter report (SCS))** **January 30, 2015**
- **End of Year Report (all):** **May 29, 2015**
- **4th quarter report (SCS if warranted)** **July 31, 2015**

Addressing Challenges in the Path Ahead

- **Budget cuts and extensive furloughs of State & local employees**
 - **Reduced capacity at State & local levels**
- **We must continue to invest in crucial areas**
 - **National Program Standards**
 - **Training & Certification Programs**
 - **Information Technology Structure**

MFRPS Quarterly Call

- **MFRPS Quarterly Call via FoodSHIELD September 17, 2:00 ET.**
- **2014-2015 MFRPS Notice of Grant Award (NGA)**
- **Go over criteria in the NGA and begin vision and discussions on planning forward through the MFRPS.**
- **Call in number and links to be provided this week.**

Crystal Ball?

- **Strong commitment from FDA to States for ongoing support.**
- **Funding proposed to continue.**
- **Integrated team of OAGS, OP Contract and Grants and Standards Implementation Staff working to give you improved and clarified guidance and outcome based reasonable deliverables.**
- **Regional support staff - Tressa Madden and myself touch most AFDOSS states, to provide assistance and guidance.**
- **Quarterly webinar conference calls expected.**



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