



FDA/ORA Office of Partnerships

AFDOSS: Fall 2015

Guy F. Delius, R.S.,
FDA ORA OP SIS



New Acting Commissioner

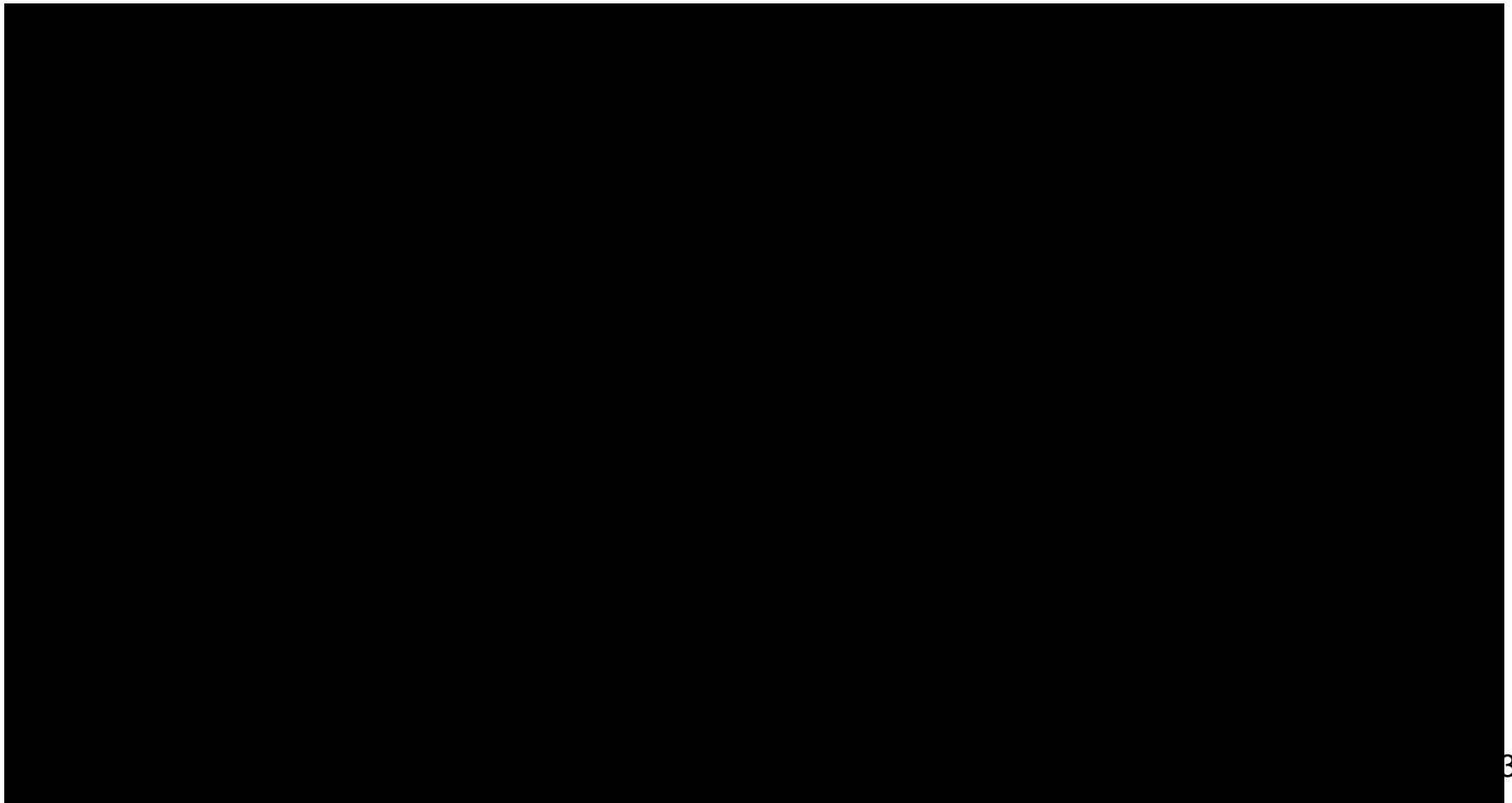
- **Dr. Stephen Ostroff, M.D., is the FDA's acting commissioner of food and drugs. As the top official of the Food and Drug Administration (FDA), Dr. Ostroff is committed to strengthening programs and policies that enable the agency to carry out its mission to protect and promote the public health.**
- **"It's a singular honor to be given the opportunity to represent the people of the FDA who every day dedicate their work to assure safe and effective medical products, foods, and cosmetics and to mitigate the health consequences of tobacco products," says Dr. Ostroff.**



ORA's Collaborative Public Health Partnerships

Dr. Steven Solomon

Deputy Associate Commissioner for Regulatory Affairs, ORA



OP Organizational Structure

- **3 Sections**
 - **Contracts & Grants Staff**
 - **Standards Implementation Staff**
 - **Integration 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

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

About OP's Organization



Immediate Office Staff

- Barbara Cassens – Acting Director
- Alan Tart- Acting Deputy Director
- Brenda Stewart-Munoz – Special Assistant
- Beverly Kent – AFRPS, Training
- Gerald Berg – FSMA, State Liaisons
- Travis Goodman – FPTF, RRTs
- Lauren Yeung - RRTs
- Ryan Cates - Commissioning
- Crystal Williams – OP Web, Speaking Engagements



Standards Implementation Staff

- Timothy Weigner - Director
- Angela Kohls - MFRPS
- Guy Delius – MFRPS
- Priscilla Neves - MFRPS
- Tressa Madden - MFRPS
- Morgan Poloni – MFRPS
- Michelle Motsinger - MFRPS
- Isaiah Isakson - AFRPS
- Alan Tart – Retail Food
- Belinda Clifton – Grade “A” Milk
- Michael Antee – Shellfish Sanitation



Contracts and Grants Staff

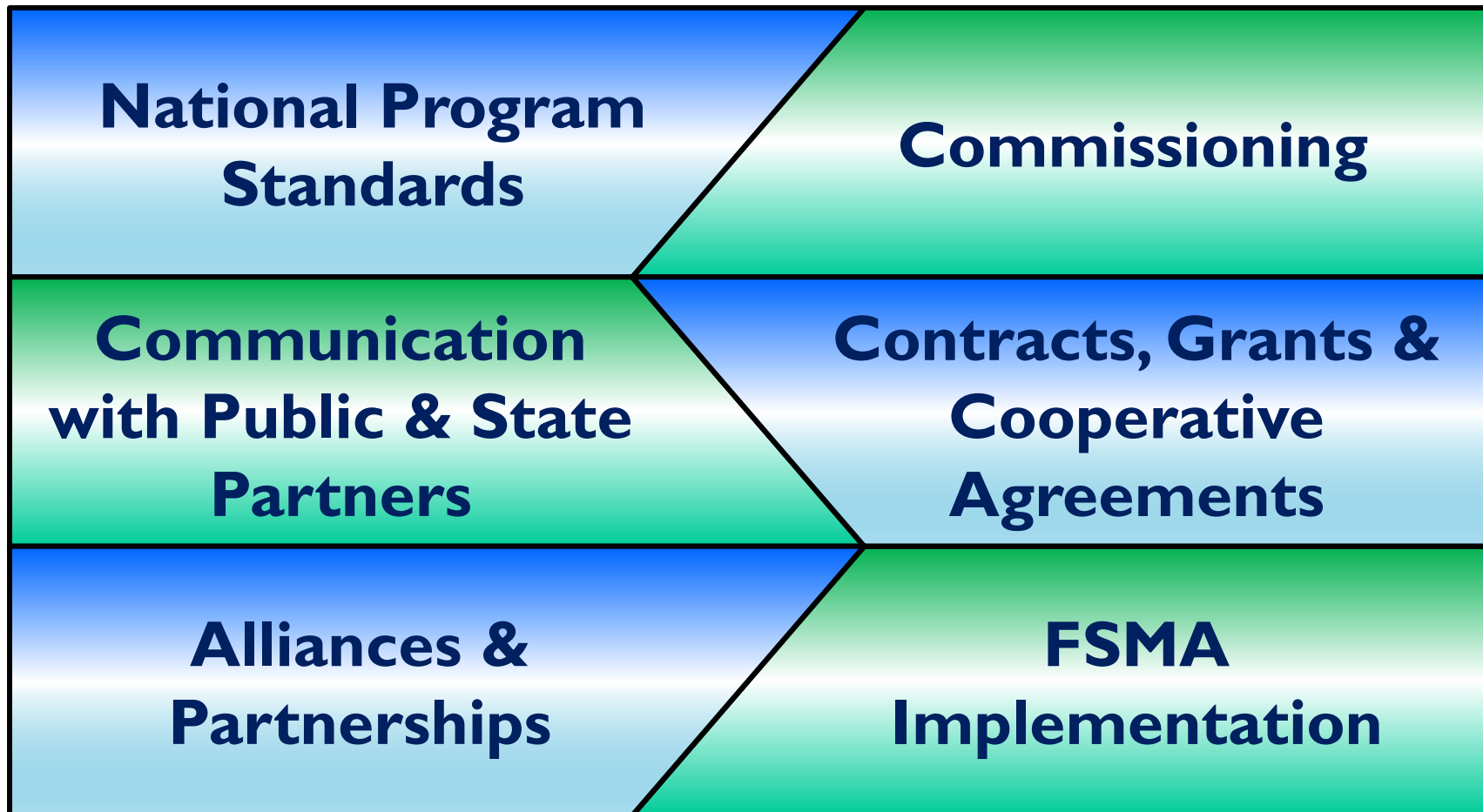
- Abram Brown, III – Director
- Wendy Campbell – PO
- Cathy Hosman – PO
- Graham Giesen – PO
- Mei-Ying Li – Contract PO
- Mercedes Laddon – Pgm Support
- Erin Woodom-Coleman – PO
- Danielle Head – Pgm Analyst
- Jocelyn Ramos – PO
- Jenny Gabb – PO
- Matthew Avis – Pgm Analyst
- Teresa Bills – PO
- Nikki Wilson – (DETAIL)



NEW! Integration Staff

- Nicola Areshenko
- Bill Boden
- Lara Snyder
- John Sproul
- Heika Tait
- Jamal Tull

OP Initiatives with State Partners





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 main heading, a spotlight section with bullet points, a recalls and alerts section with RSS feeds, a contact information section, a resources for you section, a search bar, and a news and events section.

U.S. Department of Health & Human Services

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

A to Z Index | Follow FDA | FDA Voice Blog

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 DFSSR 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 U!
- 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

301-796-5390
866-300-4374 (EMRG)
301-796-8240 (EMRG)
Fax:301-827-9221
DFSR@fda.hhs.gov

Division of Federal-State Relations
Office of Regulatory Affairs
U.S. Food and Drug Administration
12420 Parklawn Drive, ELEM-3033
Rockville, MD 20857

Manufactured Food Regulatory Program Standards (MFRPS)

Manufactured Food Regulatory Program Standards

September 2013



The collection of information has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 and has been assigned OMB control number 0910-0601.

To request a copy of the standards go to:

http://www.fda.gov/ora/fed_state/default.htm

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

OMB Control No. 0910-0601
Expiration Date: 09-30-2016

- Uniform foundation for the design and management of state programs responsible for regulating food manufacturers
- Institute a comprehensive quality assurance & standardization program

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
- **Over 600 regulatory jurisdictions enrolled**

Additional information available at:

<http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/ProgramStandards/default.htm>

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**



Integrated Food Safety System (IFSS)

“A national IFSS must be built upon mutual reliance and respect among partner agencies, recognizing and understanding each participant’s roles, limitations, and authorities...”

- **Federal, State, local, tribal, & territorial regulatory & public health partners**
- **Working collaboratively across all jurisdictions**
- **To provide comprehensive, coordinated coverage of the food supply from farm-to-table**
- **Outcome: Prevention of foodborne illness in humans and animals**
- **Accomplished, in part, through the **Partnership for Food Protection (PFP)****



Animal Feed Regulatory Program Standards



- **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**
- **13 State Programs Enrolled (obligated)**
- **Feed Meeting Held in July in Colorado**
- **More on the way!**



Rapid Response Teams (RRT)

- **Multi-year Cooperative Agreement to improve response**
 - **Unify & coordinate partners**
 - **Develop effective models that can be replicated by others**
 - **18 RRT's in Cooperative Agreement**
 - **+2 Voluntary Programs**

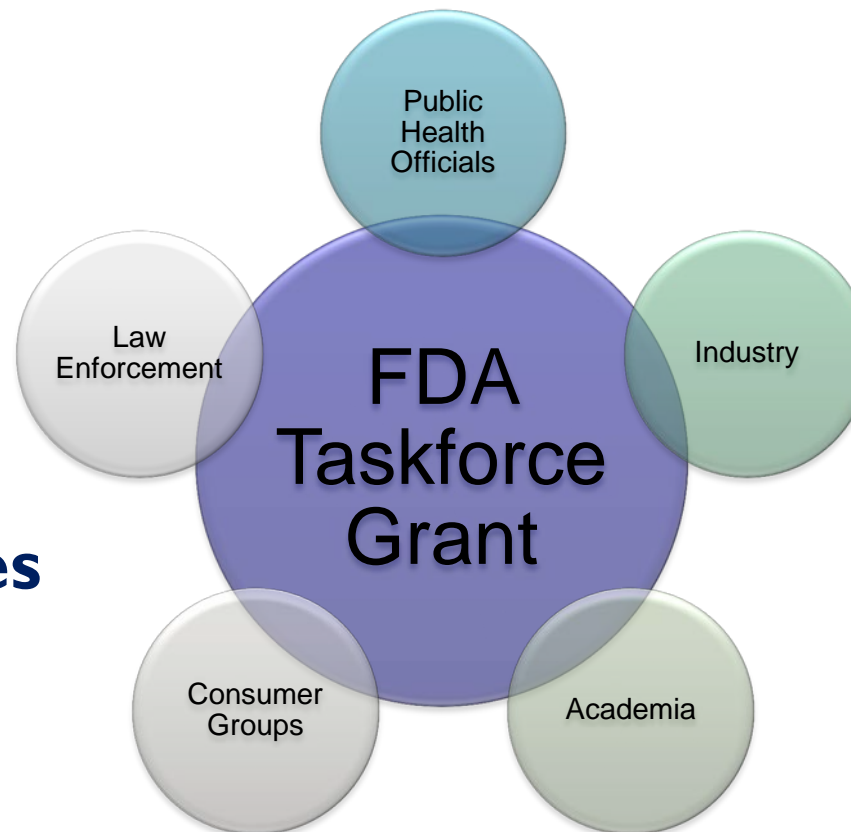


Did You Know

10 RRTs are in Public Health Agencies

10 RRTs are in Departments of Agriculture

Food Protection Task Force Conference Program Grants



Current Grantees

- 14 States

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**
- **30 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

- 30 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 and very successful system!

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





FY14 Grants & Cooperative Agreements

Programs	# of Awards
Food Protection Task Forces	18
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	40
ISO 17025:2005 Laboratory Accreditation	30
Voluntary Nat'l Retail Food Regulatory Program Standards	31
Integrated Laboratory System	1
Alliances	2
Retail Association	1
FoodSHIELD	1
Farm Survey (NASDA)	1
Total Funding	\$53.9M



FY14 Inspection Contract Programs

Program	# of Awards	Inspections
Food	45	11,047
Feed	35	4,306
Egg	7	92
Tissue Residue	17	312
MQSA*	44	6,923
Medical Device	1	20
Milk Residue	1	Data**
Totals	\$24.9M	22,700

**Mammography Quality Standards Act*

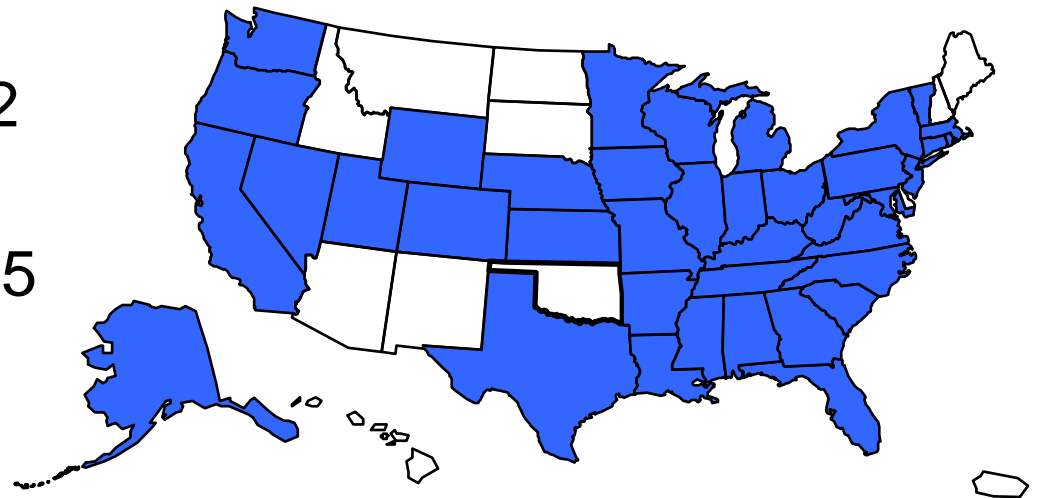
***Analysis of nearly 4 million milk residue samples*

MFRPS

- Strong Foundation
- Positive Movement
- Momentum
- Progress

Building a Stronger MFRPS Community

- 42 programs in 40 States
 - Increased from 28 programs in 2010 to 42 programs in 2015-16
 - 3 programs joined-2015
- FoodSHIELD: Workgroup
- MFRP Alliance:
 - 2nd Annual MFRPS Training conducted in 2013,
 - 3rd Annual MFRPS Training held in (Texas) 2014.
 - 4th Annual MFRPS Training held (San Diego CA), 2015.
 - 5th Annual meeting to be held in Louisville, KY Feb. 2016



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.
- 3 More Programs joining in 2015-16, SC-Ag, LA, NM!

MFRPS Phases

- Implementation Phase
 - (Building)
- Maintenance Phase
 - (Maintaining)

MFRPS Implementation (Development) 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.

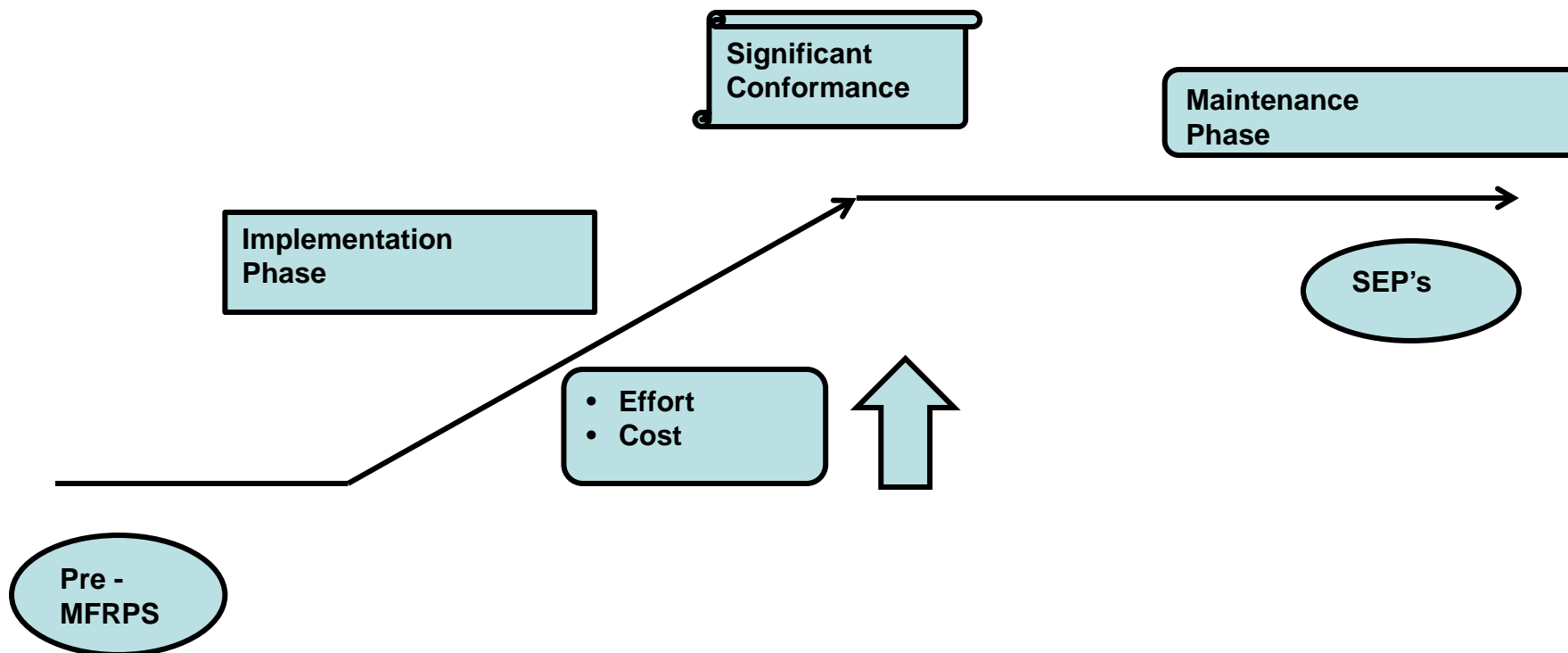
MFRPS Conformance

- In final Implementation (Development) phase, 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 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)

MFRPS Maturity



MFRPS Continuous Improvement

- New % system being incorporated into our SIS Reports.
- We now have typically 3 years of data to measure progress.
- This new addition and view will help State programs quickly see the % of compliance for the program elements – based on the Program Element worksheets.
- Program Element worksheets are populated during discussions at SIS meetings with State programs.
- Information is beneficial for State programs as well as FDA to determine progress/element – locally and nationally.

Percentage of change

STANDARD	PERCENTAGE OF IMPLEMENTATION		
	FY2013	FY2014	FY2015
Standard 1	60%	60%	100%
Standard 2	91.67%	92%	100%
Standard 3	15%	15%	80%
Standard 4	0%	0%	60%
Standard 5	21.05%	21%	75%
Standard 6	0%	0%	0%
Standard 7	100%	100%	100%
Standard 8	80%	80%	60%
Standard 9	50%	50%	100%
Standard 10	66.67%	67%	16.6%

FY = Federal fiscal year (October 1st thru September 30th)

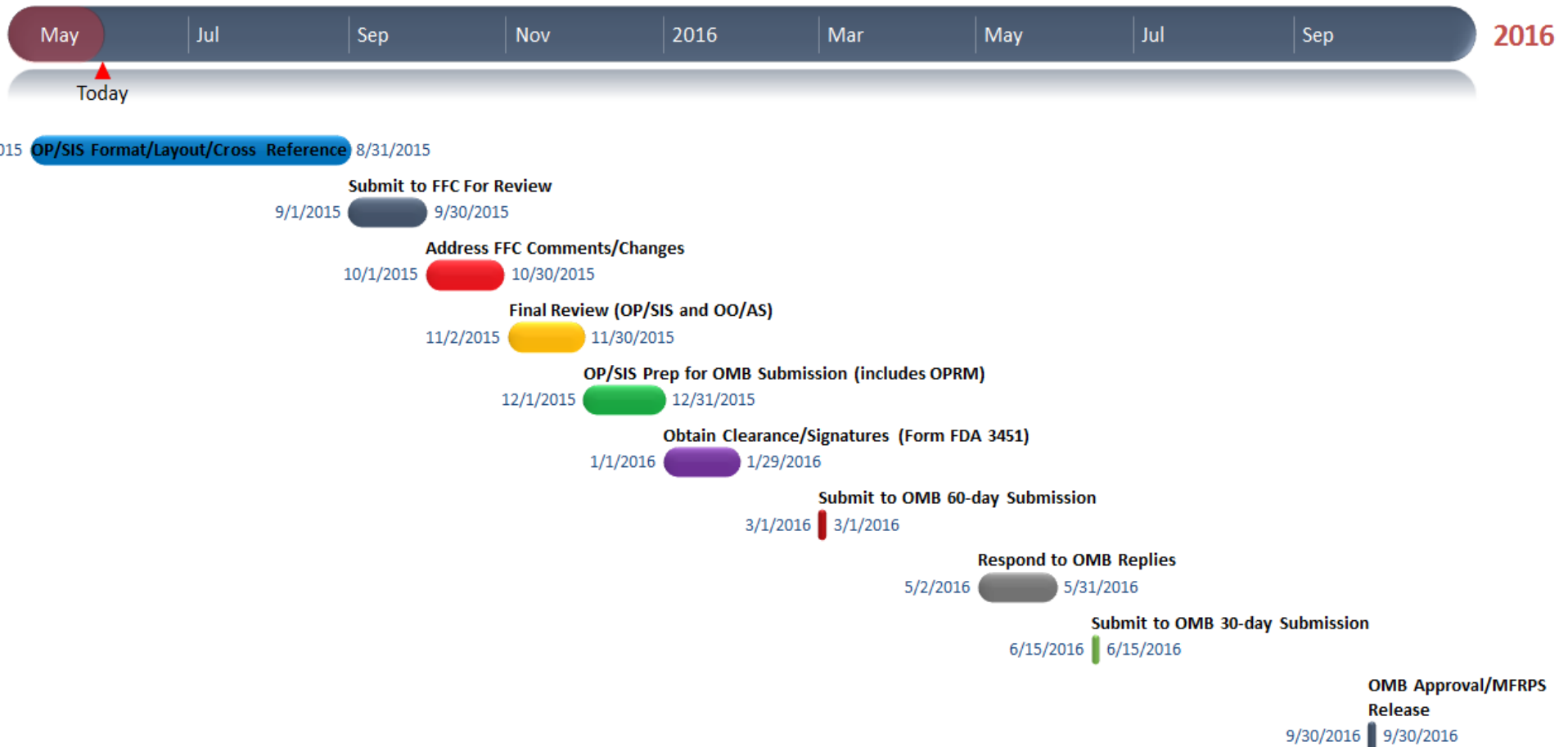
Please note that FDA/ORR/AA/Audit Staff will validate findings of implementation and/or conformance during their scheduled state assessments/audits.

MFRPS Continuous Improvement

- MFRPS Changes Proposed for 2016.
- Developed by SIS
- Reviewed/updated by MFRPS Alliance
- Concurrence at the annual MFRSP meeting
- Reviewed/updated by Partnership for Food Protection Governing Council
- Reviewed again by SIS
- Instituted common numbering system
- Provide to OMB for Review-Issuance



Office of Partnerships MFRPS Update Process Timeline



MFRPS Deliverable Due Dates

- First Quarter Report (SCS): October 30, 2015
- Mid Year Report for all and
 (2nd quarter report (SCS)) January 30, 2016
- End of Year Report (all): May 29, 2016
- 4th quarter report (SCS if warranted) July 31, 2016

FDA-State Future Funding Model



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

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.
- Periodic focused webinar conference calls expected.



FDA Office of Partnerships
12420 Parklawn Drive, ELEM- 3033,
Rockville, MD 20857
301-796-5390

Email:

Guy.Delius@fda.hhs.gov

OP-ORA@fda.hhs.gov

OP Website:

www.fda.gov/regulatorypartners