

**Building an Integrated Laboratory System to Advance the Safety of Food and Animal Feed
Cooperative Agreement # U18FD004710
Year 2 Final Progress Report**

Specific Aim #1: Design, develop, document, deliver, manage, and implement support programs for ISO/IEC 17025:2005 accreditation of food and animal feed regulatory laboratories.

Activity 1: Continue the activities of the Accreditation Work Group [later named the Food and Feed Testing Subcommittee], with input and guidance from appropriate FDA representatives. **[NOA Reporting Requirements d.]**

- The Food and Feed Testing Subcommittee focused its efforts on providing resources for achieving ISO/IEC 17025:2005 accreditation. The subcommittee develops or collects and disseminates resources, suggests content for, and participates as Subject Matter Experts (SMEs) in training courses and identifies model practices around accreditation.
- The Food and Feed Testing Subcommittee held monthly conference calls to address activities of the cooperative agreement. The agendas, reference materials, list of subcommittee participants, and accreditation resources gathered within the current reporting period are available to FDA partners via the subcommittee's workspace on the APHL SharePoint site. (<https://www.aphlweb.org/cmt/fsc/fnftsc/default.aspx>)
- The Food and Feed Testing Subcommittee met by conference call on September 23, October 28, and December 5, 2013, and January 30, February 27, April 24, May 29, July 31, and Aug 28, 2014. The annual face-to-face meeting was held March 19 – 20, 2014 at APHL. Topics discussed on these calls include the concept and development of a national work plan, provision of more ISO/IEC 17025:2005 accreditation resources and support, measuring the success of cooperative agreement efforts with appropriate, feasible, and measurable process and outcome metrics, data exchange from laboratories to state and federal agencies, and the content of the PFP Laboratory Best Practices Manual. In addition to fulfilling agreed-upon charges, this subcommittee enhances collaboration among members of APHL, AFDO and AAFCO and with FDA liaisons.
- In Year 2, FDA suggested six unfunded (*ad hoc*) laboratories to APHL for targeted assistance in achieving ISO/IEC 17025 accreditation. APHL's contractor, Yvonne Salfinger, is currently working with five of the laboratories; one laboratory (Nebraska) has declined further assistance for now and is independently on track for accreditation. On site visits have been conducted to Colorado, South Dakota, and Arizona. Conference calls are being held regularly with New Mexico, New Hampshire, Arizona, Colorado and South Dakota. Quality manuals, Standard Operating Procedures, document control efforts, and recordkeeping procedures from the five laboratories are currently undergoing review, and specific questions from the laboratories are being addressed. These visits and conference calls are documented in monthly reports to APHL.

Additional on-site visits are currently being planned to Arizona for follow-up on recommendations made in May.

- The Food and Feed Testing Subcommittee is advising contractor Yvonne Salfinger on the development of a National Plan for increasing the number of laboratories accredited to the ISO 17025 standard. Conference calls with FDA technical leads in late February 2014 led to agreement on a purpose and outline for this National Plan. This project was discussed at the in-person meeting of the Food and Feed Testing Subcommittee in March 2014 and a draft Plan was reviewed by the Subcommittee in August 2014. It will be sent to FDA early in Year 3.

Activity 2: Maintain and enhance an on-line searchable document repository on APHL's Food Safety webpage.

- The subcommittee continues to build the accreditation Resource Site, which is available to laboratories that wish to seek, maintain, or enhance their ISO 17025 accreditation. The password protected page titled "[Food and Animal Feed Laboratory Accreditation](http://www.aphl.org/aphlprograms/food/laboratory-accrediation/pages/default.aspx)" (<http://www.aphl.org/aphlprograms/food/laboratory-accrediation/pages/default.aspx>) is on the APHL Food Safety program website.
- From September 1, 2013 through August 31, 2014:
 - There were 8433 pageviews of the entire laboratory accreditation subsite (<http://www.aphl.org/aphlprograms/food/laboratory-accrediation>) with 4862 of those pageviews as unique pageviews.
 - There were 1886 total page views of the accreditation resource page (<http://www.aphl.org/aphlprograms/food/laboratory-accrediation/pages/default.aspx>), of which 1140 were unique page views.
 - There are 234 documents available under 15 ISO categories. The documents were viewed a total of 507 times with 271 unique views. Of the 234 documents available, 140 have been viewed at least once.
 - Additional publicly available resources are posted on the same web page.
- FDA invited APHL to speak on a Food Emergency Response Network (FERN)-wide conference call on November 21, 2013 to share information on both the accreditation resource site and a discussion board developed for laboratories seeking ISO 17025 accreditation. The same information was summarized in Volume 8, Number 1 of the FERN newsletter.
- FDA invited APHL to speak at the 2014 FDA ISO CAP grantee meeting in Irvine, CA on May 21, 2014. The theme of the talk presented by APHL was "Association Resources, Strategies, and Tools to Support ISO 17025 Laboratory Accreditation." In the talk, the various resources and tools available to laboratory professionals seeking ISO 17025 accreditation were demonstrated and feedback was requested on how to improve the content and functionality of the Site.
- A poster and a demonstration of the ISO accreditation resources were presented at the APHL Annual Meeting, June 1- 4, 2014. The title of the poster was "Building an Integrated Laboratory

System to Advance the Safety of Food and Animal Feed in the United States”. The information was presented at the APHL Annual Meeting to remind existing ISO CAP grantees of the resources available to them and to encourage non-CAP laboratories that test food to consider seeking accreditation to the ISO standard.

Activity 3: Develop and manage an Accreditation Discussion Board through which members will discuss specific progress, challenges, and best practices, and any needed resources that can be posted to the Document repository.

- The Accreditation Discussion Board is an online forum for the exchange of information related to becoming accredited to the ISO 17025 standard. Interested parties are encouraged to join and contribute to the discussions and answer questions posted by other laboratory professionals. An orientation session to the Discussion Board was conducted on September 12, 2013. As of Sept 16, 2014, there are 70 registered participants on the discussion board. Participants include 4 APHL staff, one APHL/AFDO consultant, one representative each from AFDO and AAFCO staff, and 63 participants from 49 different laboratories.
- As noted above, information on the discussion board was shared on a FERN-Wide conference call on November 21 and later published in the FERN newsletter.
- As noted above, APHL was invited to speak at the 2014 FDA ISO CAP grantee meeting in Irvine, CA on May 21, 2014 on the theme, “Association Resources, Strategies, and Tools to Support ISO 17025 Laboratory Accreditation”.
- As noted above, there was a poster presentation and demonstration of the ISO accreditation resources and Discussion Board available through the Associations Cooperative Agreement at the APHL Annual Meeting from June 1- 4, 2014

Year 2 metrics:

Within 1 month: Retain necessary staff or consultants to manage the series of individual work plans that will be developed with each state and/or local food and/or feed testing laboratory.

Status: Met (Yvonne Salfinger continues to fill this role)

Barriers: None

Within 3 months:

Engage in discussions with food and feed laboratories identified as interested in the development of an accreditation work plan, based on the specifications of the national work plan. Particular focus will be on those food and feed laboratories not funded by FDA Accreditation Cooperative Agreements. At least 15 laboratories will be engaged in discussions by the end of the reporting year.

Status: Met - APHL is in contact with 22 *ad hoc* laboratories that are seeking accreditation to ISO/IEC 17025:2005 standard but are not currently funded by FDA. All resources and tools provided through the Cooperative Agreement are available to these laboratories. Six of these laboratories have been selected by APHL and FDA for targeted assistance.

Barriers: None

Submit a list of participants in the Accreditation Discussion Board. Each reporting period, provide a count of conference calls convened (if any), and summaries of on-line discussions.

Status: Met - Report was submitted to FDA in August 2014. Conference calls with the participants have not been necessary this reporting period.

Barriers: None

Within 6 months: Submit reports that demonstrate active management of processes in 8 laboratories that are writing Accreditation work plans. Plans will specify the following categories of activities: building internal support, organizing a Steering Committee or other structure, hiring a dedicated Quality Assurance officer, providing general ISO/IEC 17025:2005 training to all staff, performing gap analysis and internal audits, correcting deficiencies, selecting an accrediting body, determining the initial scope, writing a Quality manual and SOP's to required standards, preparing staff to launch new processes, preparing for ISO document review requirements, conducting a final internal audit, and applying for an initial assessment.

Status: Met - Report submitted to FDA for the 5 laboratories actively receiving assistance from APHL, as selected by FDA

Barriers: Limited funding has resulted in reducing the number of laboratories that will receive assistance to 6 rather than the proposed 8.

By the end of the reporting period:

Submit summary reports from the Discussion Board that relate to collective challenges and best practices. Once approved by FDA, these reports will allow other laboratories to learn from their colleagues' experiences.

Status: Met

Barriers: None

Submit reports that demonstrate active management of processes in 12 laboratories that have started to write their Accreditation work plans.

Status: Met

Barriers: Limited funding has resulted in reducing the number of laboratories that will receive direct assistance from APHL to 6.

Each reporting period: Provide a listing of the document repository contents and metrics such as frequency of use. In Year 2, at least 10 additional documents will be posted, if available.

Status: Met, as described above. As of Aug 2014, over 60 additional documents had been added within the reporting period.

Barriers: None

Specific Aim #2: Identify, pilot test, and implement nationally the policies and procedures necessary to establish equivalency between federal, state, and local food and feed testing laboratories. [NOA Reporting Requirements c.]

Activity 1: Convene a Sampling and Sample Handling Working Group to establish guidelines for sampling and sample handling from point of sampling through generation of laboratory data. Members are drawn from AAFCO, AFDO, APHL and FDA as appropriate, and are representative of both laboratory and inspection staff. Efforts are coordinated by the AAFCO Laboratory Methods and Services and Inspection and Sampling Committees.

Drafting Guidance

The guidance document currently under construction has been titled *Guidance on Obtaining Defensible Samples* or *GOODSamples*. *GOODSamples* addresses the entire process of sampling from development of objectives to final assessment. The specific chapter titles are as follows (a first draft is developed for most chapters):

- *Definitions*
- *Management Considerations*
- *Sampling Quality Criteria (SQC)*
- *Considerations in Application of Sampling Theory*
- *Quality Control*
- *Sampling Tools and Equipment*
- *Maintaining Integrity*
- *Health and Safety*
- *Sampling Protocol Design*
- *Examples of Sampling Protocols*
- *Laboratory Sampling, Handling and Preparation*
- *Process Assessment*

A manuscript describing the efforts of this working group was published in the *TOS Forum*, a new international publication serving the sampling community that provides a communications platform for all interested in the theory and practice of representative sampling and blending. Via this platform, input of the international sampling community is sought. The manuscript can be found on page 8 at

the following link:<http://www.impublications.com/forms/TOS-forum-Issue-2.pdf>

Generating Awareness and Introduction of Concepts

Short sessions on the basics of the theory of sampling applied to food/feed are planned at strategic venues as the initial stage of implementing the new Guidelines. Talks and seminars have been finalized at the following venues:

- AAFCO General Session, Current Issues and Outreach Committee, Jan 8, 2014. An hour-long presentation was made to feed regulators and industry participants. Completed.
- MFRPA, Mar 10. An hour-long presentation was made during a half day Sampling Workshop. The meeting was also broadcast via webinar with an additional 50 web attendees. Title: GOODSamples – Guidance on Obtaining Defensible Samples, Chuck Ramsey, Instructor, EnviroStat, Inc. Completed.
- AAFCO Feed Administrators Seminar (FAS), May 6-8, 2014. A half-day Sampling Seminar was held on May 8. Title: Defensible Decisions in an Uncertain World: Have probe, will travel! Chuck Ramsey, Instructor, EnviroStat, Inc. Completed.
- AFDO, June 25, 2014. A half-day Sampling Seminar was held. Title: Defensible Food Safety Decisions in an Uncertain World: The role of sampling in food safety decision-making. Chuck Ramsey, Instructor, EnviroStat, Inc. Completed.
- 13th IUPAC International Pesticide Congress, San Francisco, CA. August 10-14, 2014. Jo Marie Cook presented “Guidance to Improve Sampling Quality and Accuracy”. Completed.
- AOAC. A symposium on Sampling was submitted to and accepted by AOAC INTERNATIONAL for their 2014 annual meeting in September 2014. Confirmed.
- AAFCO, January 10, 2015. A daylong workshop is planned in conjunction with the AAFCO Midyear meeting. Confirmed.

Fifteen state laboratories participated in a project to estimate sample preparation error in feed laboratories. Data has been being analyzed and presented to the working group. A summary was presented at the AAFCO Laboratory Methods and Services Committee Meeting in Sacramento, CA on July 26, 2014.

A survey was developed and submitted to AAFCO membership to gather input on the amount of error that feed regulatory programs can accept in data for the following analytes: protein, vitamin A, phosphorus, copper, monensin, toxic metals, and mycotoxins.

Several state feed programs have expressed interest in conducting sampling studies to evaluate various aspects of sampling variability or sampling error. August 27-28, 2014, Ramsey visited Richard TenEyck at the OR Dept. of Ag and the ID Dept. of Ag Laboratory for a pre-study exercise to determine if the protocol under review for the OR project is doable. Plans are being finalized for efforts in YR 03.

Conference Calls and Meetings

Full Working Group Conference calls were held as follows: Sept. 5, Sept., 19, Oct. 3, Oct. 17, Oct. 31,

Nov. 14, Nov. 28, Dec. 5, Jan. 30, Feb. 11, Feb. 20, Mar. 4, Mar. 13, Mar. 25, Apr. 3, Apr. 15, Apr. 24, and June 10 with others yet to be scheduled. A face-to-face working group meeting was held in New Orleans Jan. 6-7 and in Denver, June 25-26, 2014. Ramsey and Thix worked in person May 6, 7 and 8 and Novotny and Thix worked in person on June 11; and Salfinger and Thix worked in person August 25-28, 2014. In addition, numerous conference calls for sub groups working on individual chapters were held.

Membership, Interest and Impact

There has been continued interest from people desiring to join the working group reflecting the broad interest in the working group final outcomes; however, it must be noted that the burden of admitting additional members has drained resources and energy that might otherwise have been directed to completion of the guidance document. AFDO and AAFCO association interest and commitment is high and the associations are working with our subcommittee to provide training opportunities. The impact of the final guidance document is anticipated to be very far reaching.

Year 2 metrics:

Within 6 months:

Complete development of first draft of primary reference document.

Status: Unmet. Significant progress was made on the draft, but additional time is needed to bring it to completion.

Barriers: The volume of work is massive, the working group is diverse with many untrained newcomers, and conference calls have reached a point of diminishing returns due to increased complexity of the material. Additional face-to-face meetings for a core writing group are necessary to complete the writing project. The number of face-to-face writing opportunities was reduced in YR02 due to cut backs in funding.

Develop ideas for piloting the implementation of the guidelines in specific states.

Status: Met

Barriers: We have developed ideas for implementation, but they cannot be carried out without restoration of the budget. Since we are shifting the paradigm for sampling, in-person training and ample opportunity to repeatedly deliver the message across a number of venues will be necessary.

Develop mechanisms to make states and FDA aware of the availability of the reference document.

Status: Met

Barriers: None

Within 12 months:

Initiate development of mechanisms to deliver training.

Status: Met

Barriers: None

Contract development of initial training tools and deliver these to as many venues as funding will permit (4-5 venues).

Status: Met

Barriers: None

Activate mechanisms to make states and FDA aware of the availability of the reference document.

Status: Met

Barriers: None. Barriers appear to have been resolved.

Within 24 months: Initiate 2 - 4 pilot programs, as funds allow.

Status: Not On-Target.

Barriers: The current level of funding is insufficient to offer the types of pilot programs originally projected. Original budgets will have to be restored before we can fully implement pilot training.

Activity 2: Convene a Registry Work Group to establish a web-based easily searchable Subject Matter Expert (SME) registry drawing membership from APHL, AAFCO, AFDO and FDA if appropriate.

The Manufactured Food Regulatory Program Alliance (MFRPA) has developed a registry of subject matter experts (SMEs). Through the Associations Cooperative Agreement, we are encouraging registration of expertise to help with community-building, information exchange, and building a national integrated food/feed safety system. With SME registration, this database will continue to grow and integrate food and feed experts around the country. The sign-up is located at: www.afdo.org/sme.

Current areas of expertise included in the database and registrant numbers (in parentheses) are (as of September 12, 2014; increases are from mid-year report numbers):

- Animal Feed Testing (10, increase from 3)
- Civil or Criminal Investigations (10)
- Dairy (23, increase from 20)
- Environmental Health (49, increase from 47)
- Epidemiology (11)
- Food Laboratory (56, increase from 51)
- Food Law & Regulation (60, increase from 56)
- Food Processing Technologies (42)
- Laboratory Accreditation (2)

- Meat Inspection (23, increase from 20)
- Pet Food Testing (8, increase from 2)
- Regulatory Inspections - Manufactured Food (49, increase from 44)
- Regulatory Inspections - On-Farm Food Production (21, increase from 19)
- Regulatory Inspections - Retail Food (57, increase from 53)
- Sampling (2, increase from 1)
- Seafood (24, increase from 233)

A short article was published in the Winter 2014 FERN newsletter explaining the process for registration. An AFDO Subject Matter Experts Directory LinkedIn site was created and is being populated. The SME registry is being advertised as AFDO program staff attend meetings where it can be promoted, including the AAFCO annual meeting in July 2014 and mid-year meeting in January 2014, APHL annual meeting in June 2014, the InFORM meeting in November 2013. The SME Registry Workgroup Chair has sent emails to the FERN National Program Office (NPO) and staff from Florida Department of Agriculture and Consumer Services to sign up and also asked them to distribute the SME signup request cards and provided them electronic copies of the post card. Plans for additional expansion include determining if there are gaps in registrants in any laboratories nationwide and contacting respective laboratory personnel directly to see if they wish to be included. In addition, the SME registry information was posted on the APHL Food/Feed Discussion Board on February 5, 2014 and an email was sent out to the AGLABS Listserv, serving over 400 laboratory analysts.

Year 2 metrics: Registry usage is logged and reported; registration numbers are tracked

Status: Met, as described above

Barriers: None

Activity 3: Convene an Equivalency Work Group that will focus on steps laboratories can take to encourage the federal acceptance and use of laboratory data, irrespective of accreditation status.

The name "Equivalency Workgroup" was changed to "Data Acceptance Workgroup" to reflect the goals and objectives of the workgroup. This workgroup is being convened by APHL to focus on steps that laboratories can take to encourage acceptance and use of testing data by local, state, and federal agencies. Accreditation is one way to increase the likelihood of such acceptance; the recently released PFP Laboratory Best Practices Manual outlines other options a laboratory may consider (apply CLIA requirements and fill in noted gaps through negotiations with FDA, or refer their food testing to an accredited laboratory). Specific charges for the workgroup were determined on initial phone calls, including creation of educational materials and a position statement from the Associations in support of the PFP Best Practices Document.

Currently there are 30 participants in the workgroup, including FDA personnel, laboratory personnel from both grantee and non-grantee labs, APHL staff and representatives from both AAFCO and AFDO. The meeting agendas, reference materials, and summaries of calls are available via a workspace on the APHL SharePoint site

(https://www.aphlweb.org/aphl_departments/FS/dfs/daw/Shared%20Documents/Forms/AllItems.aspx)

The Data Acceptance Workgroup had its first conference call on April 30 followed by conference calls on May 16, May 30, June 26, and Aug 21, 2014. Topics discussed on these calls include the overview of the Associations cooperative agreement and the draft PFP Best Practices manual, the purpose and the charges of the workgroup, the concept of the Integrated Food Safety System (IFSS), the audience for the workgroup's activities and products, how to build awareness and reach the various stakeholders, identification of training needs, agreement to write an APHL Position Statement modeled after the AFDO Resolution in support of the PFP Best Practices Manual, and creation of an outline for a document that will describe steps food testing laboratories can take to facilitate acceptance of their data by federal and state partners.

Year 2 metrics:

Within 2 months: Identify membership of Data Acceptance Work Group

Status: Met

Barriers: The PFP "Food/Feed Testing Laboratories Best Practices Manual (Draft)" was released on December 16, 2013. Work began in early 2014.

Within 3 months: Data Acceptance work group reviews final documents of PFP Laboratory Task Group on equivalency

Status: Met

Barriers: The PFP manual was released on December 16, 2013. Work began in early 2014.

Within 6 months: Data Acceptance Work Group identified training needs around the meaning of the PFP documents and provides a report to the Accreditation Training Subcommittee (See Specific Aim 6).

Status: Met

Barriers: The PFP manual was released on December 16, 2013. Work began in early 2014.

Within 8 months: Data Acceptance Work Group suggests Resolution/Position Statement language that each Association can use to obtain formal approval of their membership to support data acceptance.

Status: Met, following the lead of AFDO in writing their resolution in support of the PFP Best Practices Manual at their Annual Education Conference, June 22-25, 2014.

Barriers: The PFP manual was released on December 16, 2013. Work began in early 2014.

Within the reporting year: Data Acceptance Work Group suggests ways to operationalize the implementation steps listed in each Resolution/Position Statement

Status: Not met

Barriers: The PFP manual was released on December 16, 2013. Work began in early 2014. Resolution/Position statements regarding the PFP will be operationalized in Year 3.

Specific Aim #3: Establish nationally accepted models for the rapid sharing and acceptance of laboratory data by FDA (and partnering regulatory agencies) in order that those agencies may pursue regulatory action and advance public and animal health. [NOA Reporting Requirements e.]

Activity 1: Continue to support the work of the data exchange National User Group created in Year 1

1. Discuss strategies for moving forward with the recommendations made in the discovery document created in year 1.

Given the recommendations APHL suggested toward improving data exchange between state laboratories and FDA systems, the National User Group discussed and evaluated the documented technical and standards work found during the discovery period and began to identify existing and recommend new approaches that will serve food and feed-testing laboratories data exchange needs. These approaches will allow for reliable, efficient data exchange for a continued response to foodborne disease outbreaks. Details of these recommendations outlined in the discovery document and progress towards these goals include:

- **Leveraging the National User Group to obtain community consensus on planned improvements:** The National User Group provided feedback to FDA on the new eLEXNET infrastructure upgrades during their in-person meeting in May. During the meeting, the group watched a demo of the new Interactive Data Analysis Tool (IDAT), a new tool designed as an all-encompassing, flexible analytical and reporting tool that will utilize charts and maps to allow the end users to explore eLEXNET data. To gain a better perspective of the new changes, APHL also reached out to other eLEXNET users in laboratories and as such 18 users volunteered to provide feedback. The volunteers participated in the demo of IDAT and test environments within eLEXNET to see the new changes.
- **Identify the minimum data elements required for adequate data exchange** (see below)
- **Leverage and research LIMS vendors capability to send information to eLEXNET** (this activity will be addressed in year 3 of the cooperative agreement)

2. Evaluate need for further standardization within the FDA required eLEXNET data elements.

As outlined by the Partnership for Food Protection (PFP) Food/Feed Testing Laboratories Best Practices Manual, the IT subcommittee recommends the structure of any data report should have a set of “minimum data elements” that meets the test reporting best practices. The National User Group has recognized the importance of identifying minimum data elements for message exchange and went through all of the core data elements, broken into 6 sections or major elements, to provide comments and feedback. Feedback included clarification and comments (where applicable) for each element and recommendations of new elements. It is the desire of the User Group that FDA will consider these changes and update the data elements used for exchange. This best practice, as alluded to in the manual, supports confidence in laboratory competency and facilitates the acceptance of laboratory data by agencies.

3. Meet in person during an annual face to face meeting

The National User Group convened in person at APHL Headquarters May 14-15 for a day and half in-person meeting. FDA liaisons and contractors also attended the meeting. During the meeting the group:

- Reviewed year 1 and 2 activities
- Continued efforts to go through the data elements and provide comments
- Watched presentations on Integration Engines and APHL’s Informatics Messaging Services (AIMS) Hub and Environment
- Watched and provided feedback of the eLEXNET demo of the new IDAT dashboard
- Discussed data entry and data exchange efforts for eLEXNET
- Reviewed metrics to measure progress of short and long term activities
- Drafted year 3 activities

4. Send an informational bulletin to the food and feed laboratories from the User Group about eLEXNET updates.

The User Group served as an information hub for informatics-related topics that may need to be shared with the food and animal feed testing community. APHL coordinated a monthly call with FDA eLEXNET staff and received updates that were sent out to APHL members. Members have received information on the discovery report release and the opportunity to volunteer to provide feedback on the new eLEXNET upgrades. Only when laboratories are up to date on the latest eLEXNET and data exchange efforts will they be able to fully participate in an integrated food safety system.

Activity 2: Build a practical grass roots approach for eLEXNET users to share ideas

With so many stakeholders involved in the data collection and outbreak response processes, and with often limited IT resources, data exchange can be challenging. In order to identify these gaps and opportunities that exist, it is critical to understand food and feed-testing laboratories data exchange and eLEXNET capabilities. To help facilitate this discussion, APHL outlined a plan to convene a national call to all food and feed-laboratories interested to generate discussion around eLEXNET and to solicit input and feedback. Discussion topics will include core data elements and standards, data import and current use trends of eLEXNET. Due to scheduling conflicts, the call will take place as part of year three activities.

Activity 3: Create marketing and promotional tools for FDA data exchange related activities

Marketing and promotional tools created in Year 2 included:

- Submitted information for APHL’s *eUpdate* about the release of the discovery document. *eUpdate* is a weekly electronic newsletter sent to all of APHL’s members
- Created an electronic informational brochure on specific aim #3 activities
- Produced information on APHL’s accreditation website about current data exchange efforts
- Published “Where We Are: Data Exchange Among Food and Feed-Testing Laboratories” and “National User Group Meets at APHL Headquarters with FDA” for the Spring and Summer 2014 editions of APHL’s *Lab Matters*. *Lab Matters* is a quarterly magazine sent to all of APHL’s members
- Submitted and presented a poster entitled “Current Landscape of Food and Feed-Testing Laboratory Data Exchange: Findings and Recommendations from APHL’s Discovery Document” at the 2014 Public Health Informatics Conference and APHL’s Annual Meeting.

Activity 4: Support FDA on internal strategic planning meetings

Released “Food and Feed Testing Laboratories Informatics and Data Exchange Capabilities” survey data collected during the discovery process to FDA for research and strategic planning purposes.

Year 2 metrics:

Within the reporting year:

A draft set of recommended standards will be ready to review by the entire data exchange National User Group.

Status: Met. The National User Group submitted the core data elements spreadsheet with feedback to FDA in August 2014.

Barriers: None

The data exchange National Data Users group will meet monthly.

Status: Met. The National User Group held monthly meetings Sept. 18, Oct. 16, Dec. 18, Jan. 15, Feb. 19, Mar. 19, Apr. 16, Jun. 18, Jul. 16, and Aug. 20. An in-person meeting was held May 14-15 at APHL headquarters.

Barriers: None

Specific Aim #4: Facilitate the implementation of a national framework for a unified laboratory response to emerging food or animal feed safety emergencies or other issues of public health significance based on the Manufactured Food Regulatory Program Standards (MFRPS), the guidelines published by the Council to Improve Foodborne Outbreak Response and other standards recognized by the Secretary. [NOA Reporting Requirements b.]

Activity 1: Establish a network of Food and Animal feed regulatory laboratory managers.

AFDO established a Laboratory Managers Steering Committee to provide leadership for facilitating state food and feed laboratory accreditation and integration with state and federal food safety surveillance, compliance, and enforcement programs. Committee activities have resulted in a draft laboratory curriculum framework, promoted knowledge of FSMA's expectations for food and feed laboratories and food safety regulatory programs, an AFDO resolution regarding support for the *PFP Food/Feed Laboratory Best Practices Manual (Draft)* (it will be posted at <http://www.afdo.org/resolutions/>), and helped to distinguish laboratory requirements to achieve accreditation and Manufactured Food Program Standards. All of these efforts are helping to build the Integrated Food Safety System.

- AFDO has developed a list of laboratory directors' contact information that can also be utilized in fulfilling the objectives of this agreement (Aim #2, Activity #2). By utilizing membership directories of the participating associations and through the FDA/AFDO's Directory of State & Local Officials (DSLO), AFDO will maintain the list's accuracy to identify the appropriate regulatory laboratory managers for food and animal feed within their jurisdiction. AFDO is engaging these individuals as the core for the structure that is being established in this proposal. The list allows cooperating organizations to build a laboratory managers network, conduct surveys, identify training needs, and provide information as needed to food and feed testing laboratories.
- The Laboratory Managers Steering Committee, with 16 members, meets every 2 weeks by conference call, and met in-person at the 2014 AFDO Annual Educational Conference in Denver, CO. They were involved in developing the agenda for the Laboratory Workshop, including a Focus Group on AFDO's IFPTI Curriculum Framework project, and a training session on mentoring as well as a Quality Manual workshop put on by APHL, and a Laboratory session at the AFDO Conference. Topics of discussion have included LabDIR and its use by FERN member

laboratories, eLEXNET, the IFPTI Curriculum Framework, and more recently, metrics for measuring success of this cooperative agreement.

- Laboratory Manager Steering Committee members and AFDO staff worked with the Office of Partnership and Office of Regulatory Science to facilitate clarification of the sampling agreement deliverable requirements of the ISO Lab Accreditation Cooperative Agreements. As a consequence, a webinar was held for laboratory and program staff by ORA with Laboratory Managers Steering Committee member participation on December 18, 2013. APHL staff also presented during this webinar regarding the importance of integration between program and laboratory activities. Webinar information was posted to the MFRPA Portal as well as the Accreditation Resource site on the APHL website.
- The Laboratory Managers Steering Committee sponsored a Sampling Workshop at the 2014 MFRPA meeting in Ft. Worth, TX to present topics which will help Alliance members build collaborative relationships with their food laboratories to ensure effective sampling and analysis programs in support of foodborne outbreak surveillance, prevention and response.
- The MFRPA Board designated the Laboratory Managers Steering Committee as the entity which will develop recommendations for changes to Standard 10 (Laboratory Standard, referencing A2LA accreditation or an ISO-like quality management system) of the MFRPS. This will ensure that the MFRPS standards are appropriate and are representative of the best practices of a high-quality regulatory program designed to protect the public from foodborne illness and injury. Select committee members participated in the MFRPA Annual Meeting to learn about the change process and communicate needs.

Activity 2: Conduct surveys of State/Local/Tribal Food and Feed Testing Laboratories:

- AFDO conducted a survey of State Food Program Surveillance Programs to help understand the scope of state surveillance programs currently being implemented, and provide information to further enhance the food safety system. A copy of the results is available upon request.
- APHL and AAFCO did not conduct surveys of their members relevant to ISO Accreditation during this reporting period.

Activity 3: Provide Task-Oriented Guidelines, as needed, to address issues that can be adopted or into regulatory laboratory programs:

No new task-oriented guidelines have been created this reporting period, partly due to decreased funding.

Activity 4: Identify and Support Pilot laboratory programs in States as needed to support implementation of regulatory program standards, accreditation, and integration.

No pilot programs are under consideration due to decreased funding.

Activity 5: Community Building/Networking:

- A web based information portal has been established (Topical Index of Laws and Guidance; <http://ti.afdo.org/>) to expand data collection and integrate both public and protected tools to allow for effective information-sharing to provide resources for improving the food/feed safety systems. Tools include resources such as document-sharing and online meetings. There are 32 documents and links under “Laboratory Accreditation” (including a link to the APHL Accreditation resource site), and 50 documents and links under the category “Laboratory”. Additional links to Sampling resources are included here as well as the MFRPA portal. A “Laboratory Accreditation” page has been established which is linked from AFDO’s Home Page which provides background information on the Co-Ag, consolidates links to the laboratory resources, and includes links to the APHL and AAFCO resources.
- The Manufactured Food Regulatory Program Alliance met March 10-13, 2014, and provided, as described under Activity 1, a session regarding sampling, highlighting a few state’s regulatory inspection and laboratory programs. There was a session on GOODSamples – Guidance on Obtaining Defensible Samples, developed through the Food and Feed Sampling Committee; a presentation on the National Sampling Plan and the ISO Sampling Agreement Assignment, state presentations, and a panel discussion for questions and answers on best practices for Developing an Effective, Well-Coordinated, Surveillance and Sampling Plan.
- The AFDO Annual Educational Conference June 23-26, 2014 pulled together laboratory participants from the United States laboratory and regulatory community to discuss accreditation efforts of food and feed testing laboratories. An APHL training session on the writing of a Quality Manual was held, along with a training session and development of a toolkit for mentoring by APHL, a focus group for furthering the IFPTI curriculum framework, and a meeting of the AFDO Laboratory, Science and Technology Committee. Additionally, a laboratory session for the main audience was held to discuss several technical subjects of interest to inspectors and laboratorians. A Sampling seminar was also held in collaboration with the Food and Feed Sampling Committee to provide GOODSamples training to regulatory food program staff and industry. The AFDO Annual Educational Conference forum helped to optimize scarce dollars by using one venue for several activities related to this cooperative agreement. These activities will enhance accreditation efforts and help to standardize activities across the food/feed testing sector, helping to standardize testing activities to meet program standards and enhance food safety.

Activity 6: Identify and coordinate training activities with FDA or other entities such as IFPTI or Cooperative Extension offices. In cases where essential training programs do not currently exist, the associations will propose new training programs to FDA for consideration and development

Achieving ISO accreditation and meeting FSMA standards requires that laboratory professionals have appropriate training and competency. Determining the scope and content of this training is the driving force behind Phase One of the IFPTI Curriculum Framework—the development of a competency

framework that describes the job competencies required by laboratory personnel. In Phase Two, the competency framework will inform the development of a training curriculum framework that will help identify training content areas, catalog existing training courses and modules, find gaps in existing training, and create new training to address those gaps. The curriculum framework will also allow food and feed laboratory professionals to identify gaps in their own professional development and allow those individuals to create personal learning paths.

- AFDO began work with IFPTI beginning in Year 1 in a face-to-face meeting with SMEs August 21-22, 2013 to develop a curriculum framework (similar to the [IFPTI Curriculum Framework for Regulatory Food Protection Professionals](http://www.ifpti.org/food-protection-curriculum)) (<http://www.ifpti.org/food-protection-curriculum>) to identify career-spanning training for food and feed laboratory professionals. IFPTI will convene and continue conducting meetings over FY2-FY3 with SMEs identified by AFDO to create this framework. AFDO has selected 7 SMEs with an appropriate range and depth of knowledge, skills, and experience in food and feed laboratories to serve as the core AFDO curriculum framework development team. It is planned that all team members attend all development meetings and provide input and feedback via other communication methods (email, teleconference, etc.) as deemed necessary by the team. APHL Training coordinator, Cathy Johnson, will be invited to become a member of the team. Deliverables include:
 - Curriculum framework diagram: A depiction of the professional development content areas that represent training that food and feed laboratory professionals should participate in over their careers.
 - Curriculum framework content area descriptions: A written description developed by the AFDO subject matter expert team, identifying the subject matter included in the content area.
- The development of the diagram progressed greatly with the initial meeting, and assignments were given to ensure continued progress. A Focus Group to vet the current version of the Curriculum Framework and accompanying definitions met at the AFDO Educational Conference in June 2014. Also, an article entitled “Developing a Competency Framework for U.S. State Food and Feed Testing Laboratory Personnel” was published about the process of this project in the Journal of the AOAC International on May 29, 2014.
http://assets1.mytrainsite.com/501440/kaml_competency_framework_lab_article.pdf?r=1366

The core working group convened on August 19-20, 2014 to continue work on the framework and accompanying definitions based on comments received at the Focus Group. Comments will be returned to participants with action taken in September 2014. Additionally, the group will begin work in Fall 2014 on competency statements to further clarify specifics for the training to be developed within each area on the framework.

- By establishing equivalency of competencies among laboratories, facilities will improve their interaction with food and feed safety programs and with other laboratories in an integrated food

safety system, and share accurate and reliable test results. In doing so, the laboratories will be helped to meet the standardization requirement of the U.S. Food Safety Modernization Act. Section 202 of FSMA calls for the development of model standards that laboratories must meet in order to be accredited by a recognized accreditation body. Finally, the project will assist all U.S. food and feed testing laboratories in gaining international accreditation under ISO/IEC 17025 (2005).

- Additional training activities are outlined under Specific Aim #6.

Activity 7: In support of FSMA, work with FDA to establish operational partnerships that assist in the capacity building of state and local agencies as well as establishing and implementing strategies for improving state and local food safety efforts. *[NOA Reporting Requirements j.]*

- See activities related to Sampling Agreements under Specific Aim #4, Activity 1 and Specific Aim #7, Activity 1.
- The Laboratory Managers Committee has developed a collaborative relationship with the MFRP Alliance to promote integration between the regulatory and laboratory communities.

Specific Aim #5:

Provide forums, including national and international meetings, to improve communication and collaboration between federal, state, and local food and animal feed testing laboratories and their associated regulatory and public health programs. *[NOA Reporting Requirements f.]*

Activity 1: Convene national calls with respective members around emergency events. Ensure effective communication with relevant experts and stakeholders

- The three Associations routinely convene national calls with respective members and other SME's that relate to important food protection episodes. No calls relevant to ISO accreditation or related food and feed topics were held this reporting period.
- Using the DSLO and the SME list enhanced under this Cooperative Agreement, relevant AFDO experts and stakeholders are better able to be identified. A plan to update the SME list on a regular basis is being developed so that the content stays current. Also, the Laboratory Managers Steering Committee meets biweekly by conference call, and provides a forum for rapid gathering of information that may be passed on to the full membership.

Activity 2: Convene national scientific or programmatic conferences and forums, as funding allows and in consultation with FDA Project Officer. Conduct training for food and feed laboratory program managers during at least one of the participating association's annual meeting.

Attendance at scientific/programmatic conferences and forums provides an avenue for exchange of ideas, leading to work towards forming a community for food and animal feed regulatory laboratory managers, and provide for them resources, tools, and network opportunities that will strengthen their ability to respond more effectively and in a more coordinated fashion to foodborne events and ensure more standardized approaches.

The annual conferences of AFDO, APHL, and AAFCO are being utilized to advance the objectives of this cooperative agreement.

- The AFDO Annual Educational Conference June 23-26, 2014 pulled together laboratory participants from the United States laboratory and regulatory community to discuss accreditation efforts of food and feed testing laboratories. An APHL-led training session on the writing of a Quality Manual was held, along with a training and toolkit building session on mentoring by APHL, a focus group for furthering the IFPTI curriculum framework, and a meeting of the AFDO Laboratory, Science and Technology Committee. Additionally, a laboratory session for the main audience was held to discuss several technical subjects of interest to inspectors and laboratorians. A morning-long Sampling seminar was also held in collaboration with the Food and Feed Sampling Committee to provide GOODSamples training to regulatory food program staff and industry. The AFDO Annual Educational Conference forum helps to optimize scarce dollars by using one venue for several activities related to this cooperative agreement. These activities enhance accreditation efforts and help to standardize activities across the food/feed testing sector, meet program standards and enhance food safety.
- AAFCO organized and led a session on Food Sampling and Sampling Agreements at the MFRPA meeting in Ft. Worth, TX on March 10, 2014.
- APHL's Annual Meeting in June 2014 included a demonstration of and a poster presentation on the resources available through the Associations Cooperative Agreement.
- AAFCO mid-year meeting sessions relevant to this Cooperative Agreement are described below.
- A poster abstract was submitted and accepted for the AOAC International on the accreditation progress for its annual conference to be held in September, 2014 in Boca Raton, FL.
- A 1.5 hour session was submitted and approved for the AOAC International meeting entitled "Laboratory Accreditation – the Key Building Block of the Nation's Integrated Food/Feed Safety System". It will be held on September 10th, 2014.

Activity 3: Convene meetings of new or active association committees and subcommittees to provide support for the proposed Cooperative Agreement.

- The following committees and workgroups with CoAg funded activities and/or speakers met at the AAFCO Midyear Meeting in New Orleans, LA, January 6-10, 2014.
 - The AAFCO Collaborative Check Sample Committee on Jan. 8
 - AAFCO Laboratory Methods and Services Committee (LMSC) on Jan 9.
 - AAFCO Inspection and Sampling Committee (ISC) on Jan. 9
 - AAFCO Current Issues and Outreach Committee on Jan. 8
 - CoAg Working Group face-to-face-meetings
 - Quality Working Group on Jan. 6

- Sampling and Sample Handling Working Group on Jan. 6 & 7
- The AFDO Laboratory, Science and Technology Committee met during the AFDO Educational Conference June 23-26, 2014 in Denver, CO.
- The Laboratory Manager's Steering Committee meets every 2 weeks by phone and met during the AFDO conference.
- The AFDO Curriculum Framework workgroup were part of the focus group held at the AFDO conference in June 2014.
- The face-to-face meeting of APHL's Food and Feed Testing Subcommittee was held March 19-20, 2014, at APHL in Silver Spring, MD.
- The face-to-face meeting of APHL's National User Group was held May 14-15, 2014, at APHL in Silver Spring, MD.

Activity 4: Support staff and member travel to external meetings and conferences.

- No member requests for travel to external meetings have been funded by the Associations this reporting period due to limited funds for this activity.

Activity 5: Conduct regular meetings of the Steering Committee for this Cooperative Agreement.

APHL convenes an Associations CoAg Steering Committee to oversee the work under this Cooperative Agreement. Members include representatives from all the three associations and FDA's Office of Partnerships.

- An Associations Cooperative Agreement Steering Committee face-to-face meeting was held in Silver Spring, MD on December 19, 2013, following the annual meeting with FDA technical leads at the Element Building. Discussions included progress on the cooperative agreement deliverables, connections to the ISO CAP grants, the public health impact of the work of the Cooperative agreement, and the formation of an Executive Steering Committee proposed by FDA leadership.
- Three conference calls were held in May 2014 with members of the Steering Committee plus technical officers from ORS (Associations CoAg Oversight Group). The purpose of these calls was to review CoAg progress and prioritize activities heading into Year 03.
- Additional calls of the Associations CoAg Oversight Group were held on June 30th and Aug 27th, 2014, for a monthly check-in on priority activities.

Year 2 metrics:

As Needed:

Schedule, arrange, and moderate national member calls around emergency events. Be able to respond within 24 hours of a request. Identify and invite relevant experts and stakeholders. Inform partners of

the outcomes of these calls. Maintain websites and collaborative work spaces to share documents and information related to the emergency.

Status: All 3 Associations are prepared to meet this metric, though no calls were necessary this year.

Barriers: None

Plan, schedule, arrange, and host new or active association committee and subcommittee meetings that support the goals of this Cooperative Agreement.

Status: Met

Barriers: Decreased funding limits the number of participants at these meetings

Arrange travel for staff and members who will attend conferences and meetings in support of Cooperative Agreement goals. Identify relevant meetings, solicit member interest, provide registration information and travel instructions, help prepare presentations (if necessary), and provide a mechanism for the member to report on knowledge gained.

Status: All 3 Associations are prepared to meet this metric, though no requests were met this year.

Barriers: Decreased funding limits this activity.

Quarterly: Schedule and lead calls of the Steering Committee for this Cooperative Agreement. Provide meeting summaries to FDA within 2 weeks of each call. Facilitate action items.

Status: Met

Barriers: None

Specific Aim #6: Provide educational opportunities, resources, tools, and mentoring for laboratories seeking to achieve, maintain, and enhancing the scope of their ISO/IEC 17025:2005 accreditation. Working in concert with the International Food Protection Training Institute (IFPTI), expertise will be applied to assess laboratory needs, develop course content, and conduct laboratory training using a multitude of in-person and distance learning.

Activity 1: Continue meetings/conference calls of the Accreditation Training Steering Committee, led by professional education specialists from APHL, AFDO, and AAFCO and comprised of members with expertise in the development and delivery of training and education materials. Include FDA and IFPTI liaisons, as appropriate.

The Steering Committee is comprised of representatives of laboratories seeking to achieve, maintain, or enhance their ISO/IEC 17025:2005 accreditation. The Steering Committee supports collaborative development of training and education courses specifically structures around the ISO 17025 standards. The Steering Committee works closely with the Food and Feed Testing Subcommittee to achieve

activities described under Specific Aim #1. Laboratories that participate in the training courses will more quickly achieve ISO/IEC 17025:2005 accreditation and the staff will be properly prepared to successfully and efficiently meet this goal.

- Conference calls of the Accreditation Training Steering Committee are held monthly.
- Four subcommittees of members meet to 1) review training materials that are already available around ISO 17025 accreditation, 2) to complete a Training Needs Assessment (TNA), 3) develop webinar content and 4) discuss in-person training needs.
 - TNA subcommittee: The TNA report is being developed by APHL Staff. The TNA is being developed for distribution in Year 2.
 - At the end of Year 2, the following topics had been addressed:
 - Laboratory Management System Requirements, including Document Control
 - ISO/IEC 17025 Technical Requirements
 - Writing a quality manual, procedures, and policies
 - Developing an accreditation action plan and timeline
 - Selecting an accreditation body
 - Defining the scope of accreditation
 - Available Training Subcommittee: The subcommittee developed a training resource document of training already available and posted it on Share Point and on the Food Safety program website. The workbook is reviewed every six months by the committee. Other training opportunities are shared on the Discussion Board and via email. The ISO 17025 standards were matched to the available training list in the excel workbook and is available at <http://www.aphl.org/aphlprograms/food/laboratory-accrediation/Pages/Training-Resources.aspx>.
 - Webinar group meets regularly, see Activity 3 below
 - In-person group meets regularly, see Activity 3 below

Activity 3: Guided by the Accreditation Training Steering Committee, build and deliver 1-5 courses on specific aspects of ISO/IEC 17025:2005 accreditation, with format and content based on the results of Steering Committee and in consultation with the FDA project officer

The training subcommittee members identified topics and prepared training activities, as informed by the training needs assessment. Laboratories that participate in the training activities will be properly prepared and informed to successfully and efficiently meet the goal of ISO/IEC 17025:2005 accreditation.

- Training Status
 - A recorded webinar “ISO/IEC 17025 Road to Accreditation: Where to Start and What to Consider” was developed and made available on September 6, 2013.

- A recorded webinar “ISO/IEC 17025 Road to Accreditation: The Journey Continues...” was developed and made available on April 3, 2014.
- A live webinar “Key Elements of a Laboratory Quality Manual for U.S. Food and Feed Laboratories” was developed, presented live, and made available for later viewing on June 12, 2014.
- A two-part live webinar on the mentoring process was developed, presented live, and made available for later viewing on June 19 and 20, 2014.
- A recorded webinar on document control systems was developed and made available in August 2014.
- An in-person workshop was conducted on How to Write a Quality Manual on June 24, 2014 in Denver, CO.

Activity 4: Develop and implement the structure of a mentoring program for laboratories that are seeking to achieve ISO/IEC 17025:2005 accreditation, utilizing the expertise of members who have already become accredited.

The mentoring program is being developed to standardize the process between mentor and mentee laboratories. The program will provide an organized approach to guiding laboratories seeking accreditation through the sharing of experiences, tools and knowledge of accredited laboratories.

- A mentoring program is in development. A two-part live webinar on the mentoring process was developed, presented live, and made available for later viewing on June 19 and 20, 2014.
- An in-person workshop on developing a mentoring tool kit was held on June 25, 2014 in Denver, CO. 35 people attended and received tools for review. From this group, a work team was formed to focus more specifically on the needs for the laboratories seeking accreditation.

Laboratories that participate in the mentoring activities will be properly prepared and informed to successfully and efficiently meet the goal of achieving accreditation to the ISO/IEC 17025:2005 standard.

Year 2 metrics:

Within 45 days: Analyze the completed TNA from Year 1.

Status: Completed

Barriers: None

Within 3 months:

Determine training calendar for Year 2 based on the TNA completed in year 1.

Status: Completed

Barriers: None

Submit a report that analyzes all course assessments and evaluations completed in Year 1.

Status: Completed in August 2014

Barriers: None

Within 1 year:

Guided by the Accreditation Training Steering Committee, build and deliver 1-5 courses on specific aspects of ISO/IEC 17025:2005 accreditation and mentoring, with format and content based on the results of the Steering Committee and in consultation with the FDA project officer.

Status: Met as described above

Barriers: None

Send out and analyze evaluations from courses delivered in Year 2 and report to the Steering Committee.

Status: Ongoing as course evaluations continue to be submitted

Barriers: None

Submit report on impact data for courses delivered in year 1.

Status: Not completed

Barriers: Course still open

Submit other reports on Impact data as available.

Status: Not completed

Barriers: Course still open and others to be offered

Develop training calendar for Year 3.

Status: Completed

Barriers: None

Specific Aim #7: Form national consensus with Federal and State regulatory officials on the acceptance of laboratory data and for the coordination of laboratory resources in response to emerging food and animal feed issues of public and animal health significance. [NOA Reporting Requirements g.]

Activity 1: AFDO Laboratory Managers Steering Committee

- AFDO Program Director Ron Klein will promote communication and collaboration between the Manufactured Food Regulator Program Alliance and state laboratory officials for issues pertaining

to Standard 10 of Manufactured Regulatory Program Standards. Steve Sobek, WI, is now a laboratory liaison for the MFRPA Board of Directors.

- The Laboratory Managers Steering Committee developed a sampling workshop that was presented to MFRPA members at the 2014 MFRPA Annual Meeting in Fort Worth, Texas. The workshop provided additional information on sampling agreements and included a presentation on GoodSAMPLE guidance developed by the Food and Feed Sampling Committee. This presentation will help improve the scientific integrity of the sampling for surveillance, food-borne outbreak response, and compliance.
- Additional accomplishments of the Lab Managers Steering Committee are described under Specific Aim #4, Activity 1.
- The Laboratory Managers Steering Committee created an AFDO Resolution 2014-4 recommending that AFDO endorse the use of the *Partnership for Food Protection, Food/Feed Testing Laboratories Best Practices Manual (Draft)* to support confidence in the integrity and scientific validity of laboratory analytical data and facilitate the acceptance of laboratory analytical data by regulatory agencies. It was approved on 6/26/14 at the AFDO Business Meeting and will be publicized as well as posted at <http://www.afdo.org/resolutions/>.

Year 2 metrics: AFDO and the AFDO Laboratory, Science and Technology Committee will work closely with FDA and the Partnership for Food Protection [PFP] to assure acceptance of laboratory data from testing conducted at state and local laboratories for the purpose of advancing a national integrated food safety system. Dan Rice, current co-chair of the committee is on the PFP Governing Council.

Status: Met

Barriers: None

Specific Aim #8: Use association infrastructure to develop an integrated approach to assist food and animal testing laboratories to achieve, maintain, and enhance the scope of laboratory accreditation and achieve conformance with applicable program standards as established by the Secretary. [NOA Reporting Requirements i.]

Activity 1: AAFCO Check Sample Program Accreditation and Expansion.

Efforts toward Accreditation to ISO 17043

- The new Data Reporting Website (DRW) has been reviewed, debugged, and is in use for the 2014 programs. The DRW is a very significant program improvement, in addition to facilitating program accreditation and expansion.
- Homogeneity testing is complete. AAFCO consultant Andy Crawford analyzed the data and presented results to the CCSP Committee. The good news is the materials tested do meet our criteria for homogeneity. The committee agreed that the materials are homogenous and that

they can be monitored using the very tight parameters of the nitrogen by combustion method considerably reducing the need for additional homogeneity testing.

- Stability testing is complete. Crawford analyzed the data, and presented results to the CCSP Committee. The committee agreed that the stability testing results could be used to assess stability without the need for additional expensive testing.
- Drafts of sections 4, Technical Requirements, and 5, Management Requirements are in review by the CCSP QA Oversight Team.
- A documentation website has been established to describe the statistical calculations used in the program, their rationale, examples and supporting literature. This meets accreditation requirements as well as client requests.
- A draft of the Quality Management Plan is in initial stages of preparation
- Due to budget reductions, the accreditation application will be pushed to YR03. The Gantt Chart has been re-built to reflect these changes.

A shortage of volunteer time and budget cuts are significant impediments to achieving accreditation of our program.

Program Expansion

- *Pet Food Program:* The first year of the Pet Food Program was very successful with 63 participant labs. Second year enrollment is at 72 labs in the US. A special group of 118 analysts at 18 different lab locations (17 in the US and 1 in Canada) has enrolled exclusively in the pet food program this year, departing the regular program. Materials for the current program and the full schedule of events are posted in Table 1.

Table 1. Schedule of Events for Pet Food Program

Quarter	1	2	3	4		
Number of subscribers	71 (+118)	72 (+118)	72 (+118)	72 (+118)	72 (+118)	72 (+ 118)
Material	Fishmeal	Potato Flour	Beet Pulp	NFDM	Canned Cat Food	Dry Pet Food
Date shipped to subscribers	2/24/14	5/21/14	8/29/14	11/21/14	6/21/14	9/22/2014
Results due from subscribers	4/10/14	7/10/14	10/10/14	1/10/15	8/10/2014	11/10/2014
Issue Date	4/30/14	7/31/14	10/31/14	1/31/15	8/31/2014	11/30/2014

- *Mycotoxin Program:* A new Mycotoxin Contaminants PT program consisting of quarterly shipments kicked off in March 2014. Animal feed or pet food materials that have been

contaminated with naturally incurred aflatoxins, fumonisins, DON, zearalenone, ochratoxin A and T-2 toxin are provided to subscribers. Contractor Andy Crawford has completed the data analysis program and the reporting tool, which was enthusiastically adopted by the CCSP Committee. The DRW has been configured for the program. Thirty laboratories have enrolled for the first year program, which is an outstanding response! The full schedule of events is posted in Table 2.

Table 2. Schedule of Events for Mycotoxin Contaminants Program

Quarter	1	2	3	4
Number of subscribers	30	30	30	30
Material	Poultry Feed	Swine Feed	Cattle Feed	Dry Pet Food
Date due to Able Labs	3/17/14	6/17/14	8/19/14	11/18/14
Date shipped to subscribers	3/20/14	6/21/14	8/29/14	11/21/14
Results due from subscribers	5/19/14	8/10/14	10/10/14	1/10/15
Issue date	5/31/14	8/31/14	10/30/14	1/31/15

- Heavy Metal Contaminants Program:* The DRW has been partially configured for the program for 2015. Method codes are available for participants to report data on the regular program materials. A plan is in place to formulate fortified PT materials. Quotes have been obtained from potential blending facilities and were evaluated. A good candidate has recently been identified and is currently working with a base bulk dry dog food to prepare the prototype. Metal salts will be spiked into the material; over the course of four quarterly materials, concentrations of approximately fourteen toxicologically significant metals will be varied. A survey was conducted to assess interest in the Program to assist with planning.
- Veterinary Drug Contaminants Program:* The DRW has been partially configured for the program for 2016. Method codes are available for participants to report data on the regular program materials.
- Drug and Antibiotics Expansion Program:* The DRW has been configured for the program. Method codes are available for participants to report data on the regular program materials. A prototype sample of combination B (chicken grower with 3 g / Ton Lincomycin, 17 g / Ton Roxarsone and 100 g / Ton Lasalocid) is at the Sample Prep Facility. Homogeneity / stability testing will be run by CFIA and provided the sample passes our established criteria for homogeneity it will be used in the Program later this year.
- Meetings:* Monthly conference calls of the steering group were held Sept. 26, Oct. 21, Nov. 18, Dec. 16, Jan. 20, Mar. 4, May 1, May 29 and July 21, 2014. The first face-to-face meeting CCSP Committee meeting was held in New Orleans, LA Jan. 8 in conjunction with the AAFCO Midyear

meeting; and a second face-to-face meeting was held in Sacramento, CA July 25 in conjunction with the AAFCO Annual meeting.

Year 2 metrics:

AAFCO Check Sample Program Accreditation

Status: Unmet in YR02. Significant progress on the application package was made, but we were unable to submit the final application. The 3rd party audit is now projected for YR03.

Barriers: Barriers to meeting target are two-fold: a shortage of volunteer time, and budget cuts. Together, these were a significant impediment to completing the application package.

Program Expansion

Status: Met

Barriers: None to date. Reduced funding is a serious threat to implementing the full roll out.

Activity 2: Revision of the AAFCO Quality Assurance Quality Control Guidelines

- The Working Group completed the 2014 revision to the *AAFCO Quality Assurance Quality Control (QA/QC) Guidelines for Feed Laboratories (Guidelines)* with conference calls as the primary mechanism to complete the work. The *Guidelines* includes feed laboratory specific accreditation requirements, section-by-section guidance for implementing the ISO/IEC 17025:2005 international requirements, an equipment calibration and verification table, quality control checks table, and example forms and procedures. This is the official guidance document for feed laboratories seeking compliance with the newly released Animal Feed Regulatory Program Standards (AFRPS) and those seeking accreditation to ISO/IEC 17025:2005.
- On Jan. 9, 2014, the *Guidelines* were presented to, and accepted by, the AAFCO Laboratory Methods and Services Committee and recommended for adoption by the AAFCO Board of Directors (BOD). The AAFCO BOD accepted and approved the *Guidelines* for publication on Jan. 10, 2014. The *Guidelines, 2014 Edition* was delivered to the AAFCO/FASS staff for order fulfillment on Jan. 31, 2014. Orders totaled 101 copies as of Mar. 1, 2014. Copies were distributed to the seven accreditation bodies approved by FDA.
- Co-chairs Snodgrass and Ogden held a two-hour Accreditation Panel at the AAFCO Annual Meeting in Sacramento, CA July 26, 2014 as a follow up to the release of the revised *Guidelines*. Survey responses are being collected for input on training to be offered in the future.
- The 2014 revision to the AAFCO Quality Assurance Quality Control (QA/QC) Guidelines for Feed Laboratories (Guidelines) is an indispensable resource to feed and pet food laboratories seeking accreditation to ISO/IEC 17025:2005 and/or those supporting Feed Regulatory programs complying with AFRPS. This revision has been updated and restructured to provide section-by-section guidance for implementing the Standard and includes a copy of the Standard. It also

lists additional requirements beyond those specified in the Standard. It is a resource for laboratories developing quality systems, and those on a track to meet the management and technical requirements of the Standard. The Guidelines will greatly facilitate the accreditation process and improve the data quality and equivalency of laboratories across the nation, as well as those beyond our borders.

Year 2 metrics: See Table 2 above

Status: Met

Barriers: None

Activity 3: Listing of Proficiency Testing Providers

A small working group was formed to develop a listing of relevant proficiency testing providers for food and feed laboratories in spreadsheet form. The spreadsheet was vetted at the AAFCO Laboratory Methods and Services Committee meeting July 26, 2014 in Sacramento, CA and is now available to FDA, APHL, AFDO and AAFCO members. This resource facilitates labs efforts to meet the requirements of ISO 17025 accreditation as they relate to proficiency testing activities.

Specific Aim #9:

Advance the efforts of FDA to achieve specific goals of FSMA related to laboratory analysis, including the rapid shipment of clinical isolates related to foodborne illnesses to public health laboratories for submission to PulseNet. [NOA Reporting Requirements h.]

Discussions at APHL, with APHL's Food Safety Committee, and with FDA technical officers, led to a decision to merge the Clinical Isolates work group started in Year 1 with APHL's existing Culture Independent Diagnostics (CID) Subcommittee, given similar work and overlapping goals. Work group members were given the option to opt out of the new arrangement. Work group members and any interested CID Subcommittee members were asked to complete FDA Y02 deliverables by August 31, 2014.

Activity 1: Gather and develop tools and resources that will assist states in implementing activities to improve rapid isolate submission.

- Foodborne disease isolates are critical to detecting foodborne disease outbreaks through PulseNet and monitoring antibiotic resistance trends through the National Antimicrobial Resistance System (NARMS). The Clinical Isolates Work Group developed two main resources during CA Y02 to provide members with tools to enhance the thorough and timely submission of foodborne disease isolates in order to improve outbreak detection and investigations.
 - The work group developed an APHL position statement that strongly encourages all jurisdictions to pursue mandatory reporting and isolate submission laws or rules if not already in place. One key implementation piece includes development of model

language for sites to use when drafting such laws/rules. The position statement will follow APHL's routine channels of approval and is expected to be finalized later this fall 2014.

- The work group gathered information from a number of state public health laboratories on in-house courier systems. Work group members developed a small set of questions that were used to collect standard information from a subset of sites via informal telephone interviews. This information was used in tandem with pre-existing survey data to inform cost analysis worksheets for various courier system models.
- The Clinical Isolates Work Group plans to disseminate and market the aforementioned position statement and courier system cost analysis worksheets through APHL's MRC, weekly electronic newsletter E-Update and at least one Lab Matters publication this fall.
 - The mandatory isolate submission position statement will be disseminated to members via blast email and APHL's website later this fall 2014 once approved by the membership. The cost analysis worksheets were sent out to members via blast email and e-Update and placed on APHL's Member Resource Center (MRC).
- The work group held seven conference calls during the reporting period.

Activity 2: Write reports/summaries/success stories on existing partnerships and share these as model practices through various venues. Multiple successful practices from differing state/regional models will be sought.

- The staff lead identified one additional success story through the interviews conducted on courier systems. This success was written up and sent out to members via e-Update and a blast email along with the courier analysis worksheets and also placed on APHL's MRC.
- Obtaining and characterizing foodborne disease isolates in a thorough and timely manner contributes to faster outbreak detection and response, ultimately reducing the burden of foodborne illness in the U.S. population. The data from such testing can be used by our federal partners for programmatic planning and policy development.

Year 2 metrics:

Each reporting period:

Provide a count of work group conference calls convened, summaries of conference call discussions, and a description of in-person meeting outcomes, as appropriate.

Status: Met, as described above

Barriers: No funding is provided for this activity. The work group will continue to identify and disseminate pre-existing tools and resources throughout the reporting period, at no cost.

Provide a count of the tools and resources collected or developed, provide a brief description of each, and dissemination efforts.

Status: Met, as described above

Barriers: No funding is provided for this activity. The work group will continue to identify and disseminate pre-existing tools and resources throughout the reporting period, at no cost.

Within 10 months: Provide a report that describes any new pilot projects that could be launched in year 3. Pilot project descriptions will include the problem being addressed, the approach to the solution, data that suggest the pilots will be successful, criteria for inclusion in the pilot study, and expected outcomes/deliverables for each selected site.

Status: Not done.

Barriers: No funding provided for this activity. The work group will continue to brainstorm suitable non-cost activities throughout the reporting period.

Within the Year:

Post summaries of existing successful partnerships as model practices in appropriate venues such as the APHL MRC. Market the availability of these successes through social media, listservs, and traditional communication outlets.

Status: Met

Barriers: No funding is provided for this activity.

Publish at least one Lab Matters article highlighting some tools and resources that are available to members.

Status: Met, as described above.

Barriers: No funding provided for this activity.

Throughout the Reporting Period: Provide reports on progress towards strengthening partnerships with clinical laboratories and their representative organizations. Report will include contacts made, discussions held, collaborations initiated, and/or joint communication strategies.

Status: Not done.

Barriers: No funding provided for this activity. The work group has been combined with a CDC-funded work group and will seek feedback from relevant stakeholders on the position statement and cost analysis worksheets in 2014.