Accreditation Insider

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The FDA's ISO Accreditation Effort

Dr. Ruiqing Pamboukian

The Food Safety Modernization Act (FSMA) gives FDA important new tools to better ensure the safety of foods while directing it to build an Integrated Food Safety System (IFSS) in partnership with State and local authorities. The Partnership for Food Protection (PFP) initiated by the FDA in 2008 is the vehicle to fully implement the Integrated Food Safety System through mutual reliance. In the effort to establish national laboratory standards and implement a fully IFSS, laboratory accreditation has been identified as a critical element by PFP for ensuring the integrity and accountability of laboratory analytical testing. In addition, Section 202 of FSMA requires that laboratories accredited by FDA-recognized accreditation bodies be used to test food under certain specified circumstances.

In 2012, FDA entered into five-year cooperative agreements with 31 state food-testing laboratories to either attain ISO/IEC 17025:2005 accreditation (23) or expand/maintain existing ISO accreditation (8). In 2015, an additional 26 food/feed testing laboratories were awarded funding to obtain ISO/IEC 17025 accreditation. FDA also awarded a five-year cooperative agreement to the Association of Public Health Laboratories (APHL) in collaboration with the Association of Food and Drug Officials (AFDO) and the Association of American Feed Control Officials (AAFCO) to support laboratory accreditation. One of the major goals of this association cooperative agreement is to facilitate long-term improvements to the national food and animal feed safety system by strengthening collaboration and supporting laboratories seeking accreditation to the ISO 17025 standard.

Collaborative efforts between FDA and above mentioned three associations have been made to promote and enhance laboratory accreditation for the Nation's food and feed testing laboratories since 2012. In addition to providing funding to support laboratory accreditation, a structured laboratory accreditation support program has been established within the FDA's Office of Regulatory Affairs/Office of Regulatory Science to provide guidance and technical assistance to state laboratories seeking ISO/IEC 17025 accreditation or to enhance the scope of already accredited laboratories. The major activities of this program include:

1. conducting on-site assessments to assist the labs to identify gaps and set priorities;
2. institute a mentor-mentee program in which an accredited lab serve a mentor for non-accredited mentee;
3. conduct one-to-one calls to provide technical assistance as needed (e.g. provide resource such as FDA testing method and ISO related, etc.);
4. review mid-year and end of year report and provide evaluation and recommendation based on the performance;
5. collaborate and provide oversight on the associations effort for promoting accreditation.

(FDA Continued on PG 6)

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PJLA will be Offering CGMP Assessments in Addition to 17025 Assessments Early 2017

Based on a high volume of requests, PJLA is in process of developing a CGMP assessment program that incorporates the requirements of 21 CFR Part 210 and 211 for food, pharmaceutical, dietary supplement and cosmetic testing laboratories. This assessment will have some overlap of areas already assessed within 17025 assessments including:

a. Quality System
b. Facilities and Equipment
c. Material system
d. Production system
e. Packaging system
f. Laboratory system

This should be completed by early first quarter 2017. Laboratories seeking this additional assessment should contact PJLA prior to their next assessment to ensure qualified staff and sufficient assessment time is allocated. Interested candidates are reminded that PJLA's assessment to these requirements will only prepare laboratories for potential CGMP audits required by FDA inspections and will not prevent audits required by the FDA or end users. Please continue to check PJLA's website for the release of this new program. ◆

PJLA Food Testing Assessor Thoughts...

Leeza Akimenko, PJLA Lead Assessor

What I've noticed with food testing labs is that not many have applied the AOAC guidelines or particularly understand the guidance well. The biggest struggle is probably with 5.9 - Ensuring the Quality of Test Results. This is the area that I've spent the most time on during assessment of food testing labs. I don't just cite deficiencies in this area and leave the lab in the dark, I try my best (if time permits) to provide explanation or clarification so that they walk away seeing the value in a requirement, want to embrace change and make improvements. Once they have an "aha!" moment then I can reap the rewards of seeing their successful implementation of the corrective actions. Plus, helping them understand a requirement or clarify a guidance while I'm siting a deficiency fosters a positive relationship between the assessor and the lab. Food testing labs are special to me because they play an important role in the industry at keeping the food safe or to alert when it's not safe, so naturally I care that they are best at what they do and use the standard to elevate themselves to that level. ◆

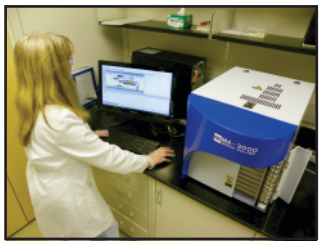
LEEZA AKIMENKO
PJLA LEAD ASSESSOR

Client Spotlight: The National Seafood Inspection Laboratory (NSIL)

The National Seafood Inspection Laboratory (NSIL) achieved ISO/IEC 17025 accreditation with PJLA. They are located in Pascagoula, Mississippi, and are under the Department of Commerce (USDC) and National Oceanographic & Atmospheric Administration (NOAA) as part of the National Marine Fisheries Service (NMFS) Office of Sustainable Fisheries, and provides analytical testing of seafood samples for the NMFS and other agency programs.

NSIL serves as the primary analytical laboratory for the NMFS Seafood Inspection Program (SIP). The USDC inspection and certification of fish and fisheries products includes safety/quality criteria that are a critical part of the SIP. NSIL supports the Seafood Inspection Program's fee-based, third-party inspection programs for seafood processors by providing analytical laboratory testing of seafood samples for bacterial pathogens, chemical contaminants, and other health hazards. NSIL also provides NMFS and the Seafood Inspection Program with environmental testing of seafood samples to support international seafood safety and trade barrier issues, in addition to general food safety and seafood Hazard Analysis Critical Control Point expertise.

In coordination with SIP of the NOAA Fisheries By-Products Export Program, NSIL provides analytical testing of fishmeal, oil, and by-product samples to validate U.S fishmeal processors and certify export of fisheries by-products to countries requiring attestation and certification by a U.S. government veterinarian. These export certificates are critically important to U.S. industry and represent over 40,000 tons of fisheries by-products exported to over 20 countries.



After many months of focused effort to develop and implement an analytical laboratory management program that meets strict international standards, NSIL reached its day(s) of reckoning in mid-August. A Perry Johnson Laboratory Accreditation auditor from Alaska (did we mention mid-August in Pascagoula, MS?!) performed a three-day assessment for the accreditation of the NSIL ISO 17025 Laboratory Management Program.

The auditor reviewed the many documents developed and revised to standardize methods and protocols, formalize analytical staff training and verification, and correct non-conformances and control laboratory operations. NSIL analysts were also assessed as they conducted analytical methods to determine seafood hazards and contaminants in seafood samples. The NSIL staff's cautious expectations were confirmed as only 4 minor deficiencies were identified in the certification assessment.

After correction and documentation of these deficiencies, PJLA awarded certification of the NSIL ISO 17025 Laboratory Management Program. NSIL considers this certification to be a serious achievement, which assures our internal agency clientele, such as the Seafood Inspection Program and Office of Law Enforcement, and their international counterparts (i.e. China, the EU, etc.) that the analytical results that NSIL provides meet international standards of process and control, as well as accuracy.

The NSIL ISO team was led by program manager Kenneth Powell, and included the entire analytical staff of lead analyst Angela Ruple, chemists Cheryl Lassitter and Lisa Price, and microbiologists Stephen Bell, Shannara Lynn, and Johnathan Likens. Administrative assistants LaShonda Finch and Diane Pierce were also key contributors to the program's development. ◆

Food Testing Top 5 NCR Summary

PJLA encourages laboratories to use this data to prepare for assessments and make the necessary improvements to decrease the number of findings on your assessment. This data includes all types of assessments performed across the globe. Below are some examples of the top 5 common nonconformities detected during Food Testing Laboratory Assessments:

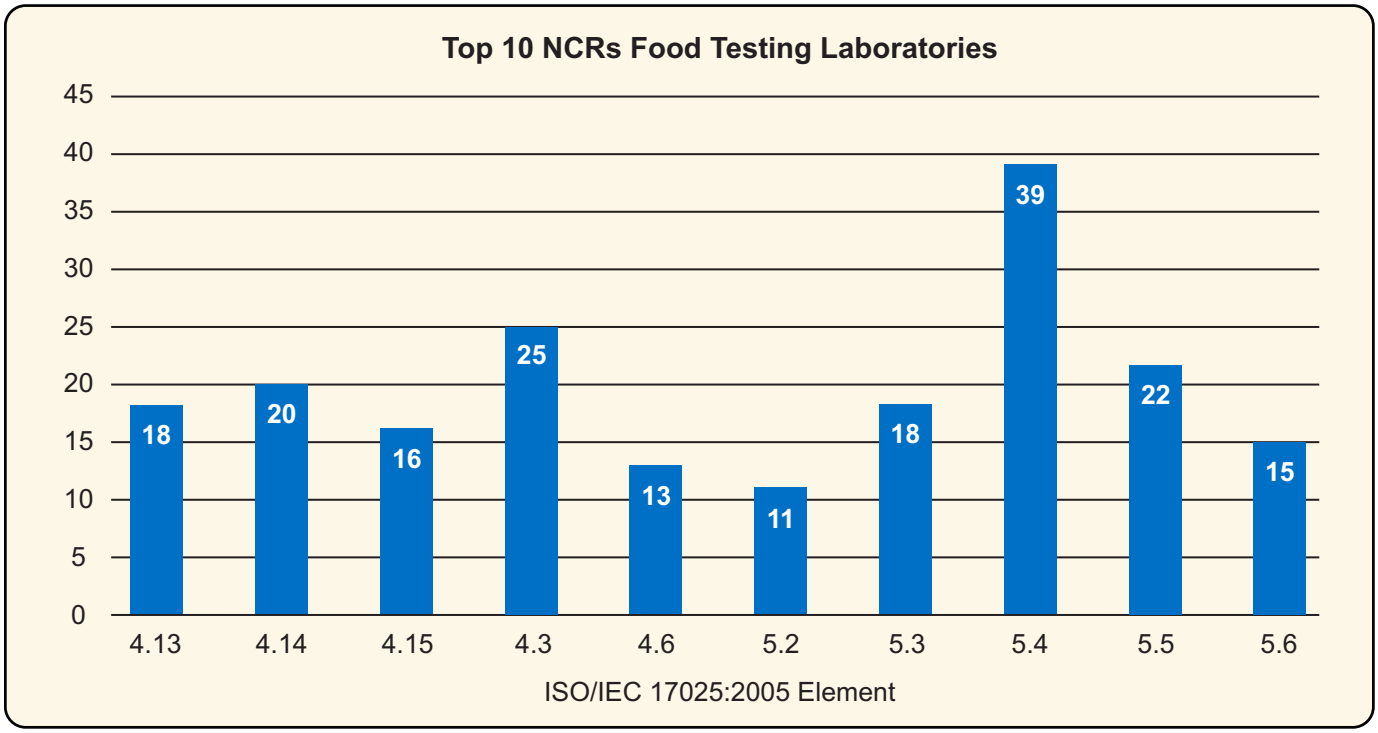
- 5.4 - No process or procedure for validating internal methods; Unable to apply a procedure for determining measurement uncertainty; Calibration Labs and Testing Labs performing their own calibrations must be able to do this; Failure to have uncertainty budget, or inadequate uncertainty budgets.

- 4.3 - No Master list or equivalent; external documents not addressed; Document changes in computerized systems not addressed; Documents are not uniquely identified as specified in 4.3.2.3 (the date of issue and/or revision identification, page numbering, the total number of pages or a mark to signify the end of the document, and the issuing authority; Revision status on document not matching master list.

- 5.5 - Records on equipment not maintained; Equipment not calibrated or checked appropriately prior to be put into service; Equipment not capable of achieving required accuracy (example: resolution or readability);No procedure in place for safe handling, transport, storage, use and planned maintenance (off site work).

- 4.14 - Internal Audits Lack of documentation and/or not covering the entire quality management system; Audits not including testing or calibration activities; Audits carried out by untrained or unqualified individuals; Auditor is not independent of the activity being audited; No corrective action on audit findings (timely).

- 5.3 - Lack of appropriately monitoring and/or recording environmental conditions. ◆



PJLA Attends the 2016 Annual AOAC Meeting and Exhibits - Dallas, Texas

Larry Lagman
PJLA Food Testing
Program Manager

PJLA attended our third AOAC meeting this year in Dallas, Texas on September 18-21, 2016. This was attended by, Tracy Szerszen, PJLA President, Larry Lagman, Food Testing Program Manager and Brett McMillen, National Sales Manager. *"This was a great opportunity for our company to network with industry experts and colleagues. We take advantage of attending several training sessions related to the chemistry and microbiological areas and provide input in support of our industry. Information learned at these meetings is passed on to our technical assessment staff and to our clients, states Tracy Szerszen, President.*

As part of our support to AOAC, we took the opportunity to exhibit allowing us to promote our organization's accreditation services, in addition to sponsoring a free training event on Method Validation. This training event was partnered with PathogenDx that presented on a new rapid microbiological pathogen detection technology for the food, dietary supplement and cannabis industry. This hosted event was very successful and educational for all attendees. PJLA would like to extend a special thank you to Larry Lagman, PJLA Food Testing Program Manager and Mike Hogan, Pathogen Dx for their invaluable presentations and efforts. ◆

Pictured Left to Right:
Larry Lagman - PJLA Food Testing Program Manager, Sumit Sen - FDA Irvine, CA, Ron Johnson - President AOAC, Tracy Szersen - President PJLA, Jon Bell - National Seafood DOC National Seafood Inspection Laboratory (NOAA)

(FDA Continued from pg 1)

Additional efforts by the association have included but not limited to:

1. develop and coordinate training programs on accreditation related topics;
2. host a web-based repository of resources organized according to the ISO standard, including examples of best practices, standard operating procedures, worksheets, records and work plans;
3. manage a Food and Feed Laboratory Accreditation Discussion Board, an online forum for exchange of ideas on how best to achieve accreditation;
4. provide direct technical assistance to 10 state laboratories seeking accreditation without the benefit of FDA ISO program funding; and
5. host the national Governmental Food and Feed Laboratories Accreditation Meeting.

As a result of this collaborative effort the number of accredited laboratories has been increased and testing capabilities and capacities for food and feed have been enhanced nationwide. As of October 2016, 21 FDA-funded laboratories have either achieved or expanded their scope of ISO 17025 accreditation. Active monitoring of cooperative agreement deliverables shows that the original FDA-funded food laboratories are on track to achieve or expand their accreditation by August 2017. FDA will actively monitor the remaining food and feed laboratories through their grant periods ending in 2020.

Use of the accredited laboratories will generate more quality and reliable data that will enable FDA to more efficiently allocate its resources to protect public from potentially harmful chemical and microbiological substances in food and feed. ◆

Dr. Ruiqing Pamboukian
U.S. Food and Drug Administration

Dr. Pamboukian is a Food Safety Regulatory Scientist and Program Lead at the US Food and Drug Administration, Office of Regulatory Affair, Office of Regulatory Science. Her leaderships include developing and leading the FDA laboratory accreditation program to promote laboratory accreditation for state regulatory food/feed testing laboratories, and leading the Food Emergency Response Network (FERN) Microbiology Cooperative Program (MCAP) to enhance the analytical capability of national food/feed testing laboratories.

Outside the FDA work, she served as a board member for the Chinese Association of Food Protection in North America which is one of the affiliate of International Association of Food Protection (IAFP) for four years and she was the president in the past year. Her work include facilitate dialogue between IAFP and China's food safety organizations and bridge communications between food safety professionals in North America and in China.

Dr. Pamboukian serves our nation as a US Public Health Service Commissioned Corps officer. She played several leadership roles in multiple committees within the corps.

In 2010 she joined FDA and prior to her work in FDA, she was a research scientist at NIH and she received her PhD degree in Biochemistry and Molecular Biology from University of Maryland in 2006.

Program Updates

DoD ELAP

As of January 4, 2017 the new version of the DoD QSM Version 5.1 will be available for assessments. The major changes are primarily in the tables including:

- Table B-15. PFAS Using Liquid Chromatography Tandem Mass Spectrometry (LC/MS/MS) and Isotope Dilution and Internal Standard Quantification
- Table B-20. Radon Scintillation (Ra-226 by Lucas Cell)
- Table B-21. GC/MS Analysis of Air Samples
- Table B-22. Organic Semi-Volatile Analysis by GC/MS in SIM Mode
- Table B-23. Incremental Sampling Methodology (ISM) Soil Preparation for Large Volume (1 kg or greater) Samples
- Table B-24. PFOA and PFOS Determination in AFFF Formulations Using Liquid Chromatography Tandem Mass Spectrometry (LC/MS/MS) and Isotope Dilution

PJLA will start to assess to these new requirements in January 2017 upon training of our assessors. The changes between 5.0 and 5.1 are not significant and laboratories should have limited obstacles meeting the new requirements.

Upcoming Tradeshows

PJLA will be exhibiting at the following:

2017 AAFCO/AFRP
January 16-19, 2017
Mobile, Alabama

2017 Emerald Conference (Cannabis)
February 2-3, 2017
San Diego, California

The Federal Communication Commission (FCC) Office of Engineering and Technology Laboratory Division Accreditation Body Recognition Program

PJLA has completed our application for the FCC OET Laboratory Accreditation Program and is awaiting final approval. Upon approval, PJLA will be a recognized accreditation body to assess laboratories testing RF equipment employing new technologies for which the testing methodologies are relatively complex or not well defined, or that otherwise are considered to have the highest potential for causing interference. Examples of devices subject to certification include, but are not limited to: mobile phones, wireless local area networking equipment, land mobile radio transmitters, wireless medical telemetry transmitters, and cordless telephones. The FCC requires that all testing laboratories obtain ISO/IEC 17025:2005 accreditation in order to be listed as an approved FCC laboratory. ◆

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