

## Message from the NVLAP Chief

Welcome to the June edition of the NVLAP News. Here in Gaithersburg, Maryland, the dog days of summer are fast approaching and so are deadlines associated with our transition to the revised ISO/IEC 17025:2017. You may recall from our January newsletter that NVLAP has established a [plan](#) for the implementation of ISO/IEC 17025:2017 in our accreditation programs. In accordance with the plan, we have reached the April 15 deadline which establishes that NVLAP will no longer accept applications to ISO/IEC 17025:2005 which require an onsite assessment. NVLAP has been working over the past few months to update our assessment documentation and train our technical assessors to support assessments to the revised standard to support this deadline. I am happy to report that our first assessments to the revised standard occurred in May.

With this issue, NVLAP is launching another new feature within the newsletter. We hope to periodically include articles from our programs and their technical

experts. Our guest contributor in this edition is Dr. Mark Hagadone. Mark is a technical expert in our Asbestos accreditation program and has been actively involved in laboratory management and specialized bulk asbestiform minerals for 38+ years. As a technical assessor for NVLAP since the inception of the NVLAP Asbestos accreditation program, Mark's article provides insight into the assessment from the assessor's perspective.

As I mentioned in the January issue, my intent with this newsletter is to engage with our community of laboratories, experts and interested parties. If you have ideas for articles that you would like to see or other feedback for me, contact me directly at [dana.leaman@nist.gov](mailto:dana.leaman@nist.gov) or through our main email account [nvlap@nist.gov](mailto:nvlap@nist.gov). I look forward to hearing from you.

My last thought was to wrap up with well wishes for a great summer, but since we have readers from around the world I will leave you with well wishes for the season you are in. Enjoy!

## IN THIS ISSUE

Message from the NVLAP Chief

NVLAP Policy Guide on Nonconformities and Nonconformity Responses in the Lab Portal

NVLAP Attends the FDA Meeting on the ASCA Pilot Program

NVLAP Presents at the 2018 Measurement Science Conference and Training Symposium

NVLAP Attends the ILAC Mid-year Meetings

NVLAP Attends the APLAC General Assembly Meetings

NVLAP Celebrates World Accreditation Day

Assessment Through the Eyes of One Assessor

NIST News

Upcoming Events

## NVLAP Policy Guide on Nonconformities and Nonconformity Responses in the Lab Portal

In early March, NVLAP alerted our accredited laboratories and applicants regarding an improvement in the assessment process. The NVLAP interactive portal functionality was upgraded to allow for electronic submission of nonconformities by the assessor and electronic response to each nonconformity by the lab. The [policy guide](#) revises the process outlined in the NIST Handbook 150-2016.

The NVLAP on-site assessment report was also updated under the instructions for the laboratory to clarify submission through the NVLAP lab portal. Training videos on these updated submission processes are available to our accredited laboratories and applicants in the *Documents Library* on the laboratory's dashboard in the NVLAP lab portal.

If there are any questions regarding this process change, laboratories are encouraged to contact their program manager.

## NVLAP Attends the FDA Meeting on the ASCA Pilot Program

On May 22-23, NVLAP attended the Food and Drug Administration (FDA) public workshop on "Accreditation Scheme for Conformity Assessment (ASCA) of Medical Devices to FDA-recognized Standards". The workshop outlined a draft design of the ASCA pilot program, including the scope and goals of the program as well as the framework for its procedures and requirements. Participants in the workshop included industry, accreditation bodies and testing laboratories.

Plenary sessions were conducted on the ASCA pilot program, ISO/IEC 17025:2017 and NIST Conformity Assessment Guidance, and ASCA Pilot Performance Metrics. Breakout Sessions were also held on the topics of biocompatibility and 60601 basic safety and essential performance.

Moving forward, NVLAP is currently evaluating how these requirement needs might be added under the NVLAP Electromagnetic Compatibility & Telecommunications (ECT) Laboratory Accreditation Program (LAP). Further details will be made available as this continues to develop.

## NVLAP presents at the 2018 Measurement Science Conference and Training Symposium

The Measurement Science Conference (MSC) and Training Symposium was held March 20-23, 2018 at the Disneyland Hotel in Anaheim, California. NVLAP was represented at the meetings by Dana Leaman and Titi Shodiya.

This year's theme was Innovation Powering Measurement. NIST conducted a number of seminars including two one-day seminars from NVLAP on the changes to ISO/IEC 17025.

About 15 students attended the NVLAP seminars to discuss the impacts and changes in the 17025 standard which was published in late November 2017.

Dana Leaman also represented NVLAP at the conference on a ISO/IEC 17025:2017 panel discussion. She presented on the operational impacts of the revised standard from the perspective of an accreditation body.

The 2019 conference and symposium is scheduled for April 16-19 at the Disneyland Hotel in Anaheim, California. We hope to see you there!



## NVLAP Attends the ILAC Mid-year Meetings

The International Laboratory Accreditation Cooperation (ILAC) held its 2018 mid-year meetings in Frankfurt, Germany from 4 to 10 April. Barbara Belzer, Brad Moore and Dana Leaman attended the meetings of the Accreditation Issues Committee (AIC), the Arrangement Committee (ARC) and the Executive Committee. Mechanisms were discussed to harmonize the application of the revised 17025 standards. It was determined that a frequently asked questions (FAQ) tool to share information would be established. There were also task groups established to look at revisions to ILAC P9, *ILAC Policy for participation in proficiency testing activities*; ILAC P10, *ILAC Policy on traceability of measurement results*; and P14, *ILAC Policy for uncertainty in calibration*.

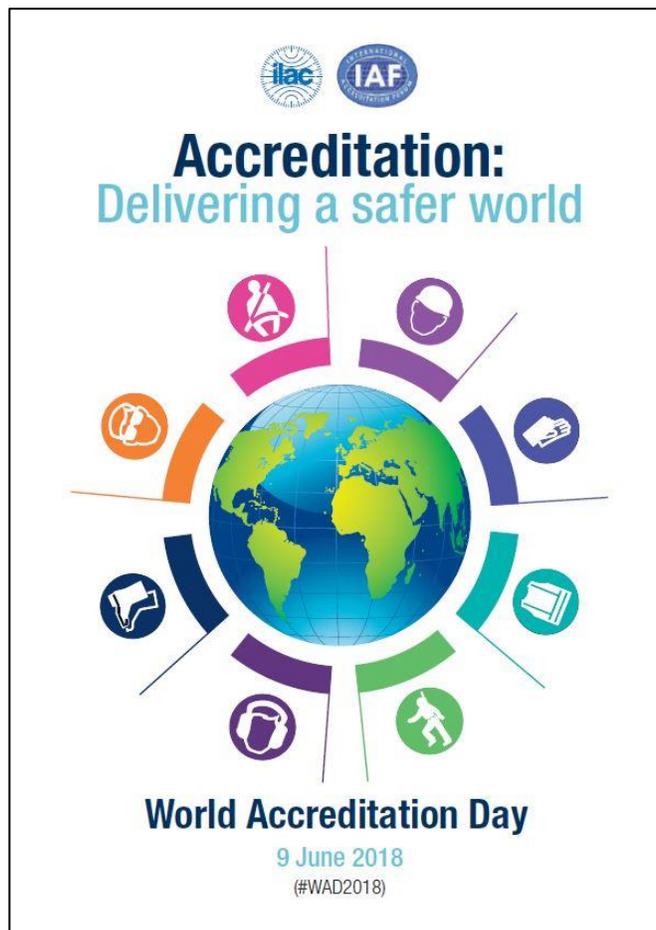
The next ILAC meetings are planned for October 2018 in Singapore.

## NVLAP Attends the APLAC General Assembly Meetings

The Asia Pacific Laboratory Accreditation Cooperation (APLAC) held joint General Assembly meetings with the Pacific Accreditation Cooperation (PAC) during June 4-8, 2018 in Kyoto, Japan. Brad Moore and Dana Leaman attended the meetings of the Proficiency testing committee, Technical committee, MRA Council, the joint General Assembly of APLAC and PAC, and

the APLAC General Assembly. During the meetings, the membership of APLAC and PAC voted to merge the two organizations into one, APAC, the Asia Pacific Accreditation Cooperation. The newly formed APAC will begin operation effective January 1, 2019.

The 1<sup>st</sup> meeting of APAC is scheduled for June 2019 in Singapore.



## NVLAP Celebrates World Accreditation Day

World Accreditation Day is celebrated each year on June 9<sup>th</sup>. NVLAP held its celebration on June 11<sup>th</sup> by hosting a table in the NIST cafeteria to promote recognition of accreditation among our NIST colleagues. This year's theme was *Delivering a Safer World*. The International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF) developed a brochure on the issues faced in the world today, the role accreditation plays, and case studies demonstrating the benefits of accreditation. Information on the full brochure is available from the ILAC website, [www.ilac.org](http://www.ilac.org).

## Assessment Through the Eyes of One Assessor

By Mark R. Hagadone, Ph.D., FACFE

Many of you reading this newsletter can identify with the following:

You receive official notice from NIST/NVLAP that your facility is scheduled for an upcoming on-site assessment by a NVLAP assessor. An assessor which you may or may not recognize is identified, and will be contacting you shortly to schedule mutually acceptable times in which to conduct the on-site visit/assessment.

A number of things run through your mind. Do I have everything in order for the review and assessment? Will critical staff members be present? Will the assessment take place at the same location, or am I about to expand or move facilities?

A common question of concern is: What should you do to prepare for the assessment, to minimize the impact on your Business Operations while maximizing the efficiency and accuracy of the assessing (assessment) process?

This brief article attempts to address this issue by garnering the personal experience of an On-Site assessor which has been conducting assessments for NIST/NVLAP since the conception of the Asbestos program back in 1987. This is a personal reflection of the process and may or may not represent the official position of NIST/NVLAP.

The first thing I would like to remind our customers, the laboratory owners, directors and quality control coordinators, is the fact that your quality management system is exactly that: **it's yours and you own it.**

I say this because there is a common misconception out there that you should create a quality management system for the **assessor's use and assessment** rather than for your own facility's needs and uses.

The Quality Management System you construct should be designed, carefully considering NIST/NVLAP requirements and ISO/IEC 17025 specifications, to track, facilitate and document **your** unique facility's quality assurance activities. It should be a vital and useful tool to the facility for this specific purpose as an important quality control apparatus. It was never intended to be solely useful to the assessor purely for the purpose of completing a checklist. Each Laboratory Facility is site specific, and the application of the ISO/IEC specifications to that facility will reflect its own unique character in its quality assurance program.

With this in mind, there are typically a limited number of problem areas which, as experienced assessors, we tend to see over and over again throughout our auditing cycles. I have listed these "usual suspects" for your reflection and consideration in the hope that it will provide some guidance during that next auditing cycle. I hope you find these observations useful.

- Do provide the Assessor with your current version of your written quality system manual for review prior to the site visit.
- Remember that the assessors have reviewed the prior assessment. Make sure you have adequately addressed any past nonconformities.
- Make sure you have your management reviews and your annual assessments available for ready review (past two years). Make sure they address all sections outlined in the NIST Handbook 150.
- Make certain your analysts and technical supervisors participate in some form of continuing education, and that the participation is documented in your records.
- If you use the optional method of dispersion staining, make sure your analysts can explain the theory behind the application of this technique for the determination of refractive index.
- Make sure your Master Document List is updated.



- Review your web pages, advertisements and your report templates to assure you are using the NVLAP term and symbol properly and that you have received the new symbol from NVLAP as found in NIST Handbook 150:2016.
- Remember that ancillary equipment present must be maintained and calibrated e.g., muffle furnaces and balances.
- Make sure you are using updated NIST/NVLAP Handbooks, remember that NIST Handbook 150 has been updated and should replace past versions listed in your Master Document List.
- Remember that your PLM microscopes must have properly aligned crosshairs in oculars with are fixed or marked in position.
- Remember your quality system must be able to clearly and convincingly demonstrate a monthly 10 % quality control replicate analysis stream, a <1 % error rate, and an inter and intra laboratory quality control program which graphically portrays your statistical performance.
- Make sure you have your monthly quality control activity summaries available for review and that they include all analytical components requested.
- Make sure you review your NIST Handbook 150-3 checklist and be certain you have all required documents (and updated versions) listed in the beginning of the checklist, readily, physically available for review.
- Make certain that your yearly audits are “sensitive” enough to detect persistent nonconformities which flow through several audit cycles. Ideally your internal audits are performed by personnel experienced in auditing without critical vested interested in the outcome.
- Point counting “shall” be used for bulk asbestos quantitation, unless you have an equivalent technique e.g., Calibrated Visual Estimation (CVE), which you have demonstrated and documented to be equivalent for quantitative analysis.
- Remember to “measure” and document (record) in writing (not simply observe and by default populate) data of primary optical concern such as dispersion staining colors, temperatures at the time of analysis, or refractive index determinations. The objective is to be able to recreate primary optical measurements (such as refractive index) from the recorded raw data if requested in the future.

These pointers are just a brief review of issues which commonly arise in our on-site assessments, but they account for the majority of nonconformities assessed.

Remember that the on-site assessments are an important part of the NIST/NVLAP program. Together with a consistent, validated analytical method, the annual performance testing program and the ISO/IEC 17025 specifications, these components comprise the body of the NIST/NVLAP Bulk Asbestos Accreditation Program.

As laboratory directors, quality assurance coordinators and owners, your continued successful participation in the NIST/NVLAP Bulk Asbestos Program is vital for the health and sustainability of the entire industry.

As assessors, we applaud your continued efforts to maintain the quality, accuracy and precision NVLAP Accreditation strives to assure and which the Industry relies upon for its continued growth and improvement.

Mark Hagadone  
 NIST/NVLAP ON-SITE ASSESSOR  
 Hagadone@techexpts.com

## NIST News

In February 2018, NIST Director, Walt Copan, released a blog post and YouTube video on "[The Romance of Precision Measurement](#)." He highlighted the NIST mission, "to ensure that U.S. industry and science has the most advanced measurement system possible so that our industries and manufacturers can make the highest-quality, most advanced products in the world." The video on the NIST YouTube Channel captures some of the NIST history and the importance of measurement science through the eyes of six former NIST directors.

An innovative measurement technique for measuring laser power is under development by NIST researchers. Their device, Radiation Pressure Power Meter (RPPM), makes measurements using the force exerted by the laser light itself. There is currently an open request to industry and other government agencies who would like to have their high power lasers calibrated with the new RPPM. More information can be found in [a recent article on the NIST webpage](#).

### Did you know...

There are several mechanisms for getting information about the exciting work going at NIST. Check out the News & Events tab on the NIST home page at [www.NIST.gov](http://www.NIST.gov) for more information or sign up for the NIST's newsletter, Tech Beat, for news and upcoming events.



NVLAP Staff (credit: Vil Cheng)

## Upcoming Events

### NVLAP at 2018 ASTM Week

Tom Hettenhouser and Beth Hackett will be attending committee meetings for Co1, Co9, Do4, D13, D18 and E36 being held during ASTM Week June 24-29 in San Diego, California.

### NVLAP at 2018 IEEE EMC Symposium

Brad Moore and Tim Rasinski will be attending the 2018 IEEE EMC Symposium July 30 – August 3 in Long Beach, California. If you are attending, stop in and see us at Booth #741.

### NVLAP at IAAC General Assembly Meetings

Barbara Belzer will be attending the IAAC GA meetings August 25-31 in Montego Bay, Jamaica.

### NVLAP at 2018 NCSLI Workshop and Symposium

Dana Leaman, Kari Harper and Titi Shodiya will be attending the 2018 NCSLI Workshop and Symposium August 27-30 in Portland, Oregon. If you are attending, stop in and see us at Booth #304.

### NVLAP at ILAC General Assembly Meetings

Barbara Belzer, Beth Hackett, Brad Moore, and Dana Leaman will be attending the 2018 ILAC GA meetings October 22-31 in Singapore.

NVLAP News is published by the National Voluntary Laboratory Accreditation Program, Standards Coordination Office, Laboratory Programs, National Institute of Standards and Technology, U.S. Department of Commerce. Please send comments to Cheryl Williams Levey, Editor, at [cheryl.levey@nist.gov](mailto:cheryl.levey@nist.gov) or [nvlap@nist.gov](mailto:nvlap@nist.gov). Visit the NVLAP web page at <https://www.nist.gov/nvlap>