

The Institute Review

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Third Quarter 2010

2011 Forum on Laboratory Accreditation

By Jerry Parr, TNI

Registration is now open for the 2011 Forum on Laboratory Accreditation to be held at the Hyatt Regency Savannah from January 31 — February 3, 2011. The January 2011 Forum will focus on implementation of the new TNI laboratory Standards that will replace the 2003 NELAC Standard on July 1, 2011. A major emphasis of the meeting will be on TNI's new National Environmental Field Activities Program.

The Forum will feature open public meetings of all TNI committees to allow quality professionals, chemists, analysts, microbiologists, engineers, and managers from federal and state agencies; commercial, municipal, state and federal laboratories; and many others who are actively involved and interested in laboratory accreditation issues to review what has been done and participate in the efforts to establish a national program for environmental laboratories. The 2011 Forum will include:

- ✦ Meetings of all TNI committees;
- ✦ A special session on EPA Efforts for Flexible Approaches to Environmental Monitoring;
- ✦ The first public meeting of the newly formed Environmental Measurement Methods Expert Committee;
- ✦ Meetings of three task groups focused on audit consistency, cryptosporidium analyses, and support for Accreditation Bodies;
- ✦ A meeting of EPA's Environmental Laboratory Advisory Board (ELAB);
- ✦ A general session with updates about TNI programs;
- ✦ A meeting of EPA's Water Laboratory Alliance;
- ✦ A training course on establishing a Quality Manual; and
- ✦ A workshop on the new TNI Standards.

For more information, go to the 2011 conference website at: <http://www.nelac-institute.org/meetings.php>.

2011 Forum on Laboratory Accreditation Preliminary Schedule

Monday, January 31

8:30am — 12pm Open Plenary

- 2011 — 2016 TNI Strategic Plan
- New TNI Quality Management Plan
- Consensus Standards Development Program Annual Report
- National Environmental Field Activities Program (NEFAP) Annual Report
- National Environmental Laboratory Accreditation Program (NELAP) Annual Report
- Proficiency Testing (PT) Program Annual Report

1:30pm — 5:00pm Concurrent Sessions

- EPA's Environmental Laboratory Advisory Board
- Laboratory Accreditation Body Committee (1:30 – 3:00)
- Laboratory On-Site Assessment Expert Committee (3:30 – 5:00)
- Policy Committee

5:30pm — 7:00pm Reception

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2011 Forum on Laboratory Accreditation Preliminary Schedule (cont.)

Tuesday, February 1

8:30am — 12:00pm Concurrent Sessions

- Laboratory Proficiency Testing (PT) Expert Committee
- Mentor Session
- Flexible Approaches to Environmental Measurement (8:30 – 10:00)
- TNI's Educational Delivery System (10:30 – 12:00)
- Information Technology Committee

12:00pm — 1:30pm Lunch Provided

12:00pm — 1:30pm Technical Assistance Committee: Working Lunch

1:30pm — 5:00pm Concurrent Sessions

- PT Executive Committee
- Laboratory Quality Systems Expert Committee
- Accreditation Body Task Force

8:30pm — 10:00pm Murder Mystery Boat Cruise

Wednesday, February 2

8:30am — 12:00pm Concurrent Sessions

- Cryptosporidium Working Group
- Stationary Source Audit Sample Committee
- Consistency Improvement Task Force
- NEFAP Executive Committee

12:00pm — 1:30pm Lunch Provided

12:00pm — 1:30pm Laboratory Accreditation System Executive Committee: Working Lunch

1:30pm — 3:00pm Concurrent Sessions

- NELAP Accreditation Council
- Field Activities Committee
- Advocacy Committee

3:30pm — 5:00pm Training Course: New Quality Manual Template

3:30pm — 5:30pm TNI Board and Chairs

Thursday, February 3

8:30am — 12:00pm EPA's Water Laboratory Alliance

8:30am — 3:00pm Workshop: The New TNI Laboratory Accreditation Standards

8:30am — 5:00pm Environmental Measurement Methods Expert Committee



Minnesota Becomes 15th NELAP-Recognized Accreditation Body

On August 2, 2010, the Minnesota Department of Health was recognized by TNI as an Accreditation Body for the National Environmental Laboratory Accreditation Program (NELAP).

The Minnesota program offers accreditations designed to accommodate the needs of many state and federal environmental programs including testing required by the Underground Storage Tank Program, Clean Water Act, Resource Conservation and Recovery Act, and the Safe Drinking Water Act. For more information about the Minnesota program, go to: <http://www.health.state.mn.us/divs/phl/accreditation/index.html>



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TNI Awarded \$1.25M in Federal Assistance Over 5 Years

By Ken Jackson, TNI

This fall, TNI received two major 5-year cooperative agreement awards from EPA. The provisions of these awards will allow TNI to continue as a leader in the development of consensus environmental accreditation standards; the accreditation of environmental laboratories, sampling, and field measurement organizations; and as a trainer and facilitator for the environmental testing community.

The first award (\$500,000) is to continue management of the National Environmental Monitoring Conference (NEMC), which TNI has already done for the past five years. The NEMC is combined with the TNI Forum on Laboratory Accreditation to create the annual Environmental Measurement Symposium. The Symposium has become a premiere event where TNI members can interact with other scientists and policy-makers to enhance their knowledge and stay abreast of new developments in environmental measurement, monitoring, quality assurance, and laboratory accreditation. The combined conference reduces the travel costs and time commitments for those who would have attended both meetings, and provides new opportunities for those who would have only participated in one of these events. Since combining the meetings, attendance has more than doubled, the number of technical papers has grown, and the quality of the exhibit program has significantly improved.

The Symposium will place more emphasis on emerging areas of environmental testing such as field sampling and on-site measurement using portable instruments and sensors; laboratory and field testing of air samples; and the coordinated national effort that is under way for the development of an environmental response laboratory network to meet the needs of homeland security in biological and select chemical agent testing. The Symposium will also feature: training courses to enhance the capabilities and capacities of communities performing environmental data operations (e.g., laboratories, field sampling and measurement organizations); technical presentations from leaders in government and industry discussing issues of concern to the environmental monitoring community; and an exhibition featuring new instruments, services, and supplies of interest to the environmental community.

The 2011 Symposium will be held on July 18 – 22 in Seattle, WA, where the NEMC portion will be around a special theme, *Environmental Monitoring Community Response to Environmental Disasters*. Technical sessions related to the Gulf oil spill are planned.

The second award (\$750,000) is titled “*Support to Develop Measurement Tools, Accreditation Standards, and Technical Support*”.

The first measurement tools to be developed will be for fundamental measurement practices such as Limit of Detection (LOD), Limit of Quantitation (LOQ), and instrument calibration to reduce quality system vulnerabilities. Secondly, TNI will develop a Methods Interpretation Request process, comparable to the process already used for responding to interpretation requests on the TNI Standard. The third measurement tool will be a Methods Compendium that will contain, or link to, all test methods used for environmental analyses.

It is anticipated that the next revision of the TNI Standard for environmental laboratory accreditation should be ready for implementation in about five years. Under the cooperative agreement, a Drinking Water Certification Task Force will be established to explore the harmonization of the TNI Standard and the EPA Office of Water (OW) Manual for the Certification of Drinking Water Laboratories. Many non-NELAP states accredit their drinking water laboratories to the OW requirements without adding the additional requirement of NELAP accreditation. Most aspects of the OW requirements are also embodied in the new TNI Standards, but there are a few differences requiring NELAP states to assure their accredited laboratories meet these requirements as well as the requirements of the TNI Standards. It will also be investigated whether the TNI Standard should be modified to provide more rigorous method validation protocols. This will require guidance and training; so TNI plans to form a workgroup to develop this guidance and then provide training on the application of this approach.

In regards to technical support, TNI plans to expand its training program by embarking on a much more comprehensive approach, termed the Educational Delivery Systems (EDS). This will include regional workshops, internet training (e.g., webcasts, webinars, self-paced training,



Call for Papers for the 2011 Environmental Monitoring and Data Quality Workshop

The Department of Defense (DoD) Environmental Data Quality Workgroup has announced the 8th Annual DoD Environmental Monitoring & Data Quality Workshop will be held in Arlington, VA from March 28-April 1, 2011.

Abstracts for technical presentations and posters are being solicited in the following areas:

- ◆ *DoD Emerging Contaminants;*
- ◆ *Indoor Air Vapor Intrusion;*
- ◆ *Military Munitions Response Program (MMRP);*
- ◆ *Laboratory Analysis and Performance;*
- ◆ *Data Management and Sharing;*
- ◆ *Project Planning / Implementing UFP-QAPP;*
- ◆ *Data Quality and Usability;*
- ◆ *Field Sampling and Analysis;*
- ◆ *Quality Systems Implementation; and*
- ◆ *Environmental Monitoring for Remedial Technologies.*

To submit an abstract, or for more information contact:

EMDQworkshop@geologics.com



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TNI Awarded \$1.25M in Federal Assistance Over 5 Years (cont.)

downloadable PowerPoint files), guidance documents, and TNI-approved training courses provided by other organizations. There will be increased outreach to water utility laboratories and state drinking water laboratories (i.e., "primacy" laboratories), many of which have been resistant to NELAP accreditation. This work will involve developing an acceptable approach for accreditation of these laboratories and providing training for laboratory staff on how to manage their NELAP accreditation.

Many data users (e.g., engineering consulting firms, regulated industry) are unaware of TNI's accreditation programs and the benefits of using accredited organizations. TNI plans to develop an outreach effort that will include providing presentations at conferences of these groups and meeting with individuals from organizations such as the American Petroleum Institute, the Air and Waste Management Association, and the Environmental Council of the States.

Revised Standards Update

By Silky Labie, LCAT

The Quality Systems Expert Committee has an outstanding Tentative Interim Amendment (TIA) to Volume 1, Module 6 of the 2009 TNI Standards that needs to be finalized by a vote of the TNI members. While the Standard is not scheduled to go into effect until July 2011, the committee has already received questions and Standard Interpretation Requests on the Standard. Based on the commonality of the requests, the Quality Systems Expert Committee decided to propose a limited number of revisions that would clarify, **but not change**, the Standard requirements. The revisions were presented to the TNI membership at a public meeting during the 2010 Summer Forum on Laboratory Accreditation in Washington, D.C.

The committee incorporated suggestions and requests from the summer meeting, and has voted to move the revisions forward to "Voting Draft Status", so the TNI membership may vote on the revisions. The revisions include:

1. New Definitions

- Analyte, Data Integrity, Parameter, Reference Method in Module 2;
- Physical Parameter in Module 4; and
- Source Water in Module 5.

2. Where warranted, changing words such as parameter or compound to "Analyte".

3. Changes to clarify Method Selection and Method Validation (affects Sections 5.4.4 and 5.4.5 of Volume 1, Module 2 and Sections 1.4 and 1.5 of each of the technical modules, Modules 3 through 7.

The ISO 17025 language in Module 2, Sections 5.4.4 and 5.4.5 was not incorporated in the current Standard, but the requirements of these two sections were found in each of the technical modules. The technical modules had confusing language regarding validation procedures (i.e., method validation by the laboratory) and demonstration of capability (i.e., intended to demonstrate competence of individuals) and included verbiage from an older version of ISO 17025.

To add clarity to the Standard, the committee proposes adding the original ISO 17025 language into Module 2, Sections 5.4.4 and 5.4.5 and substituting the similar requirements in Sections 1.4 and 1.5 of the technical modules with a reference to Sections 5.4.4 and 5.4.5. In addition, the committee added the definition of "reference method" (i.e., common to all the technical modules) to Volume 1, Module 2, Section 1.3 Terms and Definitions. To further make the distinction between Method Validation and Demonstration of Capability, the committee emphasizes that Method Validation is required before a method can be used by the laboratory, and Demonstration of Capability, which **may** be used to satisfy **some** of the method validations requirements, is intended only to establish individual competence.



2011 Call for Papers: National Environmental Monitoring Conference

The National Environmental Monitoring Conference (NEMC) provides the principal forum for addressing policy and technical issues affecting monitoring in all environmental media (i.e., water, air, soil, and waste) and across all environmental programs. Since 2007, NEMC has been combined with TNI's Forum on Laboratory Accreditation under the auspices of the Environmental Measurement Symposium to allow many attendees to minimize travel costs.

The 2011 Environmental Measurement Symposium will be held in Seattle, WA from July 18 – 22, 2011. The NEMC Board of Trustees is inviting abstracts for oral or poster presentations in a number of specific topic areas. For more information, visit the NEMC website at <http://www.nemc.us>.



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Revised Standards Update (cont.)

4. Changes to clarify when a Limit of Detection Study (LOD) or a Limit of Quantitation Study (LOQ) are required (Volume 1, Module 4).

- The current exclusion for an LOD (i.e., unchanged from the 2003 NELAC Standard) has had some unintended consequences, such as requests to perform an LOD study for pH or conductivity. To clarify the original intent of the Standard, the committee added a definition of "Physical Parameter" and deleted "the availability of quality control samples". In order to characterize, but not identify all the analytes or parameters that are excluded from an LOD study, the committee proposes that the LOD study is not required for physical parameters, any component for which spiking solutions are not available, or for tests that do not use a calibration curve.
- The determination of the LOQ uses similar exclusionary language. In addition, the laboratory has the option of either using a study to determine the LOQ or using the test conditions or instrument restrictions to establish the LOQ.

5. Several clarifications were made in Volume 1, Module 5.

- In Section 1.6.2.2, the clean quality system matrix was modified to mean the diluent, which must be sterile buffered water and/or sterile peptone water.
- In Section 1.7.3.1, sterility checks were clarified to require a test on all materials that are required to be sterile at least once per purchased or prepared lot.
- In Section 1.7.5, it was pointed out that the use of "source" was confusing. The committee clarified its use by adding a definition of "source water", changing "potable water sources" to "potable water supplies", and substituting the last "source" for client.

6. The TIA is found in Volume 1 Module 6, Section 1.7.1, Item c).

The background measurement was clarified to be different from a short term check of contamination. In addition, the background measurement for gas-proportional counters was changed from each day of use to weekly.

The committee feels that, with the exception of the TIA, none of the proposed revisions discussed above change the requirements of the 2009 TNI Standard, but clarify the intended interpretation. The committee feels that the revisions add clarity to further promote consistent application of the Standards. The revisions will be posted on the TNI website in December for voting by the TNI membership. The Committee stresses that only the revisions are to be considered; the unchanged portions of the Standard will not be posted. Proposal for changes to the Standard other than those that are posted will not be considered until the committee considers major revisions to the requirements.

The Next Round of Accreditation Body Evaluations

By Lynn Bradley, TNI

The 3-year cycle of Accreditation Body (AB) evaluations begins in December 2010. All ABs will be evaluated against the 2009 TNI Standard. Updates to all the process and procedure documents are nearing completion with one substantial change impacting the overall process. While prior evaluation rounds were conducted in "batches" based on the year of initial recognition, new Certificates of Recognition were issued to each AB at the conference in August with the 3-year period of recognition based on the date of the NELAP Accreditation Council's (AC) most recent renewal vote for that AB. Future evaluations will be staggered over a period of three years, allowing greater flexibility in appointing team members and juggling workloads.

Since the TNI Standard was adopted, the implementation of the new Standard prior to the July 2011 implementation date was agreed upon by the NELAP AC and many individuals have worked to revise the Evaluation Standard Operating Procedure (SOP) (i.e., SOP 3-102 Revision 3, when approved) to guide the process. Many improvements have been made since the previous TNI evaluations, by both the evaluators themselves and the NELAP Quality Assurance (QA) Officer, in addition to the Laboratory Accreditation Body Expert Committee (LAB). As of publication date, the SOP has been reviewed by the Laboratory Accreditation System Executive Committee (LAS EC) and returned to the LAB committee for consideration of a few more recommended improvements, but it is fast approaching closure.



Upcoming Meetings

FORUM ON LABORATORY ACCREDITATION

January 31—February 3, 2011
Savannah, GA

<http://www.nelac-institute.org/meetings.php>



If you know of any upcoming meetings of interest to environmental laboratory professionals, please contact Jerry Parr at jerry.parr@nelac-institute.org.



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The Next Round of Accreditation Body Evaluations cont.

Another SOP for the Provisional Recognition of ABs (i.e., SOP 3-XXX) was also developed in collaboration between the evaluators and the LAB; this was approved by LAB and sent to LAS EC in September 2010. This SOP will provide a reasonable alternative to suspension, when full recognition or revocation are not acceptable. It is also designed to have minimal effect on laboratories receiving primary or secondary accreditation from the AB, as well as minimal effect on the NELAP community of ABs, yet provide strong incentive to the designated AB to implement the needed corrective actions as rapidly as possible. Provisional recognition would be considered only when uncorrected findings from an evaluation might jeopardize the integrity of the assessment process. Such uncorrected findings might include, but are not limited to: one of the AB's assessors being suspected of misrepresentation, systematic failure to track PTs, or a drastic shortage of assessors to handle the evident workload. There would be an agreed-upon corrective action plus a definitive end-date before a provisional recognition would be issued.

Other documents and forms that help with the process have been updated for adoption by the NELAP AC: the application form, completeness checklist, technical review checklist, and a list of fields of accreditation being offered. Once approved, all the SOPs and tools will be posted on the NELAP AC pages of the TNI website for use by evaluators, so that the entire process will be transparent to all.

Training for evaluators, according to the 2009 TNI Standard, will be offered at the end of the Forum on Laboratory Accreditation in Savannah, early in 2011, and an online version of the training will be available as well.

An Update on EPA's Water Laboratory Alliance Activities

By Latisha Mapp, USEPA

The U.S. Environmental Protection Agency (EPA) Water Laboratory Alliance (WLA) continually strives to enhance Water Sector readiness. This summer, in particular, has seen several significant achievements including expanding security-related tools, beginning a microbiological multi-laboratory validation study, developing the first offering of WLA Training Center courses, and conducting the second multi-regional full-scale exercise. These activities support the mission of the WLA – to provide the Water Sector with a nationwide network of laboratories with the analytical capabilities and capacity to address natural, intentional, or unintentional drinking water contamination. An overview of WLA membership benefits and recent WLA progress to enhance preparedness to respond to water contamination events is provided below.

- **Benefits of Membership:** WLA benefits for laboratory members are highlighted by priority opportunities to participate in method validation studies, emergency preparedness exercises, and specialized EPA security-related training. The WLA is the water media component of EPA's Environmental Response Laboratory Network (ERLN), which also addresses contamination in other environmental matrices – specifically air, soil, and surfaces. For information about becoming a member of the WLA, please review the ERLN/WLA member requirements and application process at <http://www.epa.gov/erln/join.html>.
- **Water Contaminant Information Tool (WCIT) Expansion:** EPA supports WLA and the Water Sector by providing a number of tools and resources, such as databases and analytical methods. Among the tools is the WCIT – a secure, online database with complete contaminant profiles on more than 100 biological, chemical, and radiochemical contaminants that can threaten water systems. EPA recently expanded WCIT to include analytical methods for more than 600 contaminants.
- **Method Validation:** Improving capabilities through the validation of methods is a priority of the WLA. EPA has completed several culture-based microbiological method single-laboratory verification studies, including *E. coli* O157:H7, non-typhoidal *Salmonella*, *Salmonella typhi*, and *Vibrio cholerae* O1 and O139 for water matrices. Currently, a multi-laboratory validation study is underway for the culture-based non-typhoidal *Salmonella*



Report from Washington, DC

By Lara Autry, USEPA and Jerry Parr, TNI

The Environmental Measurement Symposium, which represents the combined meetings of the National Environmental Monitoring Conference (NEMC) and the Forum on Laboratory Accreditation (the Forum), occurred in Washington, DC this summer from August 9 – 13, 2010. This was the fourth combined meeting of the Forum and NEMC, which has only continued to grow.

Over 450 attendees participated in a week full of engaging technical presentations, thoughtful committee meetings of The NELAC Institute (TNI), special workshops, technology innovation displays, and other related events, including meetings of EPA's Environmental Laboratory Advisory Board and EPA's Water Laboratory Alliance.

The 26th meeting of NEMC had 130 technical presentations over 4 days.

- ◆ Nineteen technical breakout sessions with 100 oral presentations,
- ◆ Two day poster program with 23 posters,
- ◆ Three keynote presentations, and
- ◆ One general session with 4 presentations.

The technical presentations from the NEMC meeting can be found at <http://www.nemc.us>.

Continued on next page

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An Update on EPA's Water Laboratory Alliance Activities (cont.)

method, with preliminary analyses being completed in mid-August; EPA anticipates completing laboratory analyses by the end of 2010.

- **WLA Training Center:** To enhance preparedness to respond to water contamination events, EPA has begun developing the WLA Training Center. The first course offerings are in the late stages of development. Four webcasts are under development including a WLA overview for members, information on becoming a member of the WLA, guidance for maintaining chain of custody for criminal investigation samples, and practicing the WLA Response Plan (WLA-RP). The WLA-RP provides processes and procedures for coordinated laboratory response to water contamination incidents. An enhanced online module is also being developed to allow further practice with the WLA-RP through a virtual Table Top Exercise.
- **Multi-Regional Full Scale Laboratory Response Exercises:** WLA has validated the Water Laboratory Alliance Response Plan (WLA-RP) and practiced laboratory response capability through two full-scale exercises (FSEs). Following a successful FSE in EPA Regions 1 and 2 during 2009, EPA coordinated a second FSE during August 2010 in EPA Regions 9 and 10. This week-long FSE incorporated scenarios including toxic industrial chemicals (TICs), chemical warfare agents (CWAs), and biological select agents. In addition to state and federal agencies, a total of 25 laboratories participated in the Region 9 and 10 exercises, including 13 state laboratories, 4 commercial laboratories, 3 drinking water utility laboratories, 3 county laboratories, and 2 EPA regional laboratories.

Other participants in the Region 9 and 10 FSE included the U.S. Centers for Disease Control and Prevention's Laboratory Response Network (LRN), specifically the LRN biological and chemical sections (LRN-B and LRN-C, respectively). During the exercise, LRN-B laboratories concentrated large-volume water samples using the CDC ultrafiltration protocol. In addition, field concentration of large-volume samples (10-100 L) relied upon EPA's field-portable ultrafiltration device – another one of the tools that EPA has developed to enhance our nation's preparedness to respond to water contamination events.

In Memory of Patrick Conlon

Patrick A. Conlon 57 of Manahawkin, NJ died unexpectedly on Tuesday, August 24, 2010 in Houston, TX. He was born in Passaic, NJ, grew up in Allendale, NJ, and summered in North Beach Haven before moving there full time in 1968. He and his family divided their time between their home in Manahawkin and their condo in Barnegat Light.

Pat was a communicant of St. Francis Church, Brant Beach. He was a high school graduate of Strake Jesuit Academy in Houston, TX, received a Bachelor of Education from Rutgers College, a Bachelor of Science from Stockton State College, and an Executive MBA from Rutgers, the State University. At the time of his passing, he was employed by Environmental Standard as a Senior Chemist.

He will be greatly missed by his beloved wife Constance (nee Wiedling); daughter Tara Conlon; stepchildren, Robert Tranter and wife Carol, Ryan Tranter, Allison Tranter, Amy Tranter and husband Franklin Bridge; and his five grandchildren Olivia Bridges, Indigo Southard, Bastien Southard, Robert Tranter, and most especially Sara Bridges. He is also survived by his brothers, Thomas and Michael Conlon, and sisters, Christine Zitho and Laurie Shincer.

A Funeral Mass was held on Monday, August 30, 2010 at St. Francis of Assisi R.C. Church, Brant Beach, NJ.

Pat was an active member in TNI serving on the Advocacy Committee and Quality Systems Committee and the NEFAP Executive Committee.



Report from Washington, DC (cont.)

Fifteen TNI Committees held open meetings. In addition, the following other TNI sessions were held:

- ◆ QA Manual Template
- ◆ Assessment Forum: Improving Audit Consistency
- ◆ Mentor Session: Methods Panel
- ◆ Mentor Session: New TNI Standard
- ◆ Cryptosporidium PT and QA Program

Minutes from TNI committee meetings and presentations from the Forum can be found at <http://www.nelac-institute.org>.



TNI MISSION

The NELAC Institute is a 501(c) 3 non-profit organization whose mission is to foster the generation of environmental data of known and documented quality through an open, inclusive, and transparent process that is responsive to the needs of the community.



VISION

All entities generating environmental data in the United States will be accredited to consensus national standards.



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Organizational Members

We are grateful for the generosity of the organizations that have joined us as members:

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 A = Accreditation body
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 O = Other

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