Abstracts from the
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Quality Assurance / Quality Control of a project involving Cooperative Agreements, Intra-agency Agreements, Agency Staff and Contracts to conduct research; Ecological Monitoring and Assessment of the Great Rivers Ecosystems in the Central Basin of the United States

Allan R. Batterman, U.S. EPA ORD/NHEERL

EPA ORD's Environmental Monitoring and Assessment Program (EMAP) is a long-term research effort to enable status and trend assessments of aquatic ecosystems across the U.S. This is a national program that depends on partnerships with states, other federal agencies, tribes, and local groups to develop the science to inventory our natural resources, report their condition, and forecast future risks. From 2004-2006, EPA coordinated field crews from cooperating state and federal agencies to sample biological organisms, water, sediment, and habitat in the upper Mississippi River, Missouri, Ohio Rivers. Sampling of the lower Mississippi is planned for 2007-2009. The ecological complexities of these rivers provide scientific challenges for the EPA EMAP-GRE team. Operationally, assessing these rivers is challenged by their trans-jurisdictional nature, the number of crews needs, the diversity of samples collected. From the Quality Assurance Perspective, we will show the planning, documentation, and review processes necessary to maintain scientific assurance that the data being collected, analyzed, and reported on are comparable across all parties involved.

Key components of the Quality Assurance process are the 1) uniform sampling protocols, published as the EMAP-GRE Field Operations Manual, 2) single probabilistic survey design, 3) web-based information managements and sample tracking system, and 4) standard taxonomic/analytical laboratories procedures. Most of the components were developed in cooperation with various partners. All of the components were reviewed, documented, and audited throughout the program. EMAP-GRE requires collaborations across multiple scientific disciplines (including chemistry, hydrology, toxicology, biology, geography, genomics), as well as skills in acquisition, contract management, project management, and Information Technology (IT).

The EPA EMAP-GRE team coordinates the activities of the 15-20 state and federal partners through interagency agreements, cooperative agreements and contracts. Approximately 15 field crews were used each year to collect and process about 8000 samples from 200 sites. Samples are dispersed to nine analytical and taxonomic laboratories. Field and lab data are compiled by the EPA contract IT support staff in a web-based database. The team conducts quality assurance audits of each crew in the field and laboratory to ensure that established protocols are being followed. All field data are repeatedly reviewed. First, the crew leader reviews all data entries at the end of the sampling. IT staff reviews the completeness and logic of data as the data are entered into the database. Field crews compare 100% of the entered data with original data. Finally, EPA staff reviews the data making inter-crew and inter-annual comparisons. Changes to the database are documented to preserve lineage. All crews participate in annual training sessions. The EMAP-GRE team communicates with the partners through a newsletter, conference calls, a website "all-hands" emails, and workshops (e.g. Reference Condition; Indicators). Partners are encouraged to present preliminary results at scientific meetings.
Through networking, training, and oversight, the EMAP-GRE team has demonstrated leadership in operating across organizational boundaries - within and across both state and

federal agencies, public and private entities, multidisciplinary fields, and large geographic regions. The result has been a timely completion of our mission to develop the scientific understanding for translating environmental monitoring data from multiple spatial and temporal scales into policy-relevant assessments of current ecological condition and forecasts of future risks to our natural resources. This has required the development of ecological monitoring and assessment tools, culminating in better methods yielding better information for making more informed management decisions for our nation=s Great Rivers. Partners have both common and unique goals. Rather than fostering competition among agencies for the shrinking federal budget, involving our partners from the planning stages through analysis has allowed concurrent and timely completion of our several missions, as well as allowing the public to realize considerable savings in time and dollars. The EMAP-GRE team strategy forms the basis for the research needed to establish the condition of the nation's resources, as a necessary first step in the Agency's overall strategy for environmental protection and restoration. While condition reports are useful to managers, demonstrating how to implement a monitoring and assessment program in the future is also an important project goal. In the end, better monitoring methods will make more information more widely available to better manage the nation's great rivers.

A Strategic Framework for Implementing the EPA Information Quality Guidelines
Monica Jones, IQG Team Leader, U.S. EPA OEI Quality Staff
Laurie Ford, U.S. EPA OEI Quality Staff

This presentation will give an overview of the outcomes from the EPA Information Quality Guidelines Workshop held in Washington, DC in April 2007. The presenters will provide the audience with a summary of the discussions about:

- Assessing the Agency's information quality
- Improving Database Quality
- Enhancing the role of the EPA IQG in improving information quality
- Improving the EPA's administrative mechanism for responding to the IQG Requests for Correction
- Identifying how the EPA IQG process can improve the Agency's environmental outcomes
- Implementing Pre-Dissemination Review (PDR) of EPA's disseminated products

Quality Policy Development
Ron Shafer, U.S. EPA OEI Quality Staff

This paper will provide background and activities of the Executive Advisory Group, and the recommendations they made for revising the draft Quality Policy. The issues of scope, and roles and responsibilities will be discussed. The process used by the Executive Advisory Group to make decisions and materials used to support their decisions will be described. Any significant changes to the draft Quality Policy will be identified and discussed. The status and schedule for finalizing the Quality Policy will also be provided.

Overview of Ambient Air Quality Regulations, Projects and Issues
Dennis K. Mikel, U.S. EPA OAQPS-AQAD

OAQPS has recently promulgated new regulations in the Code of Federal Regulation (CFR) in

support of the new Ambient Air Monitoring Strategy. Chapter 40 CFR Section 50, 53 and 58 have been re-written and updated to reflect the new the Monitoring Strategy. The new Monitoring Strategy has the following recommendations:

- Including a greater level of multi-pollutant monitoring sites in representative urban and rural areas across the Nation;
- Expanding use of advanced continuously operating instruments and new information transfer technologies;
- Integrating emerging hazardous air pollutant (HAPs) measurements into mainstream monitoring networks, and;
- Supporting advanced research level stations

In addition to the monitoring regulations being re-written, a number of changes to the Quality Assurance requirements were re-written and updated. This presentation will give an overview to the changes to the 40 CFR 58 Appendix A, which deals with Quality Assurance regulations. The items added and subtracted will be highlighted. In addition, issues confronting and projects that are currently underway in EPA's Office of Air Quality Planning and Standards, Air Quality Assessment Division will be also be highlighted.

Targeting Geographic Areas Remaining At-Risk for Childhood Lead Poisoning

Margaret Conomos, Barry Nussbaum, and Heather Case
Battelle: Warren Strauss, Tim Pivetz, Jyothi Nagaraja, Elizabeth Slone, Rona Boehm, Michael Schlatt, Darlene Wells, Michele Morara and Bruce Buxton

This pilot study seeks to develop statistical models to predict risk of childhood lead poisoning within specified geographic areas based on a combination of demographic, environmental, and programmatic information sources. Exposure factors associated with childhood lead poisoning were investigated within census tracts for a community-focused set of Models in Massachusetts, as well as within counties across the U.S. in a series of National Models.Aggregated summary measures of childhood lead poisoning within defined geographic areas (census tracts and counties) are being used as the response variable in the statistical models, including geometric mean blood-lead concentration as well as proportion of children screened at or above 5, 10, 15 and 25 ug/dL.These summary measures are reported at 3-month (quarterly) intervals over a several year period of time within each geographic area, allowing EPA to assess how the risk of childhood lead poisoning changes over time using a Generalized Linear Mixed Modeling Approach.

Wednesday 9:00 AM

The Blanchard River Watershed Partnership Project 2007-2008

M. T. Homsher, The University of Findlay
H. Bryan and M. Wilson, Findlay City Schools

The Blanchard Valley Watershed has been rated "impaired" by the Ohio Environmental Protection Agency. Together students will design an action service plan that will seek to change the impaired status to one of quality while remaining sensitive to the needs of all stakeholders. As a central service project, these groups will conduct research within the watershed, identify pollution sources, analyze types of pollution while cleaning park streams, and determine a list of current and potential park activities for middle school, high school, and college students. The students will present their data to the Middle School

Student Body, the Findlay High School Environmental Club, The University of Findlay Scholarship and Creativity Symposium, the Blanchard Valley Watershed Study Partnership (BRWP), the Ohio Environmental Protection Agency, and other appropriate groups or organizations. The three groups of students will complement each other as they participate in both the social and scientific input to a public decision process.

They will develop the ability to identify and define scientific issues, seek valid answers, solve problems, and impact public decisions in a diverse and multicultural global community, while reflecting on their results and their service's ties to their topic of study. This activity is planned for the 2007-2008 academic year and includes a University of Findlay Sampling and Analysis Class with a service-learning component taught by Dr. Michael T. Homsher, a sophomore Environmental Studies Class from Findlay High School taught by Heather Bryan, and the Environmental Science Club composed of 5th grade students at Central Middle School, led by Mike Wilson. Each teacher will present the investigation and partnership to his/her respective class and develop student projects around the scientific problem-solving process and the student interests related to the Blanchard Valley Watershed. These students will partner with the Blanchard River Watershed Partnership, a nonprofit that exists to facilitate stakeholder education about the watershed, assist Ohio EPA in evaluation of the watershed, and work with stakeholders to improve watershed quality.

Measuring the Benefits of Quality Management Systems
Ron Shafer, U.S. EPA OEI Quality Staff

The Office of Environmental Information's Quality Staff is sponsoring a long-term effort to develop a more meaningful performance measurement approach for EPA's quality management system. The objectives of this effort are to identify:

- Identify better ways of measuring the results and benefits of a quality management system,
- Develop EPA quality goals for its products and services,
- Develop a long-term plan and governance process to promote continuous improvement of the Agency's quality management system, and
- Provide meaningful metrics that assist senior management in planning the future directions of the Quality Program.

To support this performance metric initiative, the Quality Staff has conducted two pilot efforts in conjunction with QAARWP reporting and conducted interviews with quality community and Agency program management staff. This technical paper will describe the objectives and the results of these efforts. The paper will also provide a proposed set of performance metrics based on the logic model approach. Finally the paper will introduce Agency-wide quality progress reporting and the elements associated with this type of reporting.

Status and Changes in EPA Infrastructure for Bias Traceability to NIST
Mark Shanis, U.S. EPA OAQPS/AQAD/AAMG

Improvement changes continue to be made in a number of the parts of the EPA QA infrastructure authorized and established by EPA's ORD-QA staff in RTP and DC in the 1980's to characterize and promote traceability of EPA ambient air monitoring data to NIST standards. EPA's benchmark Quality Assurance (QA) programs support the comparability of the calibrations that all reporting organizations use to assign values to the otherwise

undefined instrumental signals that air monitors provide as the basis of the data reported to EPA for compliance and other uses.

This discussion will address status of changes in the EPA's National Performance Audit Program (NPAP) for Ambient Air Criteria and other Pollutants, the EPA's Standard Reference Photometer (SRP) Program for traceably standardizing ambient ozone measurements, and the EPA Protocol Gas Verification by an independent, EPA-approved, third party. In 1996 EPA OAQPS agreed to take the programs over from EPA ORD, to the extent allowed every year by resources/ priorities.

The transition of the gaseous pollutant part of NPAP as a mailed, back-of-the-analyzer (BOA)-only program, into the TTP Program is about complete. A system for auditing Trace Level Precursor Gas monitors is being assembled. It will be tested and a draft SOP developed in this CY. A more portable gaseous Criteria Pollutant TTP PE system was used in 2 east coast EPA Regions in 2006. The system has advantages of lower cost and much easier access. Planning is under way to add a 2nd system for use in the west. A new data base has been developed to automate entry of NPAP audit data into AQS, and a new ACCESS-based data entry form is being developed to improve the field data capture, preparation for reporting, and to automate prescreening for transmission into AQS. Changes are being implemented to improve ease of audit point generation. Changes related to the October 2006 regulation are discussed.

NPEP TTP PEs have now been conducted by staff from 6 EPA Regions, using a sharing approach. Problems have been identified, and the causes determined in a number of states, some with strong internal programs. Changes are already being made in some programs. Attention is now being refocused on materials and high flow sampling systems. Draft TTP SOPs and an Implementation Plan are now posted on www.epa.gov/ttn/amtic/quality.

The SRP network of 10 NIST manufactured and certified systems are deployed, based, and operated in 8 of the 10 EPA Regions. They are compared to the NIST SRP using a stationary and a traveling SRP, now both based in RTP, NC. In the last 12 months, the last Regional SRP automation upgrade was completed, and coordination of the central SRP has been brought back to RTP. See latest Operator list on www.epa.gov/ttn/amtic A new accuracy-improving upgrade of the SRP is being planned by NIST.

After 1996, the ORD's EPA Protocol Gas Verification Program (PGVP) was not continued. Although the sample size of the original program was small and inexpensive, vendors paid attention, for very low cost. Results improved over the 4-5 years of the program. EPRI (ca.1998), and then EPA (2003, 2006), in response to complaints from the user communities, have performed additional blind sampling studies. The studies indicated that problems, across pollutants, have recurred. EPA has promulgated new Protocol Gas language, and is proposing more, to require verification, and has worked with stake holders to develop, review and revised a detailed PGVP Implementation Plans for establishing a vendor-funded, EPA-approved, 3rd party-operated, blind sampling, publicly-reported verification program.

Test of Hypothesis to Determine if Hispanics in NHANES 2001-2002 Have Significant Differences Using WesVar Regression Models

Dr. Hans D. Allender, P.E., U.S. EPA OPP/HED

Introduction
To evaluate pesticide exposure to US population, the Office of Pesticides Programs (OPP) at EPA works with a database produced by the Center for Disease Control's (CDC) known as NHANES, or the National Health And Nutrition Examination Survey (http://www.cdc.gov/nchs/nhanes.htm). The survey produces extensive and comprehensive information on more that 20,000 individuals that includes concentration of different pesticides. or their metabolites, on the urine of the population. Because the survey is designed to permit statistical statements to be made about certain minority groups within the population, the survey over-samples these subgroups and uses sampling weights to subsequently adjust for this over-sampling. To extend the survey results to the rest of the population, special statistics are necessary; this includes the utilization of replications for each data point. Testing hypotheses under these conditions becomes unconventional and require specialized software similar to WesVar.

The specific example in this presentation test the hypothesis that the Hispanic group in the NHANES sample is no different from the rest of the population. This will be achieved by using replication methods under the conditions of not normal data, non-random sample design, and weighed data.

Objectives of the Presentation
The objectives of this presentation are to explore how WesVar deals with a test of hypothesis under the above conditions by using a regression model.

Wednesday 9:30 AM

Pursuit of an International Approach to Quality Assurance For Environmental Technology Verification
Lora Johnson, Director of Quality Assurance, U.S. EPA National Exposure Research Laboratory

In the mid-1990's, the USEPA began the Environmental Technology Verification (ETV) Program in order to provide purchasers of environmental technology with independently acquired, quality-assured, test data, upon which to base their purchasing decisions. From the beginning, a strong program of quality assurance was specifically devised for ETV and was documented in the ETV Quality and Management Plan. During the intervening years, the ETV program and accompanying quality system, has continued to evolve. One feature of the quality system has remained constant: EPA QA staff continue to provide QA oversight for the program. This has created a conundrum for the program as the actual technology testing moves toward economic self-sufficiency (i.e. vendors pay for testing), but QA oversight remains in-house. It has presented a particularly interesting problem for collaborating with other countries where technology verification programs are also being developed and reciprocity is desired. Tapping into existing resources for accreditation and certification in the international conformity assessment arena may be a viable approach, but undoubtedly some infrastructure must be developed to replace the hands-on oversight that has historically been provided by EPA QA staff. Discussion of this approach and other activities related to development of an international approach to environmental technology verification will be the focus of this presentation.

OPPTS/OPPT New Quality System
Todd Holderman, U.S. EPA OPPTS/OPPT/IMD

OPPTs Information Management Division (IMD) is striving to ensure that quality is built into all aspects of the Division's activities, services and operations. To this end the Division is revitalizing its quality management program with the goal of interconnecting all management and performance activities as well as service delivery under the auspices of the Quality Management Plan. This briefing will highlight the various pieces of this new program – still a work in progress – to show how the Division is attempting to integrate performance management, standard operating procedures, and records management with program/project planning and budgeting. The establishment of a quality program and system where continuous improvement in all aspects of the Division's mission is the objective.

Stages of Quality

Louis Blume, U.S. EPA Great Lakes National Program Office

(Abstract Unavailable)

Transition to Primary Quality Assurance Organizations in the Air Quality System (AQS)

Jonathan K. Miller, U.S. EPA OAQPS/OID/NADG

With the promulgation of the regulations in 40 CFR Part 58, a new entity was introduced in Appendix A. As of January 1, 2007, the organization that is responsible for the submission and quality of ambient air quality data is referred to as the Primary Quality Assurance Organization (PQAO). This change was made for two primary reasons:

1. Historically this role had been referred to as the "Reporting Organization". However, it has been evident that in some circumstances the meaning of "Reporting Organization" was being used to mean "the organization supplying the data to AQS" and not necessarily the agency responsible for the results and quality of the information. It is felt that the new name more clearly describes the intended role of the defined organization.
2. To provide organizations the opportunity to reduce auditing requirements outlined in the National Performance Evaluation Program (NPEP). By defining the new role, smaller agencies have the opportunity to "combine" with other organizations to help reduce the number of audits required by the NPEP program.

As part of the creation of the PQAO role, AQS also needed to make changes in order to be consistent with the needs of the new role. The changes can be broken down into the following categories:

1. Conversion of existing Reporting Organizations to PQAO (Estimated completion in March, 2007)
2. Business Rule Changes (Estimated completion in March 2007)
3. Changes in Reports (All changes estimated to be complete by October 2007)

It is thought that there will not be significant changes in the type or volume of data required from the submitting agencies once the initial conversion is complete. The benefits of the changes should be reflected not only in the increased accuracy and consistency of the data reported to and from AQS, but also reduces the overall costs of collecting and validating the data as well.

Estimating Populations Around Superfund Sites: A Comparison Between Simple Census Block and National Land Cover Infused Geographic Interpolation

Larry Lehrman and Tom Brody
U.S. EPA Region 5 RMD OIS

A November 13, 2006 memo from EPA Deputy Administrator Marcus Peacock instructed agency staff to undertake a Workload Assessment for the Superfund Program. The Assessment was in response to several reviews that recommend EPA manage Superfund resources more effectively. Additionally, the House Appropriations Committee, in its 2007 Appropriations Report, stressed that EPA must do a better job of using limited staff resources and praised EPA for initiating a workforce assessment. A working group was formed to tackle the various facets of prioritizing initiatives in the Superfund program. One of these facets included establishing the population affected around the portfolio of sites in the program.

The working group established the definition of the population to be the "population within the site area, in addition to the population within an area which extends outward from the site boundary by one mile and encompasses the site in its entirety." Geographic Information System (GIS) Analysts from several Regions spent time generating both the site boundaries of their portfolios and developing methods to easily capture the population within a one mile buffer of these boundaries. Most groups resorted to interpolating these buffers with block data from the Census to determine the population around sites. This exercise simply appropriates the percentage of the block inside the buffer to the population number of the block with the assumption that population is uniformly distributed within the block. Although block data can be very fine in urban and even suburban settings, the interpolation method may break down in rural areas where wider blocks may capture several unpopulated areas such as farms and water bodies.

To this end, Region 5 decided to see if there are significant differences between simple interpolation of the Census Data and a method that infuses the newly released 2001 National Land Cover Dataset (NLCD 2001) first. NLCD 2001 separates developed areas from such categories as water bodies, barren land, forests, crops, and wetlands. The exercise proportioned the population in the blocks to the developed areas and then interpolated the data in the one mile boundary. This paper will show if we are seeing significant differences in the two methods, and provide some anecdotes during our exploration of the NLCD 2001.

Wednesday 10:30 AM

Quality Assurance in Modeling - Design and Implementation of New Tools

John Smaldone, U.S. EPA

Improving the application of quality assurance project plans (QAPPs) in modeling may reduce vulnerability to legal challenges. Guidance has been developed and is being implemented for assuring quality in modeling in the Total Maximum Daily Load (TMDL) program. A template and companion checklist has been designed for writing QAPPs for models used in TMDL decisions. Flexibility in the design and implementation strategy allows the template to be used for writing one, state-wide generic QAPP or project-specific QAPPs. The checklist assists QAPP writers in tracking the completeness of their work and may assist QAPP reviewers by readily identifying deviations from the template.

Examples of some noteworthy features of the QAPP template include internet links to:

- EPA quality assurance references;

- State-of-the-art modeling guidance; and
- An EPA modeling glossary

Other noteworthy specifications called for in the template include:

- Identification of model selection and model fit to problem;
- Notification of changes to model code;
- Use of independent data sets for model calibration;
- Identification of calibration stop criteria;
- Sensitivity and uncertainty analyses; and
- Modeling report requirements

Readily available new tools from Europe compliment the QAPP template. These tools place a compendium of expert consensus on good modeling practice at your fingertips. The combination of these quality system tools and best practices help ensure quality data from external partners.

Strategy for Policy Management to Improve The Quality of EPA Information (Session)

Policy implementation is not always performed as discrete activities by discipline-specific groups in an enterprise. For example, implementing quality policy is not only the responsibility of quality managers. Individuals need to understand and ensure implementation of all applicable policies. This presentation provides an overview of Agency information policies and their current status. The second presentation described how those information policies in concert with quality policies ensure the quality of a wide variety of EPA products and services. The third presentation describes how OEI is strengthening its policy management system by incorporating plan-do-check-act principles and offering this more robust system in a web-based application for use by all employees.

Information Policies and the Information Policy Process

Lyn Burger, Chair, OEI Information Policy Workgroup, U.S. EPA OEI

Information policies and associated procedures, standards, and guidelines provide the framework for the consistent delivery of information to the public. The policy development process must keep pace with Government-wide priorities, EPA mission support needs, and the public's needs. This presentation reviews the status of EPA's information policies and associated documents and describes the progress made in the last several years to improve the information policy process.

I Policies + Q Policies = EPA Product & Service Quality

Laurie Ford, U.S. EPA OEI Quality Staff

The quality policies are not the only policies that ensure the quality of EPA activities. Other policies provide for uniform work and encourage oversight to ensure implementation. Information policies, in particular, help ensure the quality of information delivery and the functionality of the systems that provide information to EPA's customers. This presentation describes how both information policies and quality policies jointly work together to ensure that there is the right information, at the right time, in the right place.

PDCA Strategy for a Policy Management System
Kevin Hull, Neptune & Company

Information policy developers are faced with many challenges. Information processes and technology frequently change and required policies to be updated. Many policies must be approved at several levels before receiving senior management approval. With a large volume of policies, the 3 year update cycle itself can create a substantial workload. Implementation of many policies in a single area can be difficult. One solution is to apply the plan-do-check-act cycle to the policy management process and provide this is a web-based form. This presentation described such a system.

Getting it Right - Best Practices for Developing an Agency Quality Glossary (Session)
Katherine Breidenstine - U.S. EPA OEI Quality Staff
Support from Project Performance Corporation (PPC) Glossary Development Team

Background:
It is critical for the Quality Assurance (QA) community to use correct terminology to communicate complex quality issues throughout our diverse disciplines. Currently, there many glossaries containing QA terms throughout the Agency, to include one developed by the Quality Staff. In our efforts to ensure consistency of terms and make improvements for our various stakeholder communities the Quality Staff has secured resources to assist in the development a fully functional Agency Quality Glossary.

Session Content:
This session will share and discuss with participants the key project efforts and challenges:

- Conducting a literature review and analysis of existing terminologies, terminology formats, and glossaries available on the EPA internet and intranet that address quality for science, engineering, and information technology/management activities.

- Establishing a Glossary Governance Council to participate in discussions for determining business rules and identify terms for inclusion in the Agency Quality Glossary.

- Establishing business rules for a comprehensive listing of all quality and information terms.

- Developing a comprehensive listing of all quality and information terms, the type of term (e.g., statistics, information quality, measurement) definitions, plain English, sources, and web links based on the current terminology used to describe, plan, implement and assess quality for Agency science, engineering, and information technology/management activities, used by the Quality Staff in their documentation.

- Developing the design for an fully-functional agency quality glossary Web site to allow for the following functionality:
  - Sorting by term type and term.
  - Linking terms in one definition to other terms in the glossary.
  - Linking terms to the appropriate Web page.

- Establishing a management system to include proposed methodologies for periodic updates to the terms contained in the glossary.

Updates and Enhancements to EPA's Quality Assurance Handbook for Air Pollution Measurement Systems (Volume IV): Meteorological Measurements
Dennis K. Mikel, U.S. EPA OAQPS-AQAD

Meteorological data has proven to be an important part of air quality management activities. Many State, Local and Tribal air agencies perform meteorological monitoring to support their efforts to improve air quality. Often times, these agencies lack clear guidance on appropriate methods and techniques to ensure the quality of the meteorological data they are collecting. This often results in poor meteorological data being collected that is unusable by the agency. EPA has addressed this lack of guidance by updating the Volume IV QA Handbook for Meteorological Measurements so that air agencies can work towards improving data quality for their meteorological data.

This presentation will provide the results of EPA's effort to identify the meteorological monitoring needs of air quality management agencies. The Handbook should be in final form and will be available to the public. The presentation will outline the enhancements, include a description of the latest state-of-the-art meteorological instruments and updated information on the calibration and auditing. The updated Volume IV will have in-depth technical discussions of wind parameters (cup/vane and sonic), temperature, solar radiation, rain measurements, discussions of vector and sigma calculations and upper air meteorological measurements.

In-depth audio/videos files were created in support of the Handbook. These AV files are medium length (5 – 18 minutes) that illustrate the calibration of typical meteorological equipment. This presentation will also illustrate these AV files.

Statistical Methods for Environmental Applications Using Data Sets With Below Detection Limit Observations as Incorporated in ProUCL 4.0
Anita Singh, Lockheed-Martin
John Nocerino, U.S. EPA, Las Vegas, NV

Nondetect (ND) or below detection limit (BDL) results cannot be measured accurately, and, therefore, are reported as less than certain detection limit (DL) values. However, since the presence of some contaminants (e.g., dioxin) in environmental media may pose a threat to human health and the environment, even at trace levels, the NDs cannot be ignored or deleted from subsequent statistical analyses. Using data sets with NDs and multiple DLs, practitioners need to compute reliable estimates of the population mean, standard deviation, and various upper limits, including the upper confidence limit (UCL) of the population mean, the upper prediction limit (UPL), and the upper tolerance limit (UTL). Exposure assessment, risk management, and cleanup decisions at potentially impacted sites are often made based upon the mean concentrations and the UCLs of the means of the contaminants of potential concern (COPCs), whereas background evaluations and comparisons require the computations of UPLs and UTLs to estimate background threshold values (BTVs) and other not-to-exceed values. The 95% UCLs are used to estimate the exposure point concentration (EPC) terms or to verify the attainment of cleanup levels; and upper percentiles, UPLs, and UTLs are used for screening of the COPCs, to identify polluted

site areas of concern and hot spots, and also to compare site concentrations with those of the background.

Even though methods exist in the literature to estimate the population mean and the standard deviation for data sets with NDs, no specific guidance with a theoretical justification is available on how to compute appropriate UCLs, UPLs, and other limits based upon data sets with NDs and multiple DLs. The main objective of this paper is to present defensible statistical methods that can be used to compute appropriate estimates of environmental parameters, EPC terms, BTVs, and other not-to-exceed values based upon data sets with NDs. This paper describes both parametric and nonparametric methods to compute UCLs, UPLs, and UTLs based upon data sets with NDs having multiple DLs. Some of the methods considered include: the maximum Likelihood Estimation (MLE) method, the regression on order statistics (ROS) methods, and the Kaplan-Meier (KM) method. Based upon our findings, it is recommended to avoid the use of ad hoc UCL methods based upon Student's t-statistic on ML estimates. It is also suggested to avoid the use of the DL/2 method on data sets even with low (<5%-10%) censoring intensities. It is shown that, just like for uncensored data sets, for highly skewed data sets with NDs, one should use the Chebyshev inequality based UCLs (e.g. using KM estimates) to provide an adequate coverage for the population mean.

Several of these methods have been incorporated into the ProUCL 4.0 software package. ProUCL 4.0 makes some recommendations based upon the results and findings of Singh, Maichle, and Lee (EPA 2006). Some examples to elaborate on the issues of distortion of the various statistics and upper limits by outliers and by the use of a lognormal model to accommodate those outliers will be discussed using ProUCL 4.0.

Reference:
Singh, A., Maichle, R., and Lee, S. *On the Computation of a 95% Upper Confidence Limit of the Unknown Population Mean Based Upon Data Sets With Below Detection Limit Observations.* EPA/600/R-06/022. March 2006.

Wednesday 11:00 AM

Creation of the Single Pass Quality Assurance Plan

Michelle Henderson, Shaw Environmental, Inc., Cincinnati, OH

Prior to the physical startup of most environmental projects a Quality Assurance Plan (QAP) must be written to describe the process and method details of the construction, remediation or experimental plan. The writing of the (QAP) is often delegated to a junior engineer or technician. These technical documents incorporating the details of how the project is to be accomplished can take many hours to complete. If the QAP does not include the appropriate detail in language understood by the client or agency, the QAP may be returned with multiple comments and requirements for revision. Sometimes multiple review rounds are required to satisfy the client or agency, wasting project time, money and resources. In addition, repeated returns of a QAP may cause low customer satisfaction and lack of confidence even before the project has begun. The single pass QAP is defined as one which has been approved on the first pass through the client and/or approving agency prior to work start. The creation of a single pass QAP requires several specific tasks, while success is never guaranteed. Upfront planning, understanding and meeting of appropriate requirements and the involvement of all stakeholders is critical in the process of the creation of a single pass QAP.

Data Entry Program for National Performance Audit Program (NPAP)
Jonathan K. Miller, EPA Office of Air Quality, Planning and Standards
Outreach and Information Division

In an effort to produce accurate information produced from the National Performance Audit Program (NPAP), OAQPS has developed a data entry program in Microsoft Access to assist field operators with the input and formatting of this data. The overall application consists of a field operator's version and a version kept at EPA Headquarters in Research Triangle Park, North Carolina (RTP). The field version of the application focuses on data entry (providing appropriate fields, look-up values, etc), and creating files to export to RTP. The field version of the application also provides a summary of the results of the audit. The RTP version of the application would focus on receiving files generated from the field version of the software as well as long term maintenance and storage of the data. The RTP version would also have a variety of summary and detail reports based on the supplied information.

This presentation would be largely a demonstration of the field version of the application allowing participants to comment on the provided user interface modules, application features, and suggestions for improvement. Reports from the RTP version of the application will also be demonstrated.

Handling Nondetects in Contaminant Trend Analysis
Douglas McLaughlin, NCASI

Substituting nondetect values with values such as 0, one-half the detection limit, or the full detection limit prior to the analysis of censored environmental data is a common practice. However, this practice is problematic as many environmental professionals consider it arbitrary with significant potential to lead to incorrect environmental decisions. It is also increasingly unnecessary. Several data analysis methods that do not require substitution of nondetects, while not new, have in recent years become easier to carry out for those responsible for the data analyses that are needed to inform environmental management decisions. Yet the number of examples of their use, including comparisons of results to those obtained using more common "substitution" methods, remains small. One type of data analysis problem that remains of interest to environmental managers and commonly involves censored data is the investigation of time trends in fish tissue contaminant concentrations and exposure. Several methods for censored data are illustrated and compared with more common "substitution" methods using a data set of fish tissue dioxin concentrations that contains nondetects. Data were analyzed using a common commercially available statistical software program. Methods used to calculate summary statistics for censored data include robust regression on order statistics (robust ROS), maximum likelihood estimation, and Kaplan-Meier. Methods used to characterize trend direction and rate include ordinary least squares regression, maximum likelihood estimation, and Akritas-Theil-Sen regression. Approaches for the examination of outliers and potential covariables during the analysis are also presented. In addition, the effects of decisions made during the analysis, for example regarding the treatment of outliers, are discussed and the results obtained from all methods are compared. This work also reinforces the importance of establishing quantitative decision criteria prior to data analysis in order to better define the relevance of differences among statistical results obtained from multiple reasonable data analysis decisions, regardless of whether substitution methods are used.

Wednesday 11:30 AM

Perspectives on Tribal Quality Assurance Training

David R. Taylor and Eugenia McNaughton, U.S. EPA Region 9 QA Office

Tribes throughout the nation are now required to provide water quality monitoring data, the collection of which is supported by USEPA to the Office of Water using STORET. These data collections efforts require the development of Quality Assurance Project Plans (QAPjPs). Following the publication of the Quality Assurance Project Plans Development Tool for Clean Water Act 106 grants (in a CD-ROM format), the Region 9 Quality Assurance (QA) Office provided a number of trainings to tribes using a variety of different formats and approaches. A summary of these training efforts and the QA Office's perspective on their effectiveness was presented at the Annual Tribal – EPA Conference in October 2006. As a result of the audience response to the presentation, the Regional Tribal Operations Committee (RTOC) Quality Assurance Subcommittee, on which Region 9 Quality Assurance Office has two members, is evaluating future tribal training needs and the most effective means of delivering that training. The results of this evaluation will be presented.

QA Issues for Energy Efficiency Measures at Ambient Air Monitoring Stations

Meredith Kurpius, U.S. EPA Region 9
Joel Craig, San Luis Obispo Air Pollution Control District

Implementing energy efficiency measures at air pollution stations reduces the cost of operating air monitoring stations and promotes improvements in air quality. In addition, there are a number of co-benefits such as possible labor savings, reduced wear-and-tear on vehicles, reduced equipment expenditure (e.g., A/C replacement), possible noise reduction, and improved instrument operation. The challenge is in implementing energy saving measures while maintaining complete and high quality ambient air data.

The major energy consumers at an ambient air quality station are likely to be heating/cooling systems, instrument pumps, and particulate matter samplers. It is also important to consider travel to/from stations and energy use by idle electronics and equipment. Numerous options exist for improving energy efficiency at air monitoring stations, including: setting up remote operation and automating monitoring tasks (less driving); reconfiguring venting of waste heat from instruments to minimize use of cooling/heating systems; enclosing instruments to minimize volume to be cooled/heated; redesigning inlets to eliminate pumps; replacing energy-intensive instruments/pumps with more efficient ones; programming calibration systems to power down when not in use; and installing solar power.

A major limitation to instituting energy efficiency measures may be state/local agency resources (staff time, upfront capital expenditures, etc.). However, other limitations are imposed by EPA QA requirement such as station/instrument temperature, residency time, and instrument equivalency designations. In addition, other QA issues to consider include calibrations at high/low temperatures, effectiveness of remote QA/QC checks, and instrument performance with ambient air at a different temperature than the instruments. EPA Region 9 has been working with San Luis Obispo Air Pollution Control District to evaluate energy efficiency options that comply with all EPA QA requirements.

The San Luis Obispo County Air Pollution Control District initiated an energy reduction program on their air monitoring network in 2006. In this program various approaches to energy reduction were tested and evaluated, while assessing any impact to data quality.

Significant reductions in station electrical consumption were achieved through alternative temperature control strategies as well as slight modification to the station designs. Reductions in driving were also achieved through automation and remote operation of the monitoring network.

A Simple Procedure for Estimating Method Quantitation Limit (MQL)
Chung-Rei Mao, U.S. Army Corps of Engineers

Method Quantitation Limit (MQL) is the lowest amount of analyte in a sample that can be quantitatively determined with an acceptable level of precision and accuracy. Several procedures are available for estimating or determining MQL. Traditionally, an MQL may be estimated based on a multiple of the Method Detection Limit (MDL) or determined based on multiple analyses of fortified samples at low concentrations. However, information on precision and accuracy are usually not available for an estimated MQL so that the estimated MQL would be of limited or no practical value. For a determined MQL, the multiple analyses could be prohibitively costly for routine applications at a production laboratory.

A simple procedure for determination of MQL based on the MDL and the Laboratory Control Sample (LCS) will be presented. Because any quality assurance program requires frequent analysis of LCS, the mean and standard deviation of LCS recoveries are well known. Using MDL and LCS data, the proposed procedure provides a reliable estimate for MQL with well defined precision and bias. An MQL determined based on the proposed procedure will provide data at or near the MQL of known quality for reliable decision-making.

Wednesday 1:00 PM

The EPA Region 2 Approach to Quality Assurance Training
Kevin Kubik, U.S. EPA Region 2

Region 2 has a centralized Quality Assurance Program and organizationally it is located within the Division of Environmental Science and Assessment and physically located in Edison, NJ. The Region 2 Program Offices are located in New York City, Puerto Rico and the Virgin Islands, and in Edison. After the March 2003 Quality Systems Assessment of Region 2 it was determined that Quality Assurance training was needed throughout the region and that the current approach to QA Training was lacking. This presentation will describe the former QA Training approach and describe the thought processes that went into the development of the new approach and how the new approach was implemented, given the logistical challenges. Results of the training program will be discussed in conjunction with the findings of the February 2007 Quality Systems Assessment of Region 2.

A Successful Strategy for implementing the EPA Information Quality Guidelines (IQG) (Session)
Monica Jones, IQG Team Leader, U.S. EPA OEI Quality Staff
Tom Nelson, U.S. EPA Region 6
Walter Helmick, U.S. EPA Region 6

At the beginning of the session, the facilitator will provide a brief overview of EPA's process for responding to an IQG Request for Correction (RFC) and Request for Reconsideration (RFR). Using an example of an actual EPA IQG RFC and RFR, each panelist will describe their role in the preparation of EPA's response to these requests. The panelist will give

examples of the successful strategies and lessons learned in preparing EPA's response to the IQG RFC and RFR. At the conclusion of the panel presentation, we will engage the audience in a dialogue of other strategies that can be used to improve EPA's response to IQG requests.

What the G-5 Rewrite Intends to Accomplish (Session)
John Warren, U.S. EPA OEI

The current G-5, *Guidance for Quality Assurance Project Plans*, is due for renewal in December 2007, and Neptune & Company is the lead contractor assisting the Quality Staff in revising and rewriting the guidance. Input from all the Programs and Regions has been solicited through regular communication with the G-5 Revision Workgroup. The workgroup has advised the Rewrite committee to focus on the use of QAPPs applied to existing data sets without losing the connection to the Uniform Federal Policy (UFP) QAPP issued in December 2005. This presentation examines the difference between the current G-5 guidance and the revised G-5 Guidance.

Progress Made in the G-5 Rewrite
Daniel Michael, Neptune & Co.

This presentation shows the progress made in developing the revised sections of G-5. The rationale for the new ordering of the elements of a QAPP will be discussed especially with reference to existing data. The presentation will conclude with a discussion of what areas are yet to be completed and where further input from the QA community is needed.

Discussion on the G-5 Rewrite
Daniel Michael and John Warren

The final presentation will be an open forum where the audience is invited to share knowledge and experience with establishing performance or acceptance criteria for the consideration of existing data for potential use in a project. It is anticipated that their advice can be incorporated into the G-5 rewrite.

Integration of Statistics, Remote Sensing and Existing Data to Locate Changes in Land Resources
Maliha S. Nash, Deborah J. Chaloud, and William Kepner, U.S. EPA LEB
Samuel Sarri, CCSN Las Vegas, NV

Stability of a nation is dependent on the availability of natural resources. When land is degraded and natural resources become limited, socioeconomic status declines and emigration increases in developing countries. Natural resource utilization without proper management may result in irreversible land degradation. Early detection of resource depletion may enable protective actions to be taken prior to significant decline in resources and associated socioeconomic conditions. We have developed a simple method based on readily available data to locate areas of concern. Our method integrates results from statistical analyses of inexpensive remote sensing data (e.g., Normalized Difference Vegetative Index) data. Results are mapped using ARCView. Ancillary information is used to verify results and to assist in identification of probable causes of significant positive and negative change. These results can be used by authorities in developing management plans to preserve or conserve natural resources and maintain or improve the socioeconomic

status of the resident population.

Notice: The U.S. Environmental Protection Agency (EPA), through its Office of Research and Development (ORD), funded and performed the research described here. It has been peer reviewed by the EPA and approved for publication. Mention of trade names or commercial products does not constitute endorsement or recommendation for use.

Wednesday 1:30 PM

Laboratory Quality Systems: Use of Information Technology to Manage Documents and Training

Robert P. Di Rienzo, DataChem Laboratories, Inc.

The laboratory shall establish and maintain procedures to control all documents that form part of its management system (internally generated or from external sources), such as regulations, standards, other normative documents, test and/or calibration methods, as well as drawings, software, specifications, instructions and manuals. ISO/IEC 17025:2005

The laboratory shall establish and maintain procedures to control all documents that form part of its quality system (internally generated or from external sources). Documents include policy statements, procedures, specifications, calibration tables, charts, textbooks, posters, notices, memoranda, software, drawings, plans, etc. These may be on various media, whether hard copy or electronic, and they may be digital, analog, photographic or written. NELAC 2003

A laboratory should have a document control system that complies with the above requirements from ISO and NELAC. The use of Information Technology to manage a document control system ensures control of documents. This presentation will identify how documents are controlled through web based technologies that are available, easy to maintain and cost effective.

The use of an internal website (Intranet) can manage documents, training, policies, procedures and applicable records. This presentation will identify how documents and managed in this fashion. This presentation will also identify required documents in a quality system that must be controlled and show simple techniques to control documents.

A well constructed documentation control system ensures that the data generated are of known and documented quality. A good document control system can improve the laboratory quality system, improve consistency in operations, increase productivity and most of all lead the laboratory toward continuous quality improvement.

The SAS Enterprise Miner: Sequence Analysis, Decision Trees, and Neural Networks

Jodi Blomberg, SAS Institute, Inc.
(Abstract Unavailable)

Wednesday 2:00 PM

APHL as Home Base for State Environmental Laboratories
Jack Bennett, State of Connecticut Department of Health

EPA recognized that there was a need for State environmental laboratories to come together and collaboratively form partnerships among themselves as well as with EPA. The importance of those partnerships was heightened by EPA's responsibilities under Homeland Security Presidential Directive 9 (HSPD 9) for the environmental aspects of an event of national significance. To meet the need EPA entered into a cooperative agreement with the Association of Public Health Laboratories (APHL). The purpose of this paper is to introduce the audience to APHL and the Environmental Laboratory Subcommittee as well as its role under the cooperative agreement and to discuss some of the Quality initiatives being brought forward by the subcommittee.

Statistical Support Pilot in the U.S. EPA Office of Research and Development
Lynne Petterson, PhD
U.S. EPA ORD, National Exposure Research Laboratory

In 2007, EPA's Office of Research and Development is sponsoring a statistical support pilot. The statistical support pilot provides a hotline service to address short-term questions via telephone or email, as well as a contract vehicle for long-term projects requiring specialized statistical support. Statistical support for short-term questions is limited to 4-6 hours and provided at no charge to ORD organizations. Long-term statistical support is funded by the requesting ORD organization and is limited to no longer than three (3) months.

The pilot will offer three types of statistical support. These include classical statistical support, spatial analysis support, and bioinformatics statistical support.

The pilot will address the management of data sets in conjunction with statistical analyses. Researchers who will generate, or use, substantial amounts of data in conjunction with their statistical analyses will be required to complete a data management questionnaire before statistical support will begin. The questionnaire will identify issues such as the size of the data, where it is stored, who has access to it, and how it will be archived. The results of the data management questionnaire will help ORD enhance scientific data management.

The statistical support pilot is designed to run for approximately 6-8 months. At the conclusion of the pilot, the service will be evaluated in terms of who requested support, the types of support provided, and the level of customer satisfaction. The final report will include recommendations for strengthening statistical training and guidance in ORD.

Wednesday 3:00 PM

Ethical Dilemmas: An On-going, Interactive Discussion of Challenges Facing Environmental Laboratories
Michael F. Delaney, Ph.D., Massachusetts Water Resources Authority

A continuing series of presentations and discussions on laboratory ethics has taken place at the quarterly meetings of the Independent Testing Laboratory Association (www.itla-ma.org). ITLA is an organization of representatives of New England certified environmental

laboratories who come together for open communication in a highly competitive industry.

Over the course of the 15 sessions in the past seven years the ethics sessions at ITLA meetings have explored a wide range of topics of importance to testing laboratories. We have looked at ethics statements of professional organizations, ethics training requirements, and various technical quandaries.

The sessions have two types of regular components:

- **Ethical Challenges.** These are open-ended items for discussion. They are intended to be realistic but also thought-provoking. Where does technical judgment leave off and impropriety begin? For example: "In every extraction batch, two method blanks are included so that if one is lost in a lab accident there will still be a valid blank. What do you do if one blank is clean and the other is dirty?"

- **Labs Behaving Badly.** Ripped from the recent headlines, these are examples of people making bad choices—and getting caught. In addition to labs, these items have included treatment plant operators, university scientists, Nobel laureates, research institutions, politicians, government regulators, celebrities, and many others. The key message is that everyone is vulnerable to making wrong decisions and that laboratories should encourage open discussion of ethical issues.

Sessions have included guest speakers, review of on-line ethics training, and examination of regulatory methods and regulations. The tone is generally light-hearted and introspective. Our goal is to make laboratory ethics discussions both fun and informative. This talk will give an overview of the ITLA Ethical Dilemma series.

Data Quality versus Information Quality: Is There a Difference?
Monica Jones, IQG Team Leader, U.S. EPA OEI Quality Staff

There is an old saying that "one person's date is another person's information". Some people use the terms "information quality" and "data quality" as synonyms. Is there a difference between these two terms? This paper will give EPA's perspective on what is meant by "information quality" and "data quality".

eQMP Project: Development and Implementation of Electronic Quality Management Plans (Session)
Gary L. Johnson, U.S. EPA
Kevin J. Hull and John Tauxe, Neptune & Company

Since 1980, EPA policy has required that all Agency organizations collecting and using environmental data for Agency decision making shall develop and implement a quality management system (QMS) in programs providing products and services based on such data. The Quality Management Plan (QMP) is the key document to describe the processes and procedures in an organization's QMS, the roles and responsibilities of personnel, and how the QMS is applied to the organization's business lines; that is, the QMP documents how an organization's QMS meets the requirements of the Agency's quality policy and implementation standards.

These QMPs have been paper documents that were written by an organization, reviewed by the Quality Staff, and approved by the Office of Environmental Information (OEI) for implementation for up to five years. The paper form of the QMP has enabled the QMP to remain a stable document, but one that may not be easy to use and that may not reflect current quality assurance practices and procedures in the organization's QMS. Building on the innovative implementation of a web-based QMP by OEI, the Quality Staff has begun a project to develop a workable framework for electronic QMPs that meets all EPA policy requirements and that provides expanded flexibility and accessibility to EPA users.

The eQMP Project was initiated in the fall of 2006. The design will ensure that the eQMP structure addresses all current QMP requirements and the new requirements expected to emerge in the expanded Agency Quality Policy in 2007. A key design goal is to build into the structure the capability for many access pathways and for linkages to other web-based information sources that pertain to the QMS and its implementation. Because of the diversity of EPA organizations, the eQMP design will be tested in pilots in two Regions, one National Program Office, and one National Research Laboratory. The long-term goal will be to implement the final design structure across EPA and to migrate existing paper-based QMPs to the eQMP framework.

This presentation will describe the progress to date in developing the eQMP framework and testing its suitability in the pilots, and outline the remaining work to be completed. The presentation will offer some possible expansions of scope to an eQMP as users consider options for links to new tools and other information sources.

Wednesday 3:30 PM

External Laboratory Audits, Problems and Lessons Learned
Zachary Willenberg, Battelle Memorial Institute

The need to assess external laboratories is a regular and ongoing process that many in the quality field have to do. Very often external audits occur because the facility is contracted by your company on a project and you need to perform an audit of their contracted work. In other cases, you may be contracted by another organization to perform assessments on their behalf at facilities that are part of a larger program (e.g. air quality monitoring stations). The need for external audits is essential, especially now that quality requirements for contracted work are becoming more common and increasingly stringent. This presentation will review typical and unusual problems or issues encountered during actual external laboratory audits and the resulting lessons learned. Areas to be addressed include audit documentation, accreditation vs. non-accreditation, scheduling, auditor/auditee interactions, travel planning, and pre- and post-audit communication.

Wednesday 4:00 PM

Laboratory Data Quality and the Bottom Line
Dianne Buckheister McNeill and Robert Thielke, ECC

Laboratory and field data are the lifeblood of many remedial investigations, feasibility studies, waste characterization activities, and monitoring projects. Often the quality and nature of the data is crucial to making project decisions that have significant impact project budgets and schedules. Far too often, project managers view costs associated with

verifying and assuring data quality, at best, as a necessary cost of doing business and, at worst, as a burden to project budgets and schedules. However, data of poor or inappropriate quality can have a direct impact upon a project's bottom lime. At times, the impact can be significant. In this paper, examples of how data quality impacts the bottom line are presented, including examples of how the using low bidder can lead to profit loss. Steps to take to avoid this issue by assuring that only qualified laboratories are selected for the bidding process, as well as some good-practice follow-up procedures, are described.

Environmental Indicators
Nancy Wentworth, U.S. EPA

The Environmental Protection Agency produces and contributes to numerous indicator reports that differ in purpose, audience, scope and scale, review and data standards, and Web presence. Even the term "indicator" is loosely used, and can mean anything from scientifically robust information about environmental conditions (as in the Report on the Environment) to information demonstrating progress on specific program/policy initiatives. Moreover, the fundamental systems from which these reports are generated differ in process, age, maturity, designer credentials, and user feedback mechanisms. Under these conditions, audiences of information about environmental status and trends are faced with trying to access a highly unorganized set of information with indicators that may be contradictory and/or may vary in quality.

In this session the speaker will tee-up this issue, briefly describe the definition and criteria for ROE indicator information, and lead a dialogue session on ways the QA community may be able to help to ensure that the environmental indicator information the Agency publishes meets minimum "bar" for information quality and peer review.

Thursday 8:30 AM

The Transition of the National Environmental Laboratory Accreditation Program (NELAC) from EPA to The NELAC Institute (TNI)
Lara Autry, U.S. EPA Office of Research and Development
David Speis, Accutest Laboratories

On November 6, 2006, a giant step towards achieving a long-term goal of the environmental laboratory and monitoring communities to have a national accreditation program was realized. After years of an evolving program under the auspices of the National Environmental Laboratory Accreditation Conference (NELAC) and the Institute for National Environmental Laboratory Accreditation (INELA), both Boards of Directors took action to form The NELAC Institute (TNI). The purpose of TNI 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.

As reflected in the new name, The NELAC Institute has combined the heritage of NELAC with the consensus process of INELA into one organization. This presentation will summarize the activities leading up to the formation of TNI, describe in detail the core programs being performed by the new organization and provide information about the future of national laboratory accreditation.

Using Data from Diverse Sources - Quality Control Procedures in Database Management
Rosanna Buhl and Suzanne Deveney, Battelle

Environmental managers are often are interested in using pre-existing (secondary) data to support management decisions. This makes sense from both schedule and financial perspectives. Large environmental databases are often placed on the Internet by federal and state agencies, NGOs, and universities and are readily available for inspection and downloading. Their use reduces the need for new field sampling and the associated cost and schedule constraints. However, the compilation of data held in a variety of sources is often not straightforward and must be conducted systematically with appropriate planning and management oversight to avoid disaster. Quality control procedures must be designed and implemented to ensure that the data are standardized and usable. Queries made against a non-standardized database can result in inaccurate data summaries, incorrect conclusions, improper protection of the environment, or legal challenges.
This paper discusses quality control procedures that should be incorporated into the data acquisition, loading, and query phases of a project. Prior to selecting data from the existing databases, the critical database fields should be identified along with details such as data types and parameters of interest and temporal and spatial boundaries. Data should be pre-screened for relevance and quality. A review of the database structure, data dictionary, and primary keys ensures that the data contents and established data linkages are understood. QC check scripts, data standardization, database codes, and duplicate record elimination are key examples of data management best practices. Best practices will ensure successful merging of data sets from multiple sources into a useable centralized project database. Two case studies will be used to demonstrate a systematic, high-quality approach to data management and the importance of performing these quality control procedures. These cases will be contrasted with examples of erroneous conclusions drawn from a database developed without rigorous quality control procedures.

Discipline-specific Standards Provide the Framework For Science and Information Quality (Session)

Scientists used analytical standards and standard methods to ensure the accuracy and precision of their measurement methodologies. Project managers use data standards to ensure that information and data are captured and stored in a comprehensive, complete, and comparable manner. Information managers use standard configurations and hardware to ensure compatibility and reliability of technology operations. This presentation provides an overview of all those standards used in the EPA for science, quality, and information operations. The terminology and standards used by these discipline-specific users will be compared and contrasted and audience members will be encouraged to share solutions for ensuring that all standards are accommodated in quality planning, regardless of the discipline-specific needs.

Science, Analytical, and Quality Management Standards
Gary Johnson, U.S. EPA OEI Quality Staff

A wide variety of standards are in use in EPA to support science and analytical applications including quality management standards. This presentation explores the basis of these standards to ensure results of the quality needed based on intended use. A summary and road map to most standards is provided.

Data, Information, and Technology Standards

Jeff Worthington, Director of Quality, U.S. EPA OEI

Highly-specific technical standards are the tools that drive the consistent operation of technology and ensure the interoperability of systems as well as the comparability of data in databases. This presentation reviews the wide array of data, information, and technology standards and considers how they support the quality of EPA products and services.

Interactive Discussion With Audience Members

The speakers will present a series of points and questions to the audience members to share lessons learned and to encourage discussion in:

- How organizations at both the program level and the project level can ensure the implementation of all standards and applicable policies and procedures are implemented.
- How to identify who has the key role for implementing each kind of standard.
- How to reconcile the various roles in ensuring implementation of standards.
- How to ensure that all the elements are implemented and there is adequate oversight.

Ohio EPA's Division of Emergency and Remedial Response's (Ohio EPA-DERR) Data Verification Review Guidance Tools

Gunars Zikmanis, Nancy Zikmanis, and Timothy Christman, Ohio EPA - DERR

Introduction:

Ohio EPA - DERR designed guidance and checklists to assist regulatory reviewers in evaluating whether analytical data provided by a laboratory may contain deficiencies which could result in data quality that is questionable for use in a project. The guidance is designed to evaluate laboratory quality control processes which could document issues with the sample and data processing within the laboratory. The checklists and guidance work hand in hand to help reviewers to better understand Quality Assurance (QA) issues and concerns as they review laboratory data. Please note this guidance is not an in depth data validation process, but an initial review of data to determine if possible errors exist. This tool allows reviewers with little laboratory experience to evaluate their data usability.
It is also part of the larger Data Quality Objective (DQO) and Data Quality Assessment (DQA) processes. Therefore, additional evaluation may be necessary to fully determine the usability of the data. The full DQO/DQA process should be adhered to in order to make well informed and appropriate decisions on data usability and accuracy required for a project.

Overview of DQO/DQA Processes with a focus leading to the Data Verification Guidance:

A brief overview of the DQO process which leads up to the development of laboratory data. The DQO process outlines the development stages of a project to ensure the user is obtaining the appropriate type and quality of data for their project. The overview denotes the DQO process steps, its iterative nature, and what a reviewer would need to think about in development of quality data (Quality Assurance Project Plans). The overview proceeds into a review of the quality steps to obtain conclusions and the DQA steps; of which data verification is the second step.

Ohio EPA's DERR's Data Verification Tools!
A review of our guidance and checklist to demonstrate what our initial review would entail using these tools. The review would include a look at QA requirements for both laboratory data review and for field data reviews, including mobile laboratory data packages. By using the guidance and checklists, reviewers would note where more information is needed in a data package or where errors may be identified and require a more indepth data review. Ohio EPA's guidance is geared toward initial review only and more indepth reviews would be conducted by more qualified personnel under a data validation process.

Let's Field Test The Process!
A case study is used to demonstrate why reviewing project data is an important step to ensure a quality project. The case study points to potential problems, how they were discovered using both the DQA process and data verification review, and the final in-depth data review to document the data quality.

Thursday 9:00 AM

TNI National Environmental Laboratory Accreditation Program
Kenneth Jackson, New York State Department of Health
Dan Hickman, Oregon Department of Environmental Quality
Judith Duncan, Oklahoma Department of Environmental Quality

The purpose of the National Environmental Laboratory Accreditation Program (NELAP) is to establish and implement a program for the accreditation of environmental laboratories. The primary components of this program are:

- The recognition of accreditation bodies,
- The adoption of acceptance limits for proficiency testing developed in the Proficiency Testing (PT) Program, and
- The adoption of the laboratory accreditation system developed in the Laboratory Accreditation System Program (LASP).

The NELAP Board has final authority for implementation of the program for the accreditation of environmental laboratories. It develops the policies and procedures that govern the operation of this program, and is responsible for ensuring the successful implementation of the program. To ensure that the program is implemented effectively and to address the needs of the stakeholder community, the NELAP Board will work in cooperation with other core programs and committees within The NELAC Institute. Specifically the NELAP Board:

- Will work with the LASP in the development of the laboratory accreditation system,
- Will work with the Consensus Standards Development Program to ensure that accreditation standards developed for this program are suitable for use, and
- Will work with the PT Board to ensure that PT acceptance limits developed by the PT Board are acceptable for use.

This presentation will summarize the activities of the NELAP Board since its formation and provide information about the plans to recognize accreditation bodies.

High Quality Systems Engineering -- Using CMMI as a Process Improvement Framework
Stephen Hufford, U.S. EPA OEI

This session explores OEI's experiences in applying the Capability Maturity Model - Integrated (CMMI) as a key contract provision within EPA's largest computer programming contract.
Topics will include OEI's strategy for assessing CMMI maturity, costs and benefits of this process improvement framework, applicable process areas (with an emphasis on process and product quality assurance), and challenges in implementing process improvement.

Thursday 9:30 AM

TNI Laboratory Accreditation System Program
June Flowers, Flowers Laboratories
Judy Morgan, Environmental Science Corporation

The purpose of Laboratory Accreditation System Program is to develop a system for the accreditation of environmental laboratories that consists of the policies and procedures, interpretations, guidance documents, and any related tools used by the accrediting authorities to implement a national environmental laboratory accreditation program.

To ensure that the program is implemented effectively and to address the needs of the stakeholder community, the Laboratory Accreditation Committee will work in cooperation with other core program within The NELAC Institute. Specifically, the LAC:

- Will work with the NELAP Board and the PT Program in the development of the laboratory accreditation system,
- Will work with the Consensus Standard Development Program to ensure that accreditation standards developed for this program are suitable for use, and
- Will seek the assistance of Expert Committees when developing guidance.

In addition to developing the laboratory accreditation system, this program is also responsible for establishing a national database of accredited laboratories. This presentation will summarize the activities of the LAC since its formation.

Addressing the Address Matchers:
Geocoding Performance Metrics for EPA Facilities
Pat Garvey, U.S. EPA OEI

Background
Reliable and accurate geocoding (i.e., the process of assigning latitude and longitude values to a location) is a core requirement for the EPA's facility management system. As geocoding requirements for the EPA's user communities grow, expectations for positional accuracy and performance become all the more significant. To this end, this paper maps out the various geocoding engines EPA has at its avail and compares their functionalities within the overarching intent of providing the EPA with the most robust geocoding solutions for all of its facility management needs. The three vendor geocoding packages used in this analysis include Oracle Geocoding 10g, ESRI ArcGIS Server (ArcSDE 9.2), and ArcIMS Route Server 9.1. Each vendor's best configuration practices will be applied to ensure consistency in deployment.

Methods
In this analysis, 108,000 EPA site locations that have missing latitude and longitude values will be randomly selected from the EPA Facility Registry System (FRS) to encompass all EPA regions and program offices. The records will be independently geocoded within the same server environment using Dynamap 2000®, version 16.1 street network data. The records pulled from the FRS database will have a minimum requirement of sufficient information to produce a geocoded latitude and longitude (records containing a street address, a city, and a state).

To confirm these latitude and longitude values, several precision and performance metrics will be utilized for each geocoding engine. Percentage of 'hits' per 'missed' values will be used to surmise the degree of compatibility of the geocoding algorithms used. Performance will be measured by timing the duration from start to finish for each geocoder. Positional accuracy will be assessed based on a comparison of 100 arbitrary GDT parcel centroid coordinates matched against expected address points. Each set of results will be tested for general variations in positional accuracy using Oracle Spatial procedures and the ESRI Geostatistical Analyst. Correlations of latitude and longitude values from each geocoding engine will be presented as well as a covariance analysis to ascertain significant trends within each engine.

Results
Results from this analysis will address relative positional accuracy for each geocoding engine, percentage of matches vs. missed locations, and coding times for each engine. Specific resource measurements will include data preparation needs for each geocoding engine, CPU memory utilization per engine, and engine parse times.

QA Guides for Improving the Data Usability Assessment Section in Project Plans
Pat Mundy, U.S. EPA OEI Quality Staff

Project personnel are often vague about how to assess project results in relation to project objectives. QA staff who review QA project plans have little guidance as to what is acceptable, so frequently make few suggestions. As a result, many project plans have little information in the section for reconciling data to user requirements (D3).

Drawing from detailed project planning guidance and examples from several sources, this presenter will highlight the planning tasks relevant to data usability and discuss how these tasks "play out" in the translation of project objectives to results. This is important to QA managers because comparing the written plan to the project results can be a tool to evaluate the effectiveness of systematic planning.

Thursday 10:30 AM

TNI Proficiency Testing Program
Carl Kircher, Florida Department of Health
Carol Batterton, The NELAC Institute

The purpose of the Proficiency Testing Program is to ensure that an effective proficiency testing system exists to support the accreditation of environmental laboratories. The PT Board has the following duties in implementing this program:

- Provide assistance to the Board of Directors on the selection of a Proficiency Test Provider Accreditor (PTPA_.

- Monitor the PTPA to assure that it is following the requirements set forth by the organization.
- Facilitate an annual caucus on proficiency testing.
- Review and evaluate PT data for the purpose of determining the appropriateness of proficiency test study limits.
- Provide recommendations to the NELAP Board as to acceptance limits.

This presentation will summarize the activities of the PT Board since its formation.

Quality-in-Depth: The Nexus of Quality Assurance And Information Assurance (Security) (Session)
Jeffrey Worthington, Director of Quality, U.S. EPA OEI

Many people feel there are really two essential issues for information:
- Information Assurance (i.e., information security) and
- Information Quality.

Information Assurance is the process to ensure the confidentiality, integrity, and availability of information services. Quality assurance is the means by which managers plan and ensure the quality of products and services.

A key concept in information assurance is to ensure security through a *defense-in-depth* approach. *Defense-in-depth* identifies various perspectives in the overall information system and encourages establishing specific protocols at each level. Quality professionals typically focus on the overall management system and the project planning components. Quality activities include: 1) assuring the quality of processes which impact the product and service quality and 2) establishing the capability to measure and understand the quality of the products and services.

Quality professionals may benefit from the information assurance *defense-in-depth* model. Because information is one of the enterprise's critical resources, information presentation and availability can be just as important as the program and project processes which established initial information content quality. Once that content has entered a system, a new model can be applied, a *quality-in-depth* approach. This suggested approach requires recognition that there are various levels, disciplines, and distinct processes which ensure quality. These include:
- Overall information system quality (which may be inherited from another organization)
- Web content/presentation quality
- Application quality
- Data base (stewardship) quality
- Program/project quality (science quality if science project, general product quality if an administrative product)
- Customer service quality

This model is not the same as Michael Porter's "value chain" model where value is imparted to a product on its path to the customer. This *quality-in-depth* model recognizes that there is no single product; what the customer gets from EPA is a matrix-product and in some cases, a product within a product. In either case, quality must be assured at each level. This presentation explores the information assurance process and provides a "how-to" for developing and implementing a "quality-in-depth" approach to quality system management that can be incorporated into a quality management plan.

Novel Electronic Tools for Improving and Streamlining Quality System Operation (Session)

Clyde M. Hedin, Yogeshkumar C. Patel, Arthur B. Clarke, and Garabet H. Kassakhian, Ph.D., Shaw Environmental, Inc.
John D. Nebelsick, U.S. EPA OSRTI

Shaw Environmental's USEPA Quality Assurance Technical Support (QATS) Program supports the USEPA's Superfund Contract Laboratory Program (CLP) by developing performance evaluation samples, scoring laboratory results, conducting data audits and on-site laboratory audits, and evaluating EPA methods. The Shaw QATS Program's Quality Management System (QMS), as required by its USEPA contract, has been ISO 9001 certified since 2001. As a result of standard mandated customer focus and continual improvement, and working with the Client to enhance customer satisfaction, QATS developed a number of novel and effective electronic tools to streamline its QMS and increase productivity. The workshop will include a *hands-on demonstration* of four electronic tools developed to streamline QMS management, along with a discussion of their applicability to your QMS.

The ***Integrated Quality System (IQS)*** is a database application that supports core QMS management functions at Shaw's QATS Program. It electronically documents customer communications, customer satisfaction reports, non-conformances, preventive actions and continual improvements, manages Standard Operating Procedure (SOP) documentation, SOP acknowledgment signatures, employee training needs assessments, and training matrices. Information from the IQS is extracted annually for monitoring performance trending for metrics including positive and negative customer feedback, corrective and preventive actions, and continual improvements. The ***Software Tools Records System*** is a data driven web site and centralized database for recording changes and modifications to in-house software applications. In addition to replacing the hardcopy verification and validation documentation with an electronic change control, the system allows for electronic sign-off and/or comment by organization management and the Quality Assurance Manager. The ***Data Archive System*** is an electronic report repository, accessed by web links which can directly access and open any and all source data files and any raw data that comprise specific deliverables. The ***Electronic Deliverable System*** is a Microsoft Share-point web-portal which allows secure transfer of deliverables to clients, to be downloaded at their convenience. In addition to reducing deliverable turnaround times by replacing the traditional express mail or e-mail, this system allows transfer to multiple clients and includes a toggle feature for customer approval.

Visual Sample Plan Expert Mentor: An Aid to Correctly Using VSP (Session)

Brent A. Pulsipher, John E. Wilson, and Richard O. Gilbert
Pacific Northwest National Laboratory

Visual Sample Plan (VSP) software, which can be downloaded free from www.dgo.pnl.gov/vsp, can be used to determine the number and location of environmental samples for a variety of sampling objectives. VSP is based on the Data Quality Objectives (DQO) systematic planning process, with particular emphasis on Steps 6 and 7 that deal with quantitative and statistical issues related to determining the number of sampled needed. Recently, an effort has begun to develop and embed an "Expert Mentor" into VSP. The purpose of the Expert Mentor is to provide guidance, help, recommendations, and warnings to the VSP user to (1) help prevent inadvertent misuse of VSP, (2) help novice users understand how VSP works, and (3) to help ensure that the number and location of

samples obtained using VSP are appropriate for the particular sampling situation at the site being studied. This paper will discuss and demonstrate the progress made to date in implementing the Expert Mentor.

The completed Expert Mentor is expected to include the following four components: (1) Pre-Design Assistance to help implement the first 5 steps of the DQO systematic planning process and to help users set up in VSP the site maps, floor plans, target populations, etc. that are needed, (2) Sample-Design Guidance for selecting the sampling design (e.g., judgmental, simple random, grid, sequential) that is most appropriate for the site, (3) Parameter Input Guidance on selecting appropriate values of performance criteria for the site, such as the probabilities of making decision errors, and (4) Data Analysis Guidance to provide assistance and recommendations with data analyses such as testing assumptions and computing statistical tests.

This paper focuses on progress to date on components 1 and 2. The presentation will include demonstrating the use of the Expert Mentor to help ensure that VSP is not used to determine the number of samples without adequate attention to systematic planning, the development of the conceptual site model, the definition of "sample support," and the practical sampling, sample handling, laboratory and measurement methods needed to assure that representative samples from the target population are obtained. Additional demonstrations of the methods developed to support implementation of site maps and other visual aspects of VSP, as well as the approach developed to provide guidance in choosing the most efficient design will be provided.

Thursday 11:00 AM

TNI Consensus Standards Development Program

Kenneth Jackson, New York State Department of Health
Jane Wilson, NSF International

The purpose of the Consensus Standards Development Program is to develop standards for the accreditation of environmental laboratories. The NELAC Institute (TNI) is a voluntary consensus standards development organization that is committed to the development of standards for use by accreditation bodies. Standards are being developed that will be widely applicable, and will therefore promote a uniform national program of environmental laboratory accreditation. These standards are modular, allowing their assembly into a series of volumes, each specifically designed for a stakeholder group (Laboratories; Accreditation Bodies; Proficiency Test Providers; Proficiency Test Provider Oversight Bodies). A volume is also being prepared for Field Sampling and Measurement. The consensus process used by TNI in standards development will be described.

Thursday 11:30 AM

TNI Advocacy Program

Jerry Parr, The NELAC Institute

The purpose of this program is to promote a national program for the accreditation of environmental laboratories by:

- Establishing relationships with other organizations (e.g., ACIL, AWWA, WEF) that have an interest in accreditation issues,

- Establishing relationships with EPA program offices,
- Developing presentations and papers to promote national accreditation,
- Developing presentations and papers to promote The NELAC Institute,
- Providing outreach at national, regional and local meetings, and
- Assisting with publication of the member newsletter.

This presentation will summarize the activities of the Advocacy Committee since its formation.