EPA

U.S. Environmental Protection Agency

April 13–16, 1999

Regal Cincinnati Hotel

Cincinnati, Ohio

18th Annual National Conference on

Managing Quality Systems for Environmental Programs

Quality for the Next Millenium

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APR 13 1999

OFFICE OF
RESEARCH AND DEVELOPMENT

Welcome to the 18th Annual National Conference on Managing Environmental Quality Systems. On behalf of the U.S. Environmental Protection Agency (US EPA) and the Quality Assurance Division (QAD), I thank you for taking time from your busy schedule to participate in this important conference.

The world around us is changing. We stand on the threshold of a new century and a new millennium. The dynamics of the business place have shown that the old ways of doing things will not work well in the future. Accordingly, quality management concepts and practices must also change in order to provide sufficient and adequate support to evolving environmental programs in government and in business.

The theme of this Conference is *Quality for the Next Millennium*. The solutions to today's problems may require new tools and approaches for use by quality professionals. We have assembled a conference program to inform you about emerging tools and approaches and to engage you in a constructive dialogue. We need to learn from you and become better equipped to meet your future needs in the environmental arena. Accordingly, this Conference will include sessions on Performance Based Measurement Systems, implementation of the National Environmental Laboratory Accreditation Program (NELAP), "secondary" data use, quality auditing, and science and law, among others. We have brought together professionals and practitioners on these subjects to share their perspectives with you. Your challenge is to engage them, to learn from them, and to provide your perspectives to them. Our goal is to leave Cincinnati better informed and better equipped to meet the needs of the next millennium.

I look forward to meeting you during the week. I believe that this will be an exciting and productive week as we seek to continually improve our quality practices and our management of quality systems.

Nancy W. Wentworth
Director
Quality Assurance Division

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THE 18TH ANNUAL NATIONAL CONFERENCE ON MANAGING QUALITY SYSTEMS FOR ENVIRONMENTAL PROGRAMS:

Quality for the Next Millennium

April 11-15, 1999
Regal Cincinnati Hotel
Cincinnati, Ohio

CI99 TECHNICAL PROGRAM OUTLINE

SUNDAY, APRIL 11, 1999

PRECONFERENCE TRAINING COURSES

8:30 am - 12:00 pm **Training Course: "Integrating Quality Assurance into Project Development" (Two Days)** Prerequisites: Completion of "Introduction to the Data Quality Objectives [DQO] Process" or equivalent experience.

The purpose of this two-day workshop is to show project managers responsible for planning and implementing projects involving environmental data collection how to integrate adequate and sufficient quality assurance(QA) and quality control (QC) into the planning of such projects. By the end of this workshop, participants will be able to :(1) explain the necessity of planning for data collection; (2)describe the linkages among Data Quality Objectives (DQOs), Data Quality Indicators (DQIs), and QA Project Plans; and (3) discuss issues related to selecting methods for assessing data quality.

This is a highly interactive workshop that will demand active co-operation between participants that have been organized into independent teams attempting to find a solution to a complex project. The workshop will be an integrated mixture of lecture, example, and the use of simulated project teams to provide the necessary inputs to achieve success at each stage of the project's life-cycle. This workshop will provide attendees with a more complete understanding of how quality assurance affects the entire project.

Workshop Materials: Agency publications EPA QA/G-4 (Guidance for the Data Quality Objectives Process), EPA QA/G-5 (Guidance on Quality Assurance Project Plans), and EPA QA/G-9 (Guidance for Data Quality Assessment: Practical Methods for Data Analysis) will be used or referenced as text materials together with supplementary papers and programs.

Instructors:

- John Warren (U.S. EPA, Quality Assurance Division, Washington, DC)
- Malcolm Bertoni (Research Triangle Institute, Washington, DC)
- Nancy Hassig (Battelle Pacific Northwest Laboratories, Richland, WA)

12:00 noon **Lunch Break**

1:00 - 5:00 pm **Training Course: "NELAP Accrediting Authority Assessor Training"**
(Enrollment is limited to State and Federal Employees.) (Continued on Monday)

The National Environmental Laboratory Accreditation Program (NELAP) recognizes State and federal organizations as Accrediting Authorities, which, in turn, accredit environmental laboratories in the United States. NELAP assessments of Accrediting Authorities are conducted by NELAP-trained assessors. These assessors must be either State of federal employees. NELAP assessors review applications for NELAP recognition and make recommendations on whether the accreditation program should be recognized. This course is intended to potential NELAP Accrediting Authority assessors. The course includes a full day of instruction on NELAP assessments and one-half day on interviewing and listening skills. Students must complete the entire course in order to receive credit for the training. Note: This course does not teach specific skills associated with laboratory assessments.

Instructors:

- Elizabeth Dutrow (U.S. EPA, Quality Assurance Division, Washington, DC)
- Fred Siegelman (U.S. EPA, Quality Assurance Division, Washington, DC)

Training Course: "Integrating Quality Assurance into Project Development"
(Continued from morning)

MONDAY, APRIL 12, 1999

8:30 am - 12:00 noon **Training Course: "Integrating Quality Assurance into Project Development"**
(Continued from Sunday)

Training Course: "NELAP Accrediting Authority Assessor Training"
(Continued from Sunday)

Training Course: "Introduction to EPA Quality System Requirements" (One Day)

In July 1998, EPA Order 5360.1 CHG 1 was issued to update the Agency's requirements for quality systems supporting environmental programs. This course provides an introduction to these requirements and discusses some of the key "tools" available for planning, implementing, and assessing the effectiveness of the quality systems. Attendees completing this course will have a better understanding of EPA quality requirements, including those for extramural agreements. (This course replaces the "QA Orientation" course.)

Instructors:

- Tom Dixon (U.S. EPA, Quality Assurance Division, Washington, DC)
- Linda Kirkland (U.S. EPA, Quality Assurance Division, Washington, DC)

Training Course: "Introduction to the Management Systems Review Process"

The U.S. EPA has developed the Management Systems Review (MSR) process to assist users in conducting management assessments of the suitability and effectiveness of quality systems. The MSR utilizes interviews, file reviews, and objective evidence of quality systems documentation to compile the needed information for the assessment. This one-day course includes a detailed discussion of the MSR process and how to plan, implement, evaluate, and report the results of the assessment to managers of quality systems, and training in interviewing and listening skills.

Instructors:

- Gary Johnson (U.S. EPA, Quality Assurance Division, Research Triangle Park, NC)
- Diann Sims (U.S. EPA, Quality Assurance Division, Washington, DC)

12:00 noon **Lunch Break**

1:00 - 5:00 pm	**Training Course: "Integrating Quality Assurance into Project Development"** (Conclusion) **Training Course: "NELAP Accrediting Authority Assessor Training"** (Conclusion) **Training Course: "Introduction to EPA Quality System Requirements for Environmental Programs"** (Conclusion) **Training Course: "Introduction to the Management Systems Review Process"** (Conclusion)
7:00 - 9:00 pm	Regional QA Managers Meeting (EPA Only) "Accreditation of State Laboratories"

Managing Quality Systems for Environmental Programs:

Quality for the Next Millennium

TUESDAY, APRIL 13, 1999

8:00 am **Welcome and Introduction of Guests**

Nancy Wentworth (Director, Quality Assurance Division)

8:15 am **Introduction of Keynote Speaker**

Nancy Wentworth (Director, Quality Assurance Division)

8:20 am **Keynote Address:**

RADM Frank C. Collins, Jr., USN (Ret.)
Frank C. Collins Associates/Survival 21
Alexandria, VA

9:00 am **The New Information Office: What Does this Mean for Quality at EPA?**

Nancy Wentworth (Director, Quality Assurance Division)

9:30 am **Break**

10:00 am **Highlights and Reports from QAD**

- Changes to Extramural Agreement Requirements
- Status Report on Requirements and Guidance Documents
- Status Report on Training Program
- Status Report on Peer Review
- Status Report on Management Assessments
- NELAP Implementation Status at EPA

11:30 am **Lunch Break**

1:00 pm **Technical Plenary Session: Report of the Inter-Governmental Task Force on Data Quality**

This plenary session will provide a status report on the Inter-Governmental Task Force on Data Quality and its efforts to harmonize quality assurance practices on environmental data collection, analysis, evaluation, and use across the Government user sector. Perspectives from EPA and other Federal departments and agencies will be presented.

Session Manager: Mike Carter (U.S. EPA, Federal Facilities Restoration and Reuse Office, Washington, DC)

Speakers:

- Jackie Sample (U.S. Navy, Naval Sea Systems Command, Charleston, SC)
- Stan Morton (U.S. Department of Energy, Idaho Falls, ID)

2:00 pm **Technical Plenary Session: Implementing Performance Based Measurement Systems in a Regulatory Setting - Issues and Answers (Panel Discussion)**

This plenary session will examine current issues affecting the implementation of Performance-Based Measurement Systems (PBMS) in a regulatory setting like that at EPA. The session will include an update on the current status of PBMS implementation at EPA, discussion of the practicality aspects of PBMS implementation, and perspectives from the user community.

Panel Moderator: Nancy Wentworth (Director, Quality Assurance Division)

Panelists:

- TBA

3:00 pm **Break**

3:30 pm **Discussion Breakout Sessions**

Following the plenary PBMS session, breakout sessions are planned to enable small group discussions of key issues to occur. Each group will be asked to consider one or more relevant issues and to develop responses based on consensus. Facilitators and recorders will be assigned to capture the results and to report them to the plenary closing session on Thursday.

5:00 pm **Adjourn Tuesday activities**

WEDNESDAY, APRIL 14, 1999

8:00 - 9:30 am **Session W11: QA for Secondary Data Use - Lessons Learned**

Developing and implementing appropriate QA and QC for data collected from sources other than direct measurements is a growing issue. Data are increasingly compiled from models, computerized data bases, the literature, etc. for use in environmental decision making. This session examines some experiences and techniques in the application of QA/QC to such "secondary data."

Session Manager: Patricia Lafornara (U.S. EPA, QAD, Edison, NJ)

Speakers:

- "Secondary Data Use - Lessons Learned" - Paul Mills (DYNCORP, Reston, VA)
- "ORD's Science Information Management System - Support for Data Usability" - Linda Kirkland (U.S. EPA, QAD, Washington, DC)
- CEIS Paper - Ronald Shafer (U.S. EPA, CEIS, Washington, DC)

Session W12: Implementing NELAP - Status Report (Panel Discussion)

A status report on the development and implementation of the National Environmental Laboratory Accreditation Program (NELAP) will be presented, including the status of NELAC standards, progress in accrediting authority recognition, and accomplishments in laboratory accreditation.

Session Manager: Jeanne Mourrain (U.S. EPA, QAD, Research Triangle Park, NC)

Panelists:

- "NELAP Activities and Status" - Elizabeth Dutrow (U.S. EPA, Washington, DC)
- "ELAB Recommendations" - Jerry Parr (Catalyst, LLC, Evergreen, CO)
- "State Experience" - Richard Sheibley (Pennsylvania Department of Environmental Protection, Harrisburg, PA)

Session W13: The QA Professional as an Expert Witness in Court

The QA professional as a factual/expert witness Previous "Science, law, and QA" sessions focused on laboratory fraud, and case law affecting the admission of junk science in the courtroom. This session will address why a QA professional would be called as a factual/expert witness, how to prepare for the courtroom, conduct oneself in the presence of a jury, and how to prevent being called.

Session Manager: George Michael Brilis (U.S. EPA, NERL, Las Vegas, NV)

Speakers:

- Dave Preston (Partner, Varnum, Riddering, Schmidt, and Howlett, LLP, Grand Rapids, MI)
- Jeffrey Worthington (U.S. EPA, Quality Assurance Division, Washington, DC)
- George Michael Brilis (U.S. EPA, NERL, Las Vegas, NV)

9:30 am **Break**

10:00 - 11:30 am **Session W21: Environmental QA/QC Practices - Emerging Issues in Research**

The application of QA/QC to environmental programs often entails a variety of concepts, practices, and procedures. This session examines experiences from several QA/QC practices that have been applied to a variety of environmental issues in a research setting but which may be applied to other organizations as well.

Session Manager: Nancy Adams (U.S. EPA, APCD/NRMRL, Research Triangle Park, NC)

- "Facility Manuals: Documentation Unique to Research Facilities" - Shirley Wasson (U.S. EPA, APCD/NRMRL, Research Triangle Park, NC)
- "Auditing New Technologies: Issues and Approaches to QA in an R&D Setting" - Nancy Adams (U.S. EPA, APCD/NRMRL, Research Triangle Park, NC)
- "Quality Assurance Project Plan Development for Hydrological Simulation Program FORTRAN (HSPF) Model - a Progress Report" - Jean Chruscicki (U.S. EPA, Water Division, Region 5, Chicago, IL)

Session W22: Implementing QA in Environmental Labs

The implementation of QA in environmental analytical laboratories involves a broad array of technical issues and considerations. This session examines several issues confronting laboratories as they seek to implement appropriate quality practices in their operations.

Session Manager: Fred Siegelman (U.S. EPA, Quality Assurance Division, Washington, DC)

Speakers:

- "NELAC and PBMS: the Good, the Bad, and the Ugly" - Jerry Parr (Catalyst, LLC, Evergreen, CO)
- "Automation in Laboratory Information Management Systems: Myths and Virtues" - Cesar Muedas (Brown and Caldwell, Nashville, TN)
- "Visual Estimation: Damage to Data Quality Through Improper Technique" - Denise K. MacMillan (U.S. Army Corps of Engineers, Omaha, NE)

Session W23 - A Sample Is a Sample is a Sample? A Comparison of Different Water Media Sampling and the QA Implications of Different Methods and Protocols

Safe drinking water and clean surface water are some of our most important natural resources, and a considerable amount of effort is spent collecting and analyzing water samples. This session will address problems in sampling different water media; sampling objectives; components of sample collection (design, sampling methods, sample handling); laboratory methods; and data analysis. The focus of the session is equally weighted on which methods and equipment to select (i.e., quality of data), and where, when, and how much to sample (i.e., quantity and representativeness of data).

This session seeks to address the following questions:

- *Are all water samples the same?*
- *What is common/distinct among different water media (i.e., groundwater, surface water, drinking water, lakes and streams) in data collection and in QA protocols?*
- *How do sampling techniques for different water media affect analysis of sampling results?*
- *What aspects of sampling have the greatest impact on the quality of results?*
- *Where should most of the sampling dollars be spent?*

Session Presenters: John Warren (U.S. EPA, QAD, Washington, DC)
Nancy Hassig (Battelle PNL, Richland, WA)

11:30 am **Lunch Break**

1:00 - 2:30 pm **Session W31: Information Management for the QA Professional (Mini-Workshop)**

This session will help participants to understand the roles that policy, technology, and coalition-building all play in developing and maintaining effective information management infrastructures. The participants will also learn what areas they need to address during the requirement phase, how to analyze problems that arise during implementation and operation, and how to bring together the best teams for building effective information systems.

Session Presenters: Greg Fraser and David Blair (Information Technology University, Central Intelligence Agency, Washington, DC)

Session W32: Environmental QA/QC Practices - Emerging Issues on Questionable Practices

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The application of QA/QC to environmental programs often entails a variety of concepts, practices, and procedures. This session examines experiences from several QA/QC practices that have been applied to a variety of environmental issues involving questionable practices.

Session Manager: Frederic Siegelman (U.S. EPA, Quality Assurance Division, Washington, DC)

- "The Use and Abuse of QA/QC Samples in Environmental Data Acquisition" - Emma P. Popek (IT Corporation, Martinez, CA) and Garabet Kassakhian (Consultant, Glendale, CA)
- "Questionable Practices in the Laboratory" - Joseph Solsky (U.S. Army Corps of Engineers, Omaha, NE)

Session W33: Benchmarking - Processes and Lessons Learned

Benchmarking has been an effective tool for quality assurance quality control managers in manufacturing operations in assessing the effectiveness of systems and processes through comparative analysis. This practice has not been as widely applied to environmental work as manufacturing. This session examines some of the basics of benchmarking and the application of these techniques to current work.

Session Manager: Esperanza Renard (U.S. EPA, Quality Assurance Division, Edison, NJ)

Speakers:

- "Benchmarking - Processes and Lessons Learned" - Silky Labie, Florida Department of Environmental Protection, Tallahassee, FL)

- "Lessons Learned While Using the Technical Project Planning (TPP) Process" - Heidi Novotny and Larry Becker (U.S. Army Corps of Engineers, Washington, DC)

- "Beyond Environmental Data - Using the Malcolm Baldrige Criteria to Assess Organizations" - Mark Doehnert (U.S. EPA, ORIA, Washington, DC)

2:30 pm **Break**

3:00 - 4:30 pm **Session W41: Information Management for the QA Professional (Mini-Workshop continued from Session W31)**

Session W42: Putting QA into Operation: Planning, Implementation, and Assessment

This session examines techniques employed by quality professionals in order to plan, implement, and assess the effectiveness of QA practices applied to environmental programs.

Session Manager: Tom Dixon (U.S. EPA, Quality Assurance Division, Washington, DC)

Speakers:

- "Operational Quality Assurance - 'Completing' the End State" - Dave Bottrell and Kevin Kelkenberg (U.S. DOE, Office of Site Operations) and Tim Harms (U.S. DOE, Office of Waste Management)

- "The Significance of Analytical Error in Project Planning, Implementation, and Assessment" - Cliff J. Kirchmer (Washington State Department of Ecology, Olympia, WA)

- "Pitfalls in Performance Auditing" - Nancy Adams (U.S. EPA, APPCD/NRMRL, Research Triangle Park, NC)

Session W43: Environmental QA/QC Practices - Oversight and Implementation

The application of QA/QC to environmental programs often entails a variety of concepts, practices, and procedures. This session continues to examine experiences from several QA/QC practices that have been applied to oversight and implementation issues.

Session Manager: Esperanza Renard (U.S. EPA, Quality Assurance Division, Edison, NJ)

Speakers:

- "Superfund QA Oversight - Where Do We Go from Here?" - Joan Fisk and Duane Geuder (U.S. EPA, Office of Emergency and Remedial Response, Washington, DC) and Conrad Kleveno and Marguerite Jones (DYNCORP, Reston, VA)

- "An Alternative Approach to Quality Assessment Sample Allocation" Daniel Michael (Neptune and Company, Los Alamos, NM) and Katherine Campbell (Los Alamos National Laboratory, Los Alamos, NM)

- "Remedial Process Quality Assurance and Optimization" - Javier Santillan, Jeffrey Perl, and Chung Yen (USAF, AFCEE/ERC, Brooks AFB, TX)

4:30 pm **Adjourn Wednesday activities**

THURSDAY, APRIL 15, 1999

8:00 - 9:30 am **Session T11: Cost of Quality - Real Dollars or Otherwise**

Determining the cost of quality has often been a struggle, particularly for environmental operations wherein QA/ QC is largely a prevention mechanism. When "poor data" are prevented from occurring because effective QA/QC has been applied, it is difficult to determine the value of the savings in dollars. Increasingly, however, techniques are emerging that enable users to determine the cost of quality (or the lack thereof). This session examines some techniques and related issues.

Session Manager: Jeffrey Worthington (U.S. EPA, QAD, Washington, DC)

Speakers:

- "Measuring the Cost of Quality - Analytical Program Considerations" - Paul Mills (DYNCORP, Reston, VA) and Jeffrey Worthington (U.S. EPA, QAD, Washington, DC)

- "An Evaluation of the EPA Quality Assurance Annual Report and Work Plan from the Perspective of a Traditional Cost of Quality Model" - Lora Johnson (U.S. EPA, NERL, Cincinnati, OH)

- "Efficient QA Through Consolidated Metrology" - Paul W. Groff (U.S. EPA, APPCD/NRMRL, Research Triangle Park, NC)

Session T12: Practical Approaches to Quality Auditing (Mini-Workshop)

Quality auditing is a continually evolving science. While there are basic principles of auditing that underpin all types of audits, auditing environmental programs often requires mastery of additional skills and techniques due, in large part, to the diversity and breadth of the environmental sector. This mini-workshop provides some practical approaches to quality auditing of environmental programs and is intended to augment existing auditing skills. The session will be highly interactive and attendees will be asked to contribute to the discussions from their own experiences.

Session Presenter: Craig R. Mesler (QMS, Uncasville, CT)

Session T13: Implementing QA in Health and Ecological Research

The implementation of suitable and effective QA/QC to health and ecological research studies may not always follow traditional practices. Such is the nature of research in general and especially in health and ecological settings in which well-known QA/QC tools and techniques may not be applicable. This session examines experiences by the research community in seeking solutions to implementation problems.

Session Manager: Joe LiVolsi (U.S. EPA, NHEERL/AED, Narragansett, RI)

- "Quality Assurance Reviews at the National Health and Environmental Effects Research Laboratory, Mid-Continent Ecology Division, Duluth" - Allan R. Batterman (U.S. EPA, NHEERL/MED, Duluth, MN)
- "Quality Assurance for the Lake Michigan Mass Balance Modeling Project" - W.L. Richardson, D.D. Endicott, and K.R. Rygwelski (U.S. EPA, NHEERL/MED, Grosse Ile, MI)
- "NHEERL Approach to Technical Systems Reviews of Health Effects Studies" - B. Michael Ray and Brenda T. Culpepper (U.S. EPA, NHEERL, Research Triangle Park, NC)

9:30 am **Break**

10:00 - 11:30 am **Session T21: Field Analytical Methods - Experiences and Lessons Learned**

The use of field analytical methods offers considerable promise in speeding up the collection and analysis of field samples. This session discusses the use of such techniques from several perspectives including Superfund site remediation, legal defensibility, and lessons learned from actual application of such methods.

Session Manager: Robert Hitzig (U.S. EPA, Office of Emergency and Remedial Response, Washington, DC)

Speakers:

- "Using Field Methods - Experiences and Lessons Learned" - Bart Simmons (California EPA, Berkeley, CA)

- "Applying Field Analytical Methods: Case Studies and Lessons Learned" - Kira Lynch (U.S. Army Corps of Engineers, Seattle, WA)

- "Using Field Methods in Superfund Projects" - Robert Hitzig (U.S. EPA, Office of Emergency and Remedial Response, Washington, DC)

Session T22: Practical Approaches to Quality Auditing (Mini-Workshop continued from Session T12)

Session T23: What's Happening in International Standards and Why You Should Care

Recent and forthcoming changes in international consensus standards pertaining to quality and environmental management and laboratories may have implications for environmental programs in the government and private sectors. Currently, ISO 9001 and ISO 9004 on quality management are being revised. Within a few months, ISO 14001 and ISO 14004 on environmental management will also be revised. Both sets of standards are being made more "compatible" with each other and the quality and environmental auditing standards are being combined into a single standard. In addition, ISO Guide 25 is being elevated to an international standard as ISO 17025. This session examines the changes taking place and discusses possible implications for traditional environmental programs which may affected by these standards.

Session Manager: Gary Johnson (U.S. EPA, Quality Assurance Division, Research Triangle Park, NC)

Speakers:

- "Overview and use of Consensus Standards" - Jeffrey Worthington (U.S. EPA, Quality Assurance Division, Washington, DC)

- "Revisions of the ISO 9001 Quality Management System and ISO 14001 Environmental Management Systems Standards - Increased Compatibility or Confusion?" - Gary Johnson (U.S. EPA, Quality Assurance Division, Research Triangle Park, NC)

- "Integration of the ISO 10011 Quality Auditing and ISO 14010 Environmental Auditing Standards - What Does It Mean to the User?" - Michael A. Ross (Registrar Accreditation Board, Milwaukee, WI)

- "ISO Guide 25 to International Standard ISO 17025" - Paul Mills (Mentorprises, Inc., Reston, VA)

11:30 am **Lunch Break**

1:00 - 2:30 pm **Plenary Wrap-up Session, Reports from Breakout Sessions**

The accomplishments of the conference will be summarized. In particular, the results from the breakout sessions on PBMS implementation issues will be presented.

Session Moderator: Nancy Wentworth (U.S. EPA, Quality Assurance Division, Washington, DC)

2:30 pm **Adjourn Conference**

FRIDAY, APRIL 16, 1999

8:00 am - 12:00 noon EPA QA Managers Meetings (Closed to public)

18TH ANNUAL NATIONAL CONFERENCE ON MANAGING QUALITY SYSTEMS FOR ENVIRONMENTAL PROGRAMS

Quality for the Next Millennium

April 11-15, 1999
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Cincinnati, Ohio

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QAD	WALDRON, Betty	564-6830	8724R	waldron-betty	565-2441
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Acromania:

OAROffice of Air and Radiation
- OAP — Office of Atmospheric programs
- OAQPS — Office of Air Quality Planning and Standards
- OMS — Office of Mobile Sources
- ORIA — Office of Radiation and Indoor Air

OARM Office of Administration and Resource Management
- OA — Office of Administration

OECA Office of Enforcement and Compliance Assurance
- FFEO — Federal Facilities Enforcement Office
- OC — Office of Compliance
- OCEFT — Office of Criminal Enforcement, Forensics and Training
- OEJ — Office of Environmental Justice
- OFA — Office of Federal Activities
- ORE — Office of Regulatory Enforcement
- OSRE — Office of Site Remediation Enforcement

OIG Office of Inspector General

OP Office of Policy
- OSPED — Office of Strategic Planning and Environmental Data

OPPTS Office of Prevention, Pesticides and Toxic Substances
- OPP Office of Pesticide Programs
  - EFED — Environmental Fate and Effects Div
  - HED — Health Effects Division
  - IRSD — Information Resources and Services Division
- OPPT — Office of Pollution Prevention and Toxics

ORD Office of Research and Development
- NCERQA — National Center for Environmental Researchand Quality Assurance
- NCEA — National Center for Environmental Assessment
- NHEERL — National Health and Environmental Effects Research Laboratory
  - AED — Atlantic Ecology Division (Narragansett RI)
  - ECD — Environmental Carcinogenesis Div (RTP)
  - GED — Gulf Ecology Division (Gulf Breeze, FL)
  - MED — Mid Continent Ecology Division (Duluth, MN)
  - NTD — Neurotoxicology Division
  - WED — Western Ecology Division (Corvallis OR)
- NRMRL — National Risk Management Research Laboratory
  - APPCD — Air Pollution Prevention and Control Division (RTP, NC)
  - LRPCD — Land Remediation and Pollution Control Division (Cinti, OH)
  - SPRD — Subsurface Protection and Remediation Division
  - STD — Sustainable Technology Div (Cinti, OH)
  - WSWRD — Water Supply and Water Resources Division (Cinti, OH)
- NERL National Exposure Research Laboratory
  - AMD — Atmospheric Modeling Division (RTP, NC)
  - EERD — Ecological Eposure Rsearch Division (Cinti, OH)
  - ERD — Ecolosystem Research Division (Athens, GA)
  - ESD — Environmental Sciences Division (Las Vegas, NV)
  - MCEAD — Microbiological and Chemical Exposure Research Division (Cinti, OH)
  - HEASD — Human Exposure and Atmospheric Research Division (RTP, NC)

OSWER Office of Solid Waste and Emergency Response
- OERR — Office of Emergency and Remedial Response
- OSW — Office of Solid Waste
- OUST — Office of Underground Storage Tanks
- FFRRO — Office of Federal Facilities Reclamation and Reuse

OW Office of Water
- AIEO — American Indian Environmental Office
- OGWDW — Office of Ground Water and Drinking Water
- OST — Office of Science and Technology
- OWM — Office of Waste Management
  - MSD — Municipal Support Division
- OWOW — Office of Wetlands, Oceans, and Watersheds

Other QA People
- OCFO — Office of the Chief Financial Officer
- ORO — Office of Regional Operations
- GLNPO — Great Lakes National Program Office
- CBP — Chesapeake Bay Program
- OIRM — Office of Information Resources Management

CURRENT ACTIVITIES OF THE INTERGOVERMENTAL DATA QUALITY TASK FORCE

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SUMMARY

In March, 1997, the EPA Office of Inspector General (OIG) issued a report titled *Laboratory Data Quality at Federal Facility Superfund Sites (E1SKB6-09-0041-7100132)*. In this report and others, the OIG has raised concerns about the quality of the environmental data upon which decisions critical to protection of human health and the environment are based. The issues raised by the OIG focus on the need for effective, intergovernmental Quality Systems and processes for developing Quality Assurance Project Plans. The OIG stated that problems due to current deficiencies lead to poorly designed Quality Assurance Project Plans, deficient Data Quality Objectives, serious problems with laboratory data quality and insufficient EPA oversight.

Recommendations in the report for the Assistant Administrator for Solid Waste and Emergency Response (OSWER) include:

- Develop a national quality management plan,
- Assess the adequacy of DOD's and DOE's environmental data management systems,
- Issue guidance that specifies regional oversight responsibilities for Federal facility Superfund cleanups, and;
- Issue program specific QAPP guidance.

To address the recommendations, the Federal Facilities Restoration and Reuse Office (FFRRO) led the formation of the Intergovernmental Data Quality Task Force (IDQTF), composed of representatives from EPA Program Offices, Regional Offices, DoD, DOE and other Federal Agencies.

CURRENT ACTIVITIES

The representatives from the Regional Offices and the other Federal Agencies have made it clear that they will participate in the IDQTF only if their organizations derive significant benefit from that participation; simply helping OSWER address Office of Inspector General recommendations is not sufficient justification for their participation. The goals of the IDQTF are as follows:

- To develop a written agreement on what constitutes and adequate QA program,
- To develop guidance/framework that outlines the roles and responsibilities of the EPA (Headquarters and Regions) and Federal Facilities with regard to QA/QC oversight, and;
- To develop guidance for Federal Agency-wide requirements and procedures regarding data quality.

The additional goals of the Departments of Defense and Energy involve the establishment of national consistency in the implementation of the quality assurance guidance and framework. They quite understandably express the need and benefits of being held to a single standard of quality assurance/quality control instead of different requirements in each Region and under every EPA media program. This standardization of monitoring requirements across the entire Agency was the driver for the establishment of the Environmental Monitoring Management Council a number of years ago.

The members of the IDQTF from the Regions have also made it clear that their participation is strongly motivated by the need to conduct Quality Assurance business in a more efficient and effective manner in the future. In too many instances, basic quality assurance functions, such as the development, review and approval of Quality Assurance Project Plans (QAPPs), has become a perfunctory exercise that accomplishes very little. We heard anecdotal accounts of QAPPs that are largely boilerplate, based on little or no thought given to their real purpose. Reviewers of QAPPs recount experiences where they had to look through 20 pages of language cut and pasted from previous QAPPs just to find one relevant paragraph. Apparently it is not unusual to find the wrong site name on the QAPP because it was a part of the cut and paste from another QAPP.

With these goals and objectives in mind, the IDQTF is working to develop Quality Assurance requirements with enough specificity to provide standardization, while allowing flexibility to deal with project specific needs. The use of the term "requirements" has become an important consideration if the efforts of the IDQTF are to be effective. The IDQTF is concerned that simply providing yet another set of guidance will not accomplish the national consistency, effectiveness and efficiency that are needed to meet the needs of the federal quality assurance community. Quality Assurance activities across the Agency could also benefit from the same approach to conducting the business of quality.

The documentation the IDQTF is developing is based on the American National Standard *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*, ANSI/ASQC E4-1994 (E-4). While compliance with the E-4 standard is required for all Federal agencies, that compliance takes many forms. Therefore, the IDQTF concluded that the only way to achieve consistency in the application of E-4 is to provide much more detail and specificity for implementation. Requirements documents are under development for QA Management Systems, corresponding to Part A of E-4, and for the collection and evaluation of environmental data, corresponding to Part B of E-4.

The review comments for the first draft of the QA Management Systems document made it clear that the relationship between E-4, *EPA Requirements for Quality Management Plans, EPA QA/R2* (R2) and the IDQTF must be explicit. The introduction of a third QA Management requirement, in the absence of a specification of the precedence and the relationship of all the documents, produces confusion, not consistency. IDQTF requirements must either stand alone with no need to refer to E-4 or R2, or they must exactly follow the format of the source document. They must provide a solid requirements base to establish consistency and they must not cause confusion in implementation.

For detailed guidance on the preparation of QAPPs, the IDQTF selected the Region I QAPP guidance as a starting point. The other Federal agencies and all EPA Regional offices have been asked to provide a critical review, comments and recommendations on the Region I guidance as a model for a national standard. The IDQTF representatives from the other Federal Agencies and the EPA Regional Offices were adamant that development of requirements and guidance on the collection and evaluation of environmental data must be led by those who are actually involved with that collection and evaluation. The IDQTF agreed with that position and the work group leaders are all from the Regions.

CONCLUSION

The objective of the IDQTF is to establish national, intergovernmental standards for quality assurance, leading to consistency and reciprocity between EPA Regions and other Federal Agencies. These standards must be clear and concise and they must be implemented consistently. The goal of the effort is the production of environmental data of known and acceptable data that can be used to establish environmental restoration and waste management requirements and monitor compliance with regulations and compliance agreements.

SECONDARY DATA USE: HOW GOOD ARE THE DATA?

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SUMMARY

Users who plan to "mine" primary data from computerized databases for a secondary purpose must specify, "How good do the data need to be?" With these established criteria, the primary data can be evaluated to determine "How good are the data?" Unless the primary data are specifically qualified, flagged, identified with quality indicators, cataloged, segregated, and stored by quality characteristics, the data may not meet secondary use needs. How can the data be accessed?

What must you know about the various primary data sets--censored data, outlier treatment, estimated results, screening data, etc.? Standards are needed that allow users to decide whether the data are suitable for their (secondary) use. What should those standards be? How can they be developed and applied to environmental data? What decisions don't require validated data? Which ones do? Is data quality adequately described by DQO levels and PARCCS indicators? What about other data without such descriptors--*caveat emptor*?

This paper discusses and suggests standards for, and uses of, secondary data, using the Contract Lab Program (CLP) laboratory data reports as a source of primary analytical data. The CLP has specified the answers to many of these questions, and serves as a model for discussion.

INTRODUCTION

(EPA Order 5360.1 CHG 1, July 1998); (EPA July, 1998) refers to "secondary data" as "environmental data collected for other purposes or from other sources, including literature, industry surveys, compilations from computerized data bases and information systems, results from computerized or mathematical models of environmental processes and conditions." Primary data, actual empirical results from environmental measurements, are used to make the decision called for in a project's DQOs. Secondary data use could be to "mine" the data for other purposes, such as how well samplers, labs, methods, etc. perform. Secondary data, then, is derivative, using previously collected data for decision-making purposes, other than its original intent. So how can you determine that the data collected by someone else for a different purpose can meet the data quality needs of your project? What would some of those uses be? Secondary data could be used to identify trends and tendencies for programmatic and conceptual reporting. Examples of the possible uses of secondary data from environmental databases include:

1) Building a profile of a lab, to determine its performance against established criteria over time, and compare it with a desired model as well as other labs. What indicators would be used to determine if there were problems requiring on-site visits for detailed inspections? The power of the database and secondary data usage is in the identification of patterns that would not be

visible if looked at on a project-specific basis. Trends and changes would not be noticed unless some comparisons were made.

2) Plot the number of samples and matrixes by lab to determine if there are capacity and related quality trends—more samples mean more problems, or are the SDGs too much for a lab's capacity?
3) Toxic Release Inventories and information from EPA reports have been used by independent environmental activist organizations to provide Web-accessible maps of "Hazardous Waste Sites in your Zip Code." The data may not be qualified regarding timeliness, currency, quality, or associated risk. It is dangerous to release unqualified information for general use. The quality of the data in the database that would be included in such reports must be known and documented (i.e., CLP criteria).

CLP DATA: OF KNOWN AND DOCUMENTED QUALITY

The CLP 's analytical services provide customers with various options for combinations of analytical parameters, data turnaround times, and detection limits. CLP services help data users to make the best use of their limited analytical testing resources while reducing the overall cost of analytical services at the site. CLP operations bring efficiencies in sharing information regarding labs' performance and quality, uniform methods and variances, standardized monitoring, timely and effective PE samples, prompt validation, consistent treatment of performance problems, and overall lower prices.

Quality: By specifying standardized services, the Quality Assurance Project Plan's elements are defined for: analytical method, preventative maintenance for laboratory equipment, calibration and corrective action for laboratory equipment, chain of custody forms for sample shipment, analytical precision and accuracy (including quantitation limits), laboratory quality control requirements, data management and documentation for laboratory analysis including the structure and format of the data package.

Standardized data submissions and evaluations are comparable over time. Readily available program-wide statistics are available for cross-lab comparisons, and trending.

Performance results and lessons learned are shared quickly with all program users.

Legal: Contracts are standardized, with known performance requirements and conditions, and liquidated damages clauses. Records retention, management, and access procedures protect data integrity. Constant monitoring reveals suspicious patterns of activity, prompting investigation for possible fraud. Environmental data of known and documented quality are produced that can withstand independent review and confirmation.

Technical: A central repository of historic and current analytical data is available through the information infrastructure, as well as the tools to assess these data. Performance of standardized methods is captured in a database, and method options, waivers, exceptions, and improvements can be tracked and shared. This will enable Performance Based Measurement Systems to be implemented effectively.

Data Validation and Assessment: CLP data deliverables allow different levels of validation and assessment - from a review of sample results to a full evaluation of raw analytical data. Data are validated as hardcopy and electronic versions are available immediately, not held as raw data are until after all testing is completed. Delays are avoided in detecting and solving problems. All contracts awarded under a solicitation have identical requirements, ensuring delivery of consistent analytical data.

PRINCIPLES OF SECONDARY DATA USE:

The quality of the primary data in any database is the paramount consideration for any secondary usage, in applications like data mining, and has to be considered in data warehousing. Is "Garbage In, Garbage Out" (GIGO) true? Yes! Identify and segregate data by quality, before it is stored in any database! The following are additional recommended guiding principles developed in response to questions about secondary data usage. The CLP approach to the production and review of primary data is referenced as a model.

How are the data accessed? The CLP stores data electronically, and in hard copy format. Requests for the data are handled by Regional and contractor points of contact, based on EPA authorizations to see the data. Data may be in summary form, electronic format (diskettes, tapes, computer hard drives), and in raw form. It may be complete in one set (Sample Delivery Group, or SDG), or spread over time across a number of data packages (multiple SDGs in a case) by a particular analytical method (Statement of Work). The user must specify the data desired.

Who is responsible for data quality? First, responsibility is held by the originators of the data. In the CLP, the laboratories append data qualifiers as required by the Statement of Work (SOW) for the particular analysis. Second, the CLP program Contract Laboratory Analytical Support Services (CLASS) contractor applies semi-automated and manual Contract Compliance Screening (CCS) software programs that check each data package's electronic deliverables for completeness and compliance with the SOW. The CLASS contractor uses an automated Data Assessment Tool (DAT) to review the electronic data and provide EPA Regions with PC-compatible reports, spreadsheets, and electronic files to facilitate transfer of analytical data into Regional databases. QC data are examined for all the analytical results and evaluated against applicable review criteria. Third, the Regional data users conduct a manual hardcopy data review, using the National Functional Guidelines for Data Validation, and apply a different set of qualifiers based on the data's intended use. Each responsible party in this process has the responsibility not to misuse the data, to twist it from its original purpose or stretch it to cover more. How those qualifiers are used later, by others, must be addressed by providing as many indicators of data quality as possible on the original data set.

How can primary data quality be determined? Data quality can be described by DQO levels, PARCCS indicators, and other data acquisition elements. (EPA's QA/R-5, October 1998) In (EPA, October 1998) Elements B1 through B10 list the manner in which data acquisition elements (primary data use) are to be described. Element B1, Sampling Process Design, says to classify all measurements as either "critical" that is, required to achieve project objectives, or "non-critical" for information purposes only. For sampling (B2) and analytical methods (B4) selected, the method citations should specify exactly which options were selected. B5, Quality

Control, requires specification of the QC procedures needed for each sampling, analysis, or measurement technique, and how the QC statistics were calculated. B9 discusses data acquisition requirements for decision-making that uses data from non-direct measurement sources, such as computer databases, programs, literature files, and historical databases. "Define the acceptance criteria for the use of such data in the project, and discuss any limitations on the use of the data resulting from uncertainty in its quality. Document the rationale for the original collection of data and indicate its relevance to this project." B10, Data Management, is a key in this discussion. "Describe the project data management scheme, tracing the path of the data from their generation in the field or laboratory to their final use or storage...Describe or reference the standard record-keeping procedures, document control system, and the approach used for data storage and retrieval on electronic media. Discuss the control mechanism for detecting and correcting errors and for preventing loss of data during data reduction, data reporting, and data entry to forms, reports, and databases." By specifying standardized services, the CLP Quality Assurance Project Plan's elements are defined for the categories of:

- analytical methods,
- preventative maintenance for laboratory equipment,
- calibration and corrective action for laboratory equipment, chain of custody forms for sample shipment,
- analytical precision and accuracy (including quantitation limits),
- laboratory quality control requirements,
- data management/documentation, including the structure and format of the data package.

<u>How should data be qualified?</u> Flag the data with qualifiers, and add the "reason codes" to show why it was qualified. Also indicate whether the data are resubmitted/corrected. From Q/R-5, D1, Data Review, Validation, and Verification Requirements: "State the criteria used to review and validate—that is, accept, reject, or qualify—data in an objective and consistent manner." D2, Validation and Verification Methods: "Describe the process used for validation and verifying data." D3, Reconciliation with User Requirements: "Describe how the results obtained from the project or task are reconciled with the requirements defined by the data user or decision maker...Describe how issues will be resolved and limitations on the use of the data will be reported." CLP data are properly assessed using the National Functional Guidelines.

<u>What about other data without such descriptors?</u> Data that do not clearly state the data acquisition elements and acceptance criteria are less certain, and should be used with greater care in drawing any conclusions. The CLP provides qualifiers for indeterminate or estimated data.

<u>What are the detection and reporting limits, the effects of errors throughout the measurement system?</u> These must be reported with the original data and maintained with any secondary use, to include adjustments made to reporting limits. The CLP requires reported data to be adjusted for % moisture content of samples, dilutions, sub-optimal sample volumes, or other reasons. CLP labs report their Method Detection Limits (organics), Instrument Detection Limits (inorganics) and must meet Contract Required Reporting Limits for specified analytes. Quality control sample information is reported in each data package so the user can readily determine the affects of sample matrixes upon recovery and reproducibility, and if any contamination occurred during sample shipment, storage, and processing.

Who should be the keeper of the data—EPA or its designates? Should the data be maintained in its original form, or in a reduced form? The producer of the original primary data has the responsibility for maintaining its security and integrity. The CLP lab maintains the original raw data until EPA requests it, or for the duration specified in the laboratory's contract. Copies of the data are distributed from the lab for data assessment of the contract deliverables. If the data are released in any form, the qualifiers associated with the data acquisition elements must be taken as an integral part of the data.

How should any transformations be documented? The database should have a tracking system that indicates who accessed it, when, and what changes were made to the data. Database security procedures are essential in maintaining data that can be trusted. Any data reduction of the primary data set must be described, stating the algorithms used and the extent of transformations, their purposes and effect. It must be possible to reconstruct the data back to its original source.

How current is the information? Were the latest methods used, or were out-dated ones applied? Version control for methods must document the specific sampling and analytical methods used to produce primary data. CLP contracts specify the version of methods to be used, and the deliverable requirements. Traffic Reports and Chain of Custody documentation describe the samples collected as grab or composite samples, and as one-time-only or continuous, quarterly, or annual monitoring. The exact location of the sample in time and space is recorded.

What models were used, and what are their weaknesses? Is the quality of data acceptable for the model? Are the scales of measurement used by the model consistent with that of the original data? If pollutant transport models, for example, were used, their version must be noted, along with any information about the inputs that applied. Are project-specific data appropriate for use in a programmatic model?

How should data be used for ecological risk assessment? Assumptions about the data, and the decisions made must be clearly stated. For example, "non-detect" data may be treated as "zero," or as ½ the MDL, or the CRDL, or the IDL.

How much of the data were actually validated, and to what extent? 100% full CLP validation lends more confidence to the data set than only 10% validation of a summary level package, with no raw data examined. If a percentage check were to be applied, what data were assessed, and which were not? What conclusions and qualifications were made and applied across the entire data set? Was there a semi-automated screen, or full manual validation, or both? How do these agree? These amounts may vary depending on individual projects' needs. The CLASS contractor applies the DAT check to 100% of the electronic data.

What decisions don't require validated data? If you are interested in patterns, or relative performance, rather than ultimate decision-making, perhaps validated data aren't required.

How were outliers treated in the data set? The originators should state if there were any data "censored," or not used for some reason. The CLP deliverables package must indicate data that failed acceptance criteria, and the attempts made to correct laboratory problems.

CONCLUSION

The CLP data specifies a known level of data quality, provides quality indicators and a system for verifying and maintaining established quality levels. Other analytical programs may start from scratch to establish project-specific DQOs, and to set up all the programs necessary to qualify analytical data, including auditing programs, data validation systems, etc. With data specifically qualified by CLP programs, secondary data user can readily determine the quality of the primary data.

REFERENCE LIST

"EPA Quality Manual for Environmental Programs." EPA Order 5360.1 CHG 1 (July 1998), USEPA, Office of Research and Development, National Center for Environmental Research and Quality Assurance, Quality Assurance Division, Washington, DC.

"EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations." EPA QA/R-5, External Review Draft Final, (October, 1998) USEPA, Office of Research and Development, National Center for Environmental Research and Quality Assurance, Quality Assurance Division, Washington, DC.

"USEPA Contract Laboratory Program National Functional Guidelines for Organic Data Review," EPA540/R-94-012 (February, 1994)

"USEPA Contract Laboratory Program National Functional Guidelines for Inorganic Data Review," EPA540/R-94-013 (February, 1994)

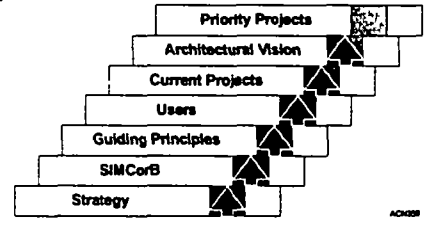
Linda Kirkland, Ph.D., Robert Shepanek, Ph.D
Gary Collins, Ph.D.
U.S. EPA Office of Research Devel.

ORD's Science Information Management System - Support for Data Usability

Linda Kirkland, Ph.D., Robert Shepanek, Ph.D. and
Gary Collins, Ph.D.
USEPA Office of Research and Development

Introduction: Implementation Planning Process

- Goals and vision derived from strategic documents and program plans.
- Definition of coordination and leadership roles.
- Articulation of guiding principles used throughout SIMCorB activities.



- System IM requirements derived from user and client needs.
- Assessment of current IM organization and ORD activities.
- Articulation of an IM system vision and architecture.
- Definition of specific implementation projects.

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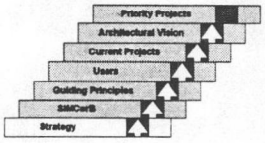
Strategy: ORD Strategic Plan



- Develop scientifically sound approaches to assessing and characterizing risks to human health and environment.
- Integrate human health and ecological assessment methods into a comprehensive multimedia assessment technology.
- Provide common sense and cost-effective approaches for preventing and managing risks.
- Provide credible, state-of-the-art risk assessments, methods, models, and guidance.
- Exchange reliable scientific, engineering, and risk assessment/risk management information.
- Provide leadership in identifying, assessing, and preventing emerging environmental issues.

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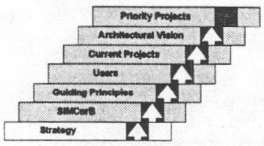
Strategy: IM Component Goals



- Planning
  - ORD will integrate IM planning into its research planning process to ensure ORD information is made available.
- Awareness
  - ORD will provide the awareness, tools, and services needed to make stakeholders aware of ORD information.
- Access
  - ORD will provide communication paths and equipment required to allow stakeholders access to ORD information.
- Usability
  - ORD will provide the planning, policies and standards, training, and user tools required to make ORD information available to stakeholders.

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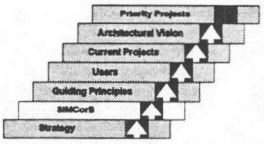
SIMCorB: Science IM Coordination Board



- Charter and Organization
  - ORD—Chief Information Officer
  - SIMCorB participation
  - Project Management Strategy
  - SEAC—Executive Sponsorship of SIMCorB projects

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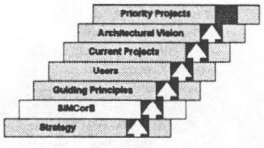
SIMCorB: Science IM Coordination Board



- SIMCorB Standing Sub-Groups
  - Requirements Definition and Planning (NCEA and NERL, co-leads)
  - Data Administration and Quality Assurance (NCERQA lead)
  - Systems Engineering and Operations (NRMRL and ORMA, co-leads)
  - Advanced Technology Evaluation and Modeling (NERL lead)
  - Science Direction (NHEERL and OAA, co-loads)
  - Outreach and Liaison

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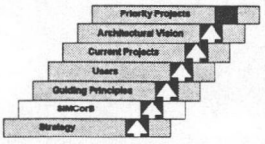
SIMCorB: Science IM Coordination Board



- SIMCorB Operations
  - Evaluation and adoption of scientific information management policies.
  - Recommendations on priorities and strategic IM direction.
  - Coordination and leadership on cross-cutting issues and multi-project initiatives.
  - Sponsorship, oversight, and management of IM development projects.

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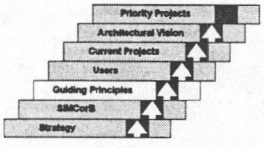
Guiding Principles



- Information Management
  - Quality of ORD scientific information must be known.
  - Information systems/documentation demonstrating quality must be developed.
  - Methods and costs must be recognized and documented.
  - Scientific data must be made publicly available in a timely manner.

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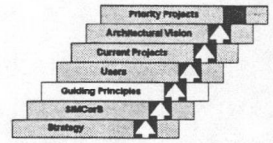
Guiding Principles



- Policy
  - ORD will be a catalyst for information standards.
  - ORD will identify, prototype, and produce information standards internally, within EPA, and across other agencies.
  - ORD will adopt and/or re-evaluate existing agency IM policies and procedures.
  - ORD IM must be cost-effective in deployment of information technology and associated procedures.

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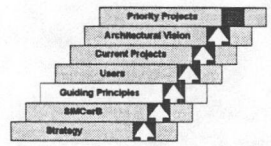
Guiding Principles



- Data and Data Administration
  - Metadata should be created for all data; data should not be distributed without accompanying metadata.
  - All projects are subject to documentation, quality control, archival, and directory recording policies adopted by ORD.
  - Implement common definition and tracking of information pedigree, archiving, quality, and physical security.

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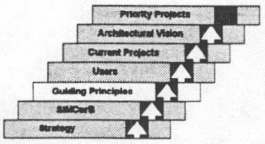
Guiding Principles



- System Design
  - Economy, efficiency, and interoperability should be key criteria in system development.
  - IM systems must support the risk management/risk assessment mission of ORD.
  - System designs should employ a common language to define function and operation of system components.

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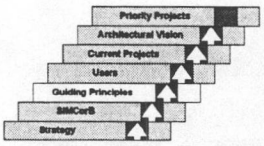
Guiding Principles



- Operations
  - Operations should provide secure, quality services.
  - Operations should facilitate sharing of data and software.
  - Operations should enable effective communication of project and scientific information.

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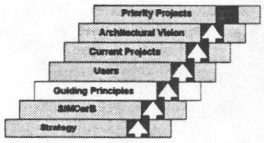
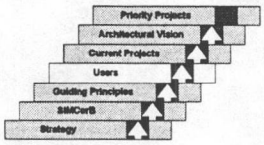
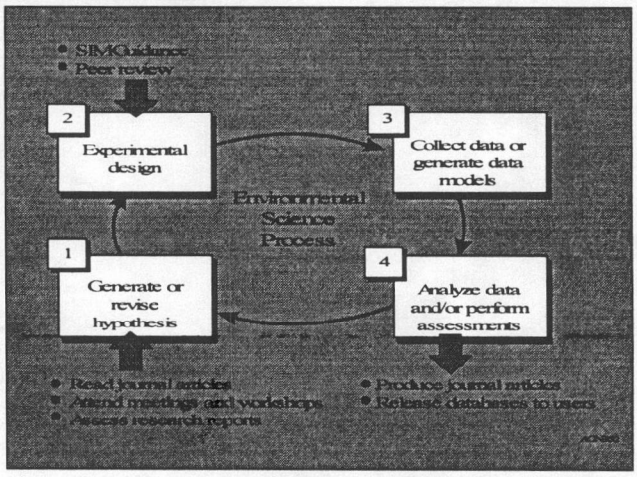


Guiding Principles

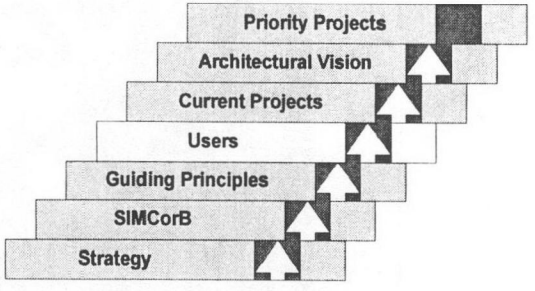
- Outreach and Liaison
  - ORD information should be made available to users in a timely manner and in a usable format.
  - Facilitate collection and recognition of user requirements.
  - ORD should understand the scientific IM direction of other organizations and promote collaboration where appropriate.

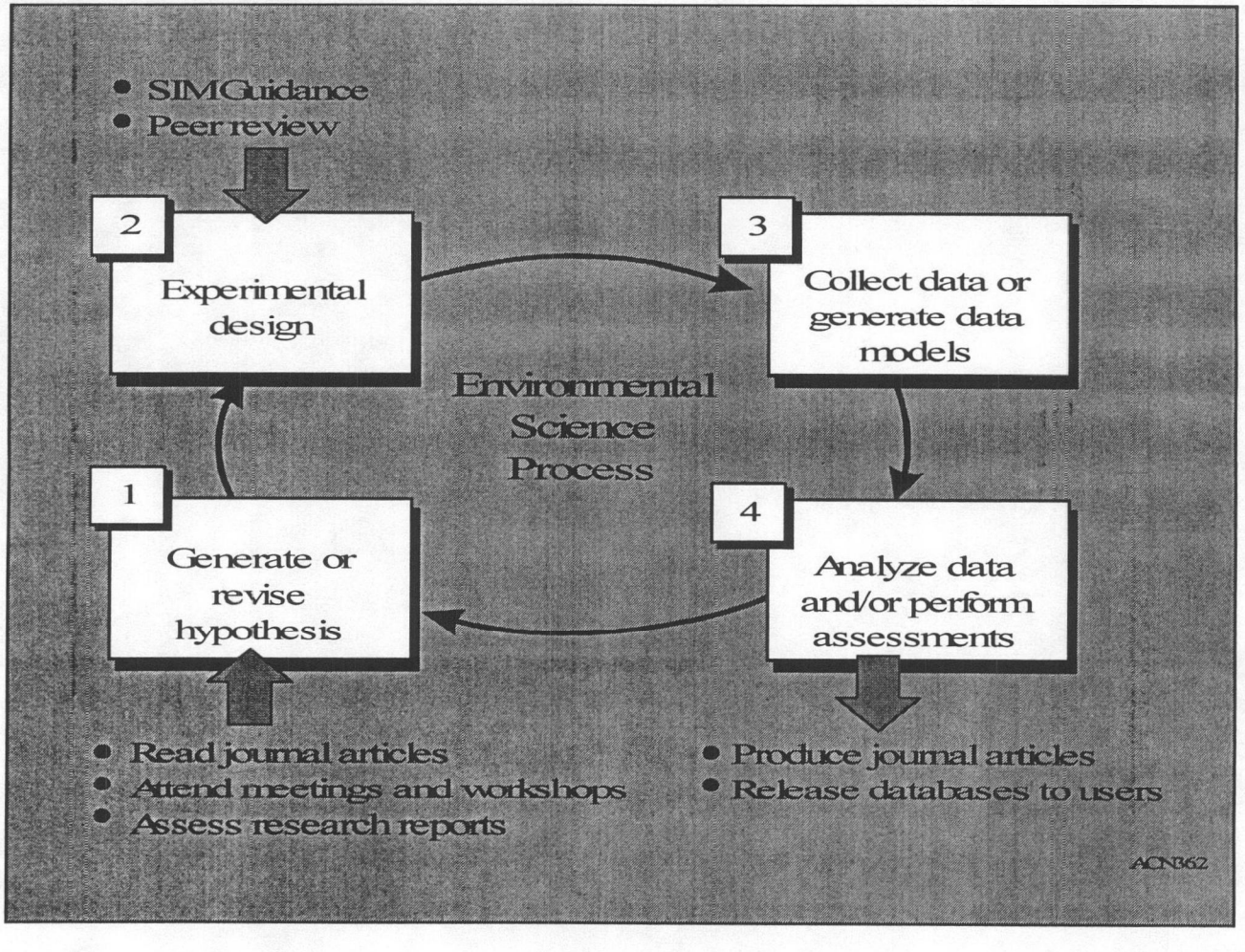


ORD User Requirements

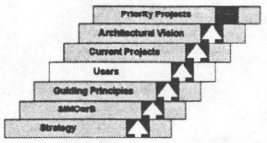


ORD User Requirements





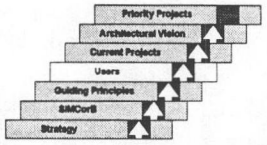
ORD User Requirements



- Requirements for ORD Research Scientists
  - Planning/Design
  - Data Access
  - Data Integrity
  - Modeling, Visualization, and Analysis Tools
  - Documentation
  - Queries and Reports
  - Methods, Indicators, and Reference Databases
  - IM Research Tools

ORD/SIMCorB

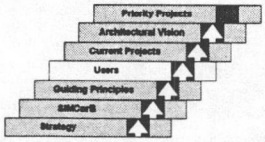
ORD User Requirements



- Requirements for ORD Executives and Managers
  - Researcher Support
  - Cost Efficiency
  - Cooperative Inter-office Efforts
  - Risk Assessment/Risk Management
  - Accountability
  - Publicity

ORD/SIMCorB

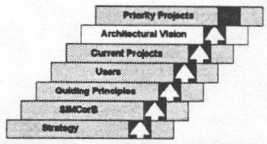
ORD User Requirements

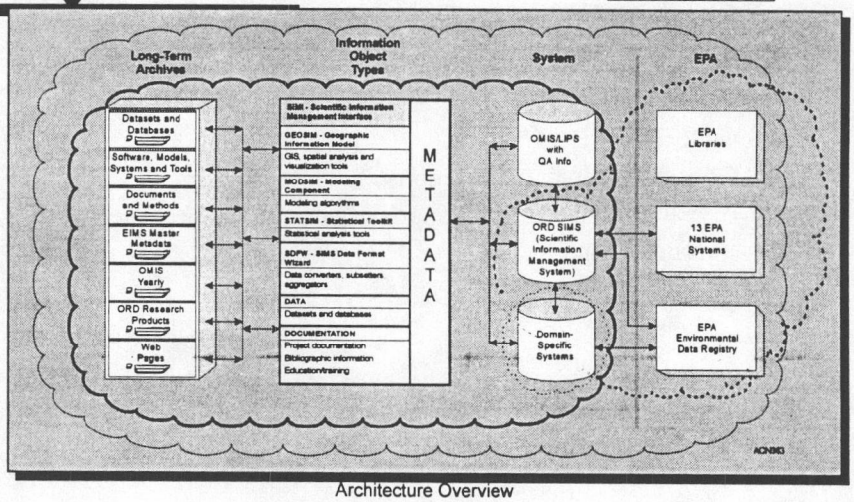


- Requirements for External Users
  - Information Access
  - Data Integrity

ORD/SIMCorB

Architecture: Overview

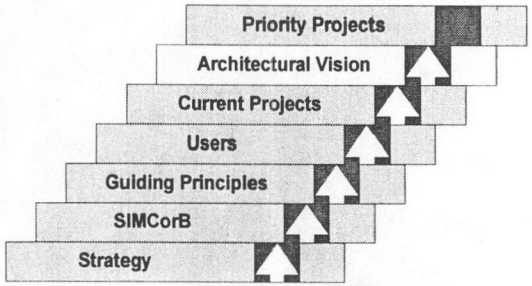




Architecture Overview

ORD/SIMCorB

Architecture: Overview



Long-Term Archives

- Datasets and Databases
- Software, Models, Systems and Tools
- Documents and Methods
- EIMS Master Metadata
- OMIS Yearly
- ORD Research Products
- Web Pages

Information Object Types

- **SIMI - Scientific Information Management Interface**
- **GEOSIM - Geographic Information Model**
  - GIS, spatial analysis and visualization tools
- **MODSIM - Modeling Component**
  - Modeling algorythms
- **STATSIM - Statistical Toolkit**
  - Statistical analysis tools
- **SDFW - SIMS Data Format Wizard**
  - Data converters, subsetters, aggregators
- **DATA**
  - Datasets and databases
- **DOCUMENTATION**
  - Project documentation
  - Bibliographic information
  - Education/training

METADATA

System

- OMIS/LIPS with QA Info
- ORD SIMS (Scientific Information Management System)
- Domain-Specific Systems

EPA

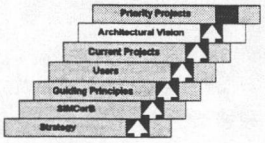
- EPA Libraries
- 13 EPA National Systems
- EPA Environmental Data Registry

ACN363

Architecture Overview

ORD/SIMCorB

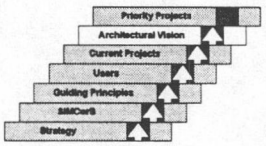
Architecture: Data and Information



- Data and Information Architecture
  - Health-General
  - Hazard Identification
  - Dose-Response
  - Exposure Assessment
  - Health-Risk Characterization
  - Ecological-General
  - Problem Formulation
  - Characterization of Exposures
  - Characterization of Effects

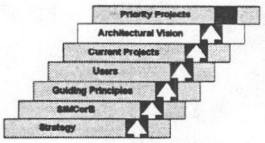
ORD/SIMCorB

Architecture: Function

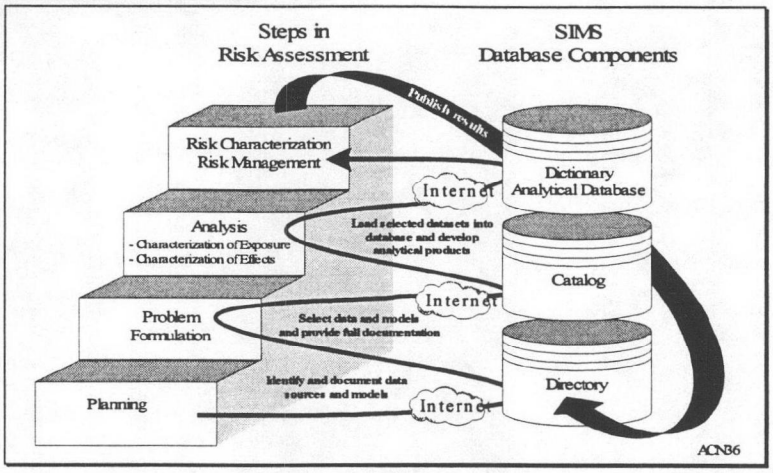


- Function Architecture
  - Data administration and security
  - Project definition and tracking
  - Metadata management
  - Human health and ecological risk assessments
  - Spatial analysis
  - Development of methods, models, and indicators
  - Report publication
  - Data distribution
  - Administration

ORD/SIMCorB

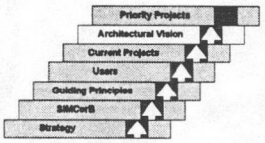


Architecture: Function



Risk Assessment and SIMS

ORD/SIMCorB

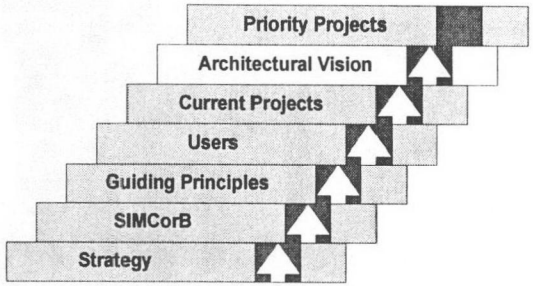


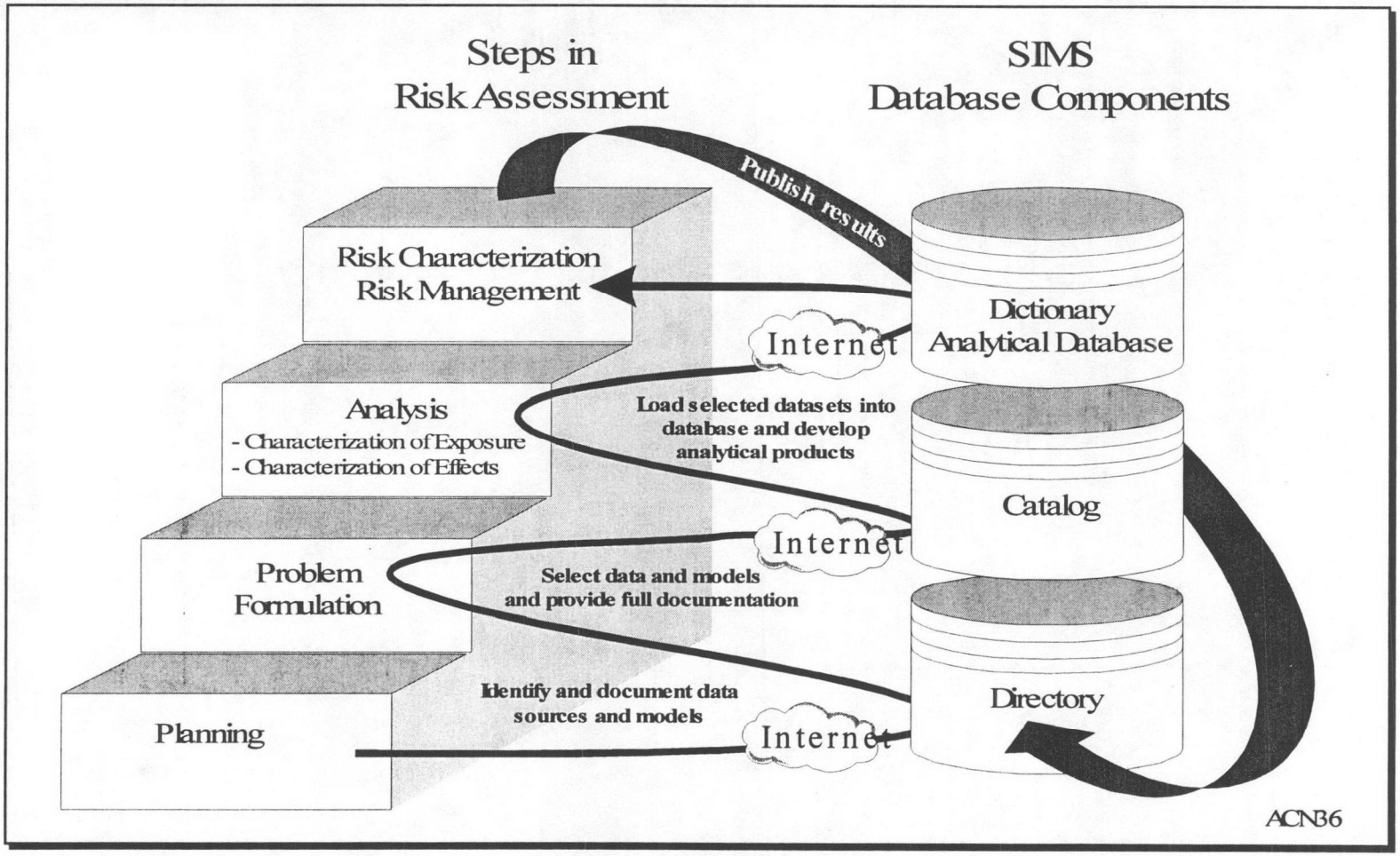
Architecture: Network

- Network Architecture
  - ORD Central Computing Network
  - ORD Laboratories and Centers
  - Public Access to ORD Information

ORD/SIMCorB

Architecture: Function

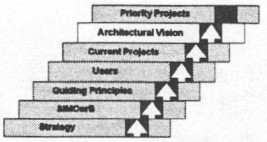




Risk Assessment and SIMS

ORD/SIMCorB

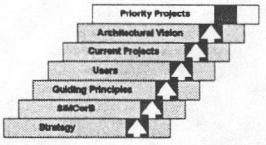
Architecture: Organization



- Organizational Architecture
  - NHEERL
  - NCERQA
  - NCEA
  - NERL
  - NRMRL

ORD/SIMCorB

Priority Projects: Organization



- Activities Supporting the Organization of ORD Scientific Information Management
  - Architecture for Development of the Knowledge Base for Scientific Information Management Across ORD.
  - Enhance Capacity for Scientific Information Management Coordination in ORD Laboratories and Centers.
  - Fully Develop SIMCorB Coordination and Advisory Capability.

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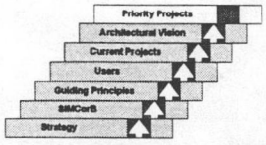
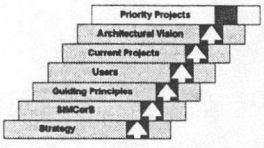
Prio Projects: Policy



- Projects Supporting Scientific Information Management Policies, Procedures, and Standards
  - Develop Data Administration and Quality Assurance Standards for Scientific IM.
  - User Requirements and Policies/Standards Development.

ORD/SIMCorB

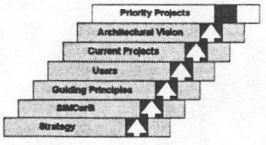
Prio Projects: Outreach



- Projects Supporting Outreach Activities for Scientific Information Management
  - Develop a SIMCorB Web Site to Publicize and Promote Awareness of Scientific IM Activities within ORD.
  - Develop a Strategy to Promote Partnerships with Other Organizations.

ORD/SIMCorB

Prio Projects: Development



- Projects Supporting Development of Common System Components for Scientific Information Management
  - Implement Architecture for the Scientific Information Management System (SIMS).
  - Implement Architecture to Support Long-term Scientific Data Archives.
  - Implement Architecture to Support System Integration with External Systems.
  - Evaluate New and Emerging Technologies for Scientific IM.
  - SIMS Proof of Concept Project—Information Management for Endocrine Disruptors.
  - Current Development Project for Integration of Scientific Data into SIMS.

ORD/SIMCorB

Environmental Laboratory Advisory Board

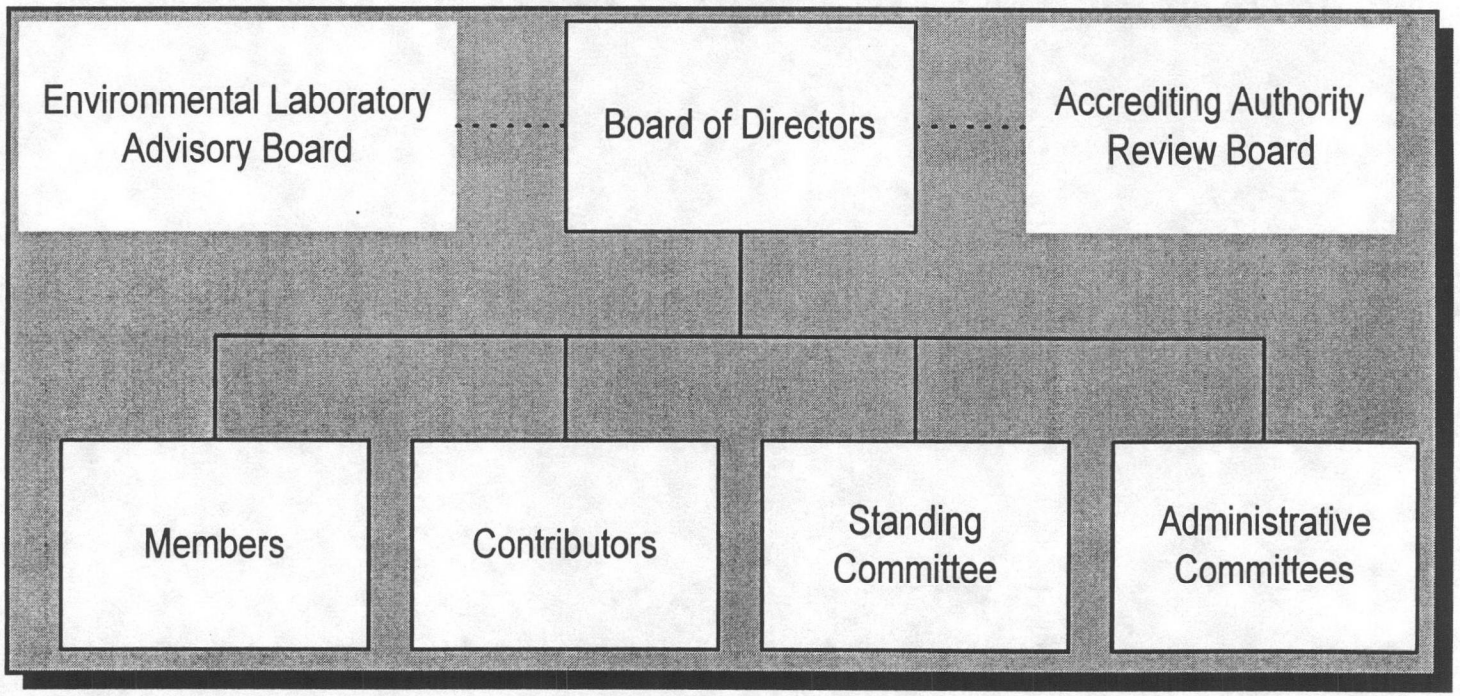
Issues on NELAC Implementation

Managing Quality Systems for Environmental Programs

March 1999

Jerry Parr
Catalyst, LLC, Evergreen, CO

NELAC Structure



ELAB Overview

- Established in accordance with the Federal Advisory Committee Act (FACA)
- Develop recommendations regarding requirements for accreditation of environmental laboratories
- Provide analyses, conduct reviews, produce reports, and perform all other activities necessary
- Fairly reflect the opinions and positions of the affected public

NELAC Charter

ELAB advises EPA and NELAC on matters affecting the interests of the regulated laboratories and other interested parties. *1.6.2*

Composition

- Environmental laboratory industry
- Regulated community
- Environmental public interest groups
- Academia
- Local government
- Indian tribes
- Laboratory assessment bodies
- EPA as Co-Chair

FACA/ELAB Requirements

- Open meetings
- Opportunity to file comments or make statements
- No compensation

Current ELAB Issues

- **NELAC Implementation**
- **Interim Status**
- PBMS
- Audit Checklists
- Small Lab Issues
- Sample Preservation
- ...

ELAB Members

- J.Wilson Hershey
- Janet Hall
- Kathy J. Dien Hillig
- William G. Kavanagh
- Gary Kramer
- Jerry Parr
- Patricia O'Brien Pomerleau
- Romano Travota
- Michael J.Smolen
- Allen W. Verstuyft
- Frieda White
- Sandra Wroblewski

ELAB Recommendation on NELAC Implementation

- NELAC standards become effective and enforceable one year after adoption
- For the first group of laboratories, the 1999 standards be used for compliance and the related timelines for acceptance of applications be adjusted accordingly

Rationale for ELAB Recommendation

- Standards approved in voting sessions during the Annual meeting
- No specification for when the newly approved standards become effective
- 1999 Standards are "better"
- Implementation schedule can allow

ELAB Proposed Implementation Schedule

- 6/99: First accrediting authorities approved
- 7/99-9/99: Laboratory applications in first round processed
- 9/99-6/00: Accrediting authorities review all first round applications and perform many on-sites
- 7/00: First round of laboratories approved and announced
- 8/00-6/01: Remainder of on-sites completed for first round

Issues Presented by ELAB Proposal

- SOPs may need to be modified
- Regulations may need to be modified.
- State-provided copies of the standards delayed until after June 1999
- New checklist for the laboratory on-site assessment
- Laboratory applications delayed until July 1999
- Interim status provisions require modification

Changes to Standards Since 1997

- More flexibility for labs
- Well rounded PT program
- Qualifications for Technical Directors
- Exceptions for small labs
- More stringent training for assessors
- Details
- Clarity

Increased Flexibility

- -Calibration
- -MDL

Details

- Calendar vs working days
- Use of logo
- Glossary
- etc.

ELAB Recommendation on Interim Status

- Interim status not be recorded in database

Rationale for ELAB Recommendation

- Allow 2 years for first round
- Allow AA to prioritize labs
- Requires full conformance except for on-site
- Prevents unwarranted marketing advantage

Closing Thoughts

- On-site details finalized by 1999
- States must be able to address one-year timeline
- Many resources available to help labs
  - NELAC Website
  - State Websites
  - Catalyst
  - Lab Associations
- Current delay in schedule is marginally acceptable

Do you have a NELAC Issue? Call me!
or Wilson, or Gary, or Janet, or ...

Jerry L. Parr

The Information Resource for Environmental Professionals

Catalyst Information Resources, L.L.C.
303-670-7823
catalyst@eazy.net
www.catalystinforesources.com

8

DAUBERT GUIDLINES

Determine...

- The "falsifiability" of the theory, is it testable and has it been tested
- The "known or potential error rate" associated with applications of the theory
- Whether the findings have been subjected to peer review and publication, and
- The "general acceptance" of the science being offered

GENERAL ELECTRIC v JOINER (1997)

- Expanded the triers' latitude to determine whether Daubert's specific factors are, or are not, reasonable measures of reliability in a particular case.

KUMHO v CARMICHAEL (1999)

- Re-enforced the Joiner decision by upholding the District Courts' decision to exclude the scientific evidence at hand because the District Court did not question Carlson's qualifications, but excluded his testimony because it initially doubted his *methodology* and then found it unreliable after examining the transcript in some detail and considering respondents' defense of it.

SUMMARY

- Quality Assurance and Peer Review will play an increasingly important role because they have been identified as specific factors to be considered by the courts and provide some flesh on the bones of the Daubert decision.

The Role of The

Quality Expert In Legal Decision Making

By David E. Preston

Partner - Varnum, Riddering, Schmidt & Howlett LLP,

SUMMARY

All too often the attorney and technical expert do not understand how the weaknesses and strengths of technical data may contribute to the success of a legal decision-making strategy. Communication between the attorney and quality expert at the earliest stages of strategy development concerning objectives, data reliability, alternative approaches, and available resources will result in better legal decision-making.

THE QUALITY EXPERT

In the past decade sensational trials and the popularity of legal themes in television heightened professional and public awareness of the role and potential problems faced by the quality expert in trial proceedings. As a direct result of this attention quality professionals may tend to give high priority to that brief period of activity which precedes testimony at trial and performance during direct and cross-examination. The significance of these activities should not be minimized. These activities and preparation for testifying as an expert can shape the objectives and scope of work performed by the quality professional for months and perhaps years before the relatively brief period of trial. Quality professionals who offer their services as expert witnesses may suggest to potential clients that their value lies in their experience and credentials as presented before the trier of fact. Although these qualifications are critical, the most important work of a quality expert in preparing for trial occurs outside of the courtroom in preparations conducted before trial. This is also true in a host of routine legal and technical decision-making processes which do not involve the types of trial court proceedings which are more familiar to the general public.

LITIGATION STRATEGY

In the early stages of preparing litigation strategy the quality expert and the attorney can assist each other by reviewing and discussing available data resources, legal and technical theories, and information needs. The quality expert should understand that while counsel may have a firm grasp on the procedure for qualifying and introducing

evidence at trial, he may have only the most limited understanding of reliability of available data, and opportunities for developing better information before trial. Counsel can assist the expert by providing an accurate description of client objectives, available information, schedule, and the resources available to develop additional data. Such communications between the attorney and the quality expert can strengthen the litigation strategy.

LEGAL DECISION-MAKING

This approach also applies to a range of legal decision-making processes involving business transactions or similar contexts other than litigation. Common examples of these processes include environmental due diligence in the sale or purchase of a business or real estate, and acquiring environmental permits and licenses. A third example is the evaluation of environmental data in development of new regulations. In each of these examples, a clear grasp of objectives, available resources, information, and opportunities for development of additional information contribute to a comprehensive and stronger strategy. Using as an example environmental due diligence, the environmental cleanup laws passed in the early 1980s created a keen awareness on the part of industry of the current environmental conditions and past hazardous substance handling practices at candidate sites for acquisition. The potential that a purchaser, by acquiring property, could become liable for the hazardous substance disposal activities of his predecessor at that location, quickly caused purchasers to examine the history of past practices and current environmental conditions prior to completing the transaction.

ENVIRONMENTAL INVESTIGATION

The scope of these environmental investigations is as wide-ranging as the complexity of the transactions which they involve. At the highest level the acquirer must understand the extent of environmental liabilities and compliance obligations of the target, perhaps involving many facilities in many countries. At the lower end of the spectrum the acquirer must, for example, determine if there has ever been an underground storage tank on the property. Attorneys are often involved at the initial stages of these efforts because they help shape other aspects of the transaction and can recommend contractual methods of sorting out responsibility for addressing these concerns. For example, funds can be escrowed, or sales price adjustments can be made, to account for environmental remediation costs. The attorney for a buyer or a seller will normally consult technical experts to assist in the evaluation of environmental conditions at an acquisition target.

These evaluations pose data acquisition and evaluation challenges which are

similar to those confronted in the traditional litigation setting. Technical experts may be presented with an extensive or very limited body of technical data concerning conditions on the property. They may be faced with time limits to conduct the evaluations and gather necessary data. There are far-reaching legal and financial consequences associated with the evaluations. For example, if investigators fail to discover environmental problems, a potential purchaser may end up shouldering all or part of the burden of an environmental cleanup. A prospective purchaser may face difficulties in establishing legal defenses to liability afforded by federal and state environmental cleanup laws.

STANDARDIZATION

The risks associated with these undertakings resulted in the standardization of these environmental investigations. ASTM standards for due diligence investigations developed which describe in detail the level of investigations which should be conducted. These standards enable the legal and technical communities to predict the required level of work and assure themselves of the sufficiency of the investigation efforts. The standard for due diligence investigations generally does not call for generating new environmental testing data. This is not to say that performance in accordance with the standard is the last word on evaluation of environmental conditions. Discovery of a contamination problem will lead to a choice to conduct further investigations including the likely possibility of sampling and testing. The standardization of due diligence investigations illustrates how legal decision-making needs have influenced development of a set of data quality criteria aimed at supporting the efficient completion of business transactions.

PERMITTING

Another area where data quality evaluations are closely related to a legal decision-making process is environmental permitting. Federal and state statutes often require extensive technical information gathering to support decisions by regulators to issue or renew environmental permits. The scope and extent of data gathering are dictated by the affected media, types of contaminants involved, and the significance of potential impacts. To illustrate the combined data quality and legal issues, consider the air emissions of a proposed new manufacturing facility which seeks to obtain an emissions permit to construct a source of air contaminants. A permit application for a new source of air contaminants must project the types, concentrations, and amounts of emissions. Based on these projections, regulators will make findings concerning applicable regulatory requirements and whether a permit can be granted. Data supplied by the applicant is used to establish mass and rate emission limits in the form of permit conditions.

Accurate projections of emissions must be developed by the applicant to satisfy permit application requirements, determine which control requirements may apply, determine associated operating and construction costs, and make sure that compliance can be achieved in practice. Failure to do so could result in project delays, permit application rejection, or non-compliance if emission limitations cannot be achieved.

The tools available to environmental technical professionals to project emissions are wide-ranging. Emission projections can be based on contemporary testing at similar facilities, mass balance determinations, and emission factors available in scientific publications. Depending on the available resources, very accurate projections of emissions can potentially be made. The quality expert, in making a judgment about the data to use as the basis for projecting facility emissions, might easily be able to help solve the legal problem of getting a permit with available published data, but ultimately find that the facility is so dissimilar from those used to determine the emission factors that compliance cannot be achieved in practice. Here again, planning and available resources can have a significant effect on the chain of legal and technical decisions involved in obtaining a permit, and later in complying with permit conditions. The attorney must make the data quality expert aware of applicable legal requirements and resources available to meet data collection objectives. The data quality expert must provide the attorney with information concerning limitations of available data. All of the participants must understand that business and compliance objectives will shape the information gathering and evaluation tasks of the quality experts. In the ideal situation the problems of data quality will be discussed at the planning stages rather than discovered during operation.

REGULATORY PROGRAMS

A third example of the role of data quality experts in legal decision-making is the development of new regulatory programs in which information concerning the emission of contaminants from industrial processes is collected and considered for the purpose of establishing emission control standards. The development of the Maximum Achievable Control Technology (MACT) standards, mandated under the Clean Air Act Amendments of 1990, provide a good example of the data quality problems faced by industry and regulators in establishing new requirements for affected industries.

In general, the law requires that the U.S. EPA establish standards regulating the emission of air toxics for specified types of industries based on the level of control achieved by the top twelve percent (12%) of industry operations in an industry category. The U.S. EPA is faced with the task of collecting information of varying quality from the affected industry and making determinations about the reliability of the data. The legal

consequences of establishing these requirements are significant, including the requirement to install new emission controls at affected industries.

Recognizing the potential effects of these new regulatory programs, industry groups have formed to work with and/or monitor the U.S. EPA information collection activities so that their constituents understand the information collection efforts and recognize that the quality of information provided will bear on the outcome of the U.S. EPA's efforts. Data quality concerns have been given high priority by industry groups working with the Agency. For example, trade associations have worked closely with their constituents urging them to respond completely and accurately to the U.S. EPA questionnaires. Organized industry groups have formed many years in advance of the U.S. EPA information requests to review the questionnaires and consider issues of data availability.

The MACT development process also illustrates other legal decision-making concerns that can affect data quality. One industry group found that a key roadblock to collection of actual test data is the difficulty of reaching an agreement with the government under which the tested industry groups would be immune from penalties if violations were discovered in the course of testing. Industry trade associations that have attempted to collect information from their constituents have had to consider the development of safeguards to protect the identities of respondents who would otherwise be unwilling to share the results with their competitors.

CONCLUSION

Data quality issues are encountered routinely in connection with legal decision-making. The unique facts and circumstances which drive the decision-making process will often set the stage for considering data quality objectives. In decisions involving environmental requirements, careful establishment of quality requirements can improve the potential for success in meeting business and compliance objectives. Frequently technical and legal partners in these endeavors are unaware that there may be alternative and better solutions to solving these problems. In almost all cases legal counsel and the quality expert will better understand the risks and benefits of data quality issues through discussion of these matters in the planning stages leading to the legal decision.

EXTENDED ABSTRACT

RECONCILIATION OF NON-AUTHENTIC ANALYTICAL DATA

Jeffrey C. Worthington, CQA. CQM
Quality Assurance Division
National Cernter for Environmental Research and Quality Assurance
USEPA Office of Research and Development
401 M Street S.W. (89724R)
Washington, DC 20460

Analytical laboratories, including environmental laboratories, strive to ensure the delivery of analytical data which meet their customer's requirements. Assurance that the data are authentic is often simply assumed by the user and often also assumed by the data producer. In fact, sometimes the data are not authentic. This problem is not unique to the analytical or environmental community.

Many organizations and individuals are responsible to develop and deliver data that are authentic. These include research organizations, individual researchers, government agencies at all levels, and the regulated community. There are a host of terms that are used in reference to this non-authentic data. Some people use the term "data integrity" as an all-encompassing term to consider all issues. When the data are reported intentionally as non-authentic, the concerns on the part of data users are greater because more issues are involved than the quality of the data. Indeed, when the reporting of non-authentic data is purely an error, this is solely a quality problem. It is also a quality problem even if the reporting were done intentionally.

Another term used when the reporting is done intentionally is scientific misconduct. Others link this terminology to research integrity. Another term used often is "ethical behaviour."

This presentation explores the role of the quality manager in attempting to identify and separate the quality issues from the other issues. If that is possible, the quality manager can then develop and implement a system to "reconcile" the quality of the data for possible use of the data. This presentation provides a systematic approach for such a process.

Facility Manuals: Documentation Unique to Research Facilities

Shirley Wasson, M.S.
Quality Assurance Staff
Air Pollution Prevention and Control Division
National Risk Management Research Laboratory
Office of Research and Development
Environmental Protection Agency
Research Triangle Park, NC 27711

In our Division, planning for cutting-edge research projects is generally handled differently from that performed for the large multi-year, expensive projects often associated with EPA. Many of our projects are conducted in specially-constructed facilities in which the location, equipment, instruments, documentation, procedures, and other features generally stay the same; however, the projects conducted within the facilities change with time.

Our projects generally proceed in incremental steps. Each step requires planning, often building on the results of those preceding. While no one disputes the value of planning, researchers often find it difficult to justify the time to produce a full-blown "R-5 style" QA plan* for each step of the project. They express concern that it takes more time and resources to write the plans than it does to carry out the work, that producing these plans are an inefficient use of scarce resources, and that the many individual plans contain repetitious material. Examples of such material are laboratory layouts, descriptions of facilities and instrumentation, descriptions of facility documentation such as log books, instrument manuals, health and safety manuals, and training records, and preparation of procedures such as facility operating procedures, calibrations, quality control procedures, and health and safety protocols.

Research data producers and users understand the value of the information and the need for it to complete the study record, particularly in long-term, high-profile, or sensitive projects. Therefore, APPCD decided to gather the material common to all the projects performed in their facilities into living documents, and to reduce the plan-writing requirements to address only those elements which change from step to step. This presentation explores how the facility manual concept is implemented in our Division. It discusses our experiences with the production and use of the facility manual, successes, failures, and lessons learned.

**EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations*, EPA QA/R-5, USEPA, Quality Assurance Division, Washington, DC 20460, 1994.

Documentation Unique to Research Facilities

Shirley Wasson
Air Pollution Prevention and Control Division (APPCD)
NRMRL, ORD

Acknowledgements

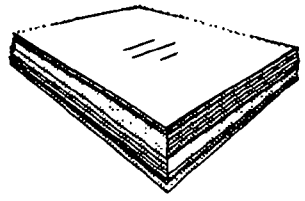
- Judith Ford, former APPCD Quality Assurance Officer, for the initial concept of facility manuals
- Laura Beach, ARCADIS, APPCD's in-house contractor Quality Assurance Manager, for coordinating and overseeing contractor personnel during preparation of facility manuals
- All the APPCD facility managers and operators for their time, energy, and resources. Without them, facility manuals would not exist.

Facility Manuals in the APPCD

- *What* they are
- *Why* they exist
- *Who* prepares them and *who* uses them
- *When* they are prepared
- *Where* they are kept
- *How* they are prepared and used

What is a Facility Manual?

- A living document containing the generic information about a research facility, written by the managers and operators, accessible to assessors of projects performed by the facility, and to users of generated data.



Facility Manual Generic Index

- 1.0 Introduction
- 2.0 Facility Charter
- 3.0 Management
- 4.0 Description
- 5.0 Equipment
- 6.0 Documentation
- 7.0 Operation
- 8.0 Quality Assurance
- 9.0 Quality Control
- 10.0 Data Handling
- 11.0 Corrective Action
- 12.0 Health and Safety

Appendices

- A. Current Facility Personnel
- B. Operating Procedures
- C. Standard Methods
- D. Technical Systems Audit Checklist
- E. Performance Evaluation Audit Ranges

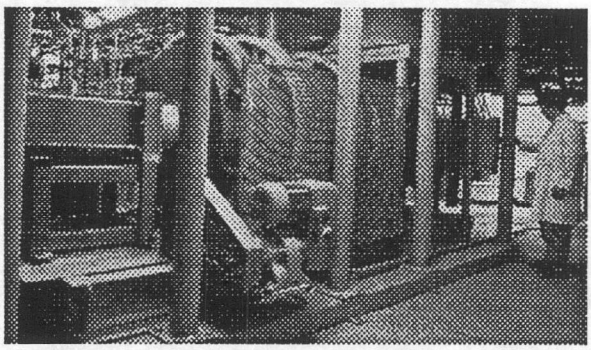
Who Prepares Facility Manuals

- *EPA owns all the facilities, but they may be*
- ► EPA managed and operated, or
- ► Contractor managed and operated under Work Assignments
- ► If EPA managed, EPA Principal Investigators, researchers, and analysts write the facility manual
- ► If contractor managed, facility manuals written as a task under work assignments for projects performed in the facility

Large Scale Facilities in the APPCD (Partial List)

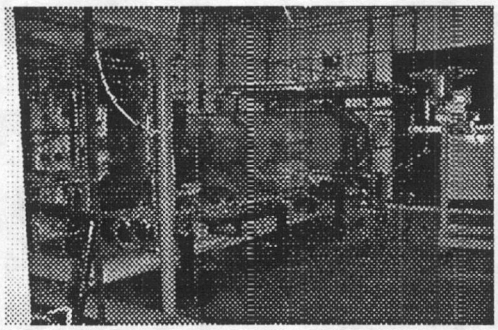
- ► Rotary Kiln Incinerator Simulator
- ► Rainbow Horizontal Tunnel Combustor
- ► Package Boiler Simulator
- ► North American Package Boiler
- ► Flue Gas Cleaning System
- ► Large Indoor Air Quality Environmental Test Chamber

Rotary Kiln Incinerator Simulator

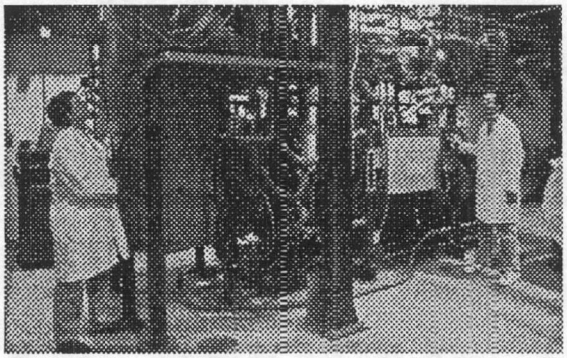


Rainbow Furnace

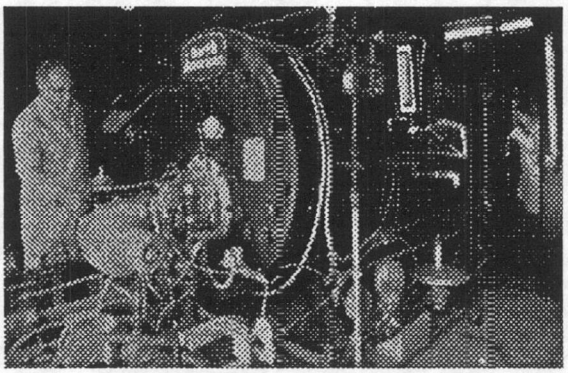
Horizontal Tunnel Combustor



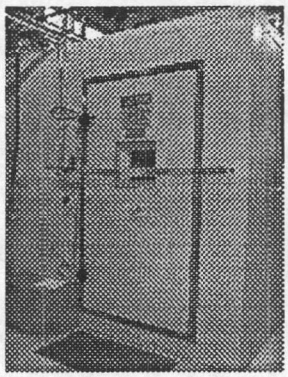
Package Boiler Simulator

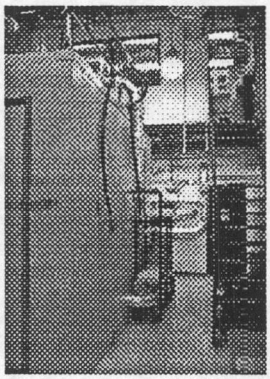


North American Package Boiler

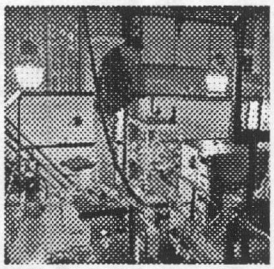


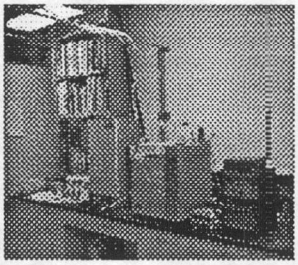
Large Chamber





Large Chamber Sampling and Analysis



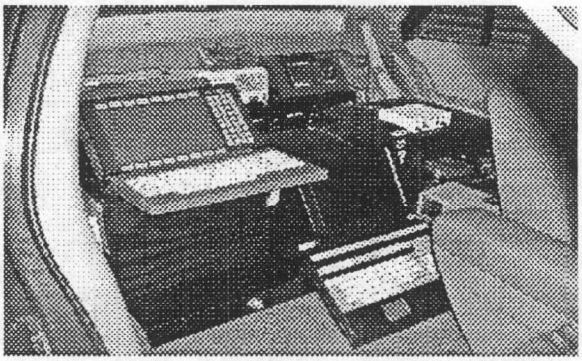


Mobile Facilities in the APPCD

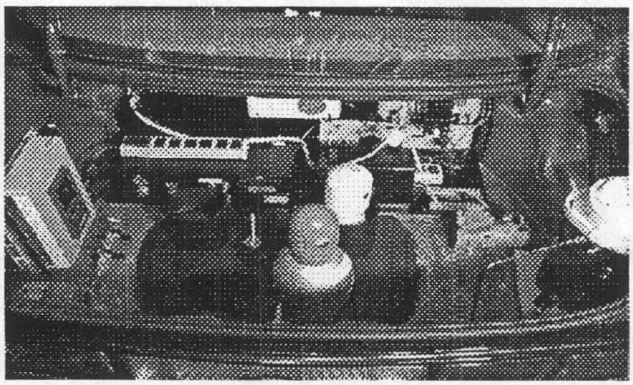
- On-Road Diesel Emissions Characterization Facility
- Instrumented Car

Mobile Facilities

Instrumented Car



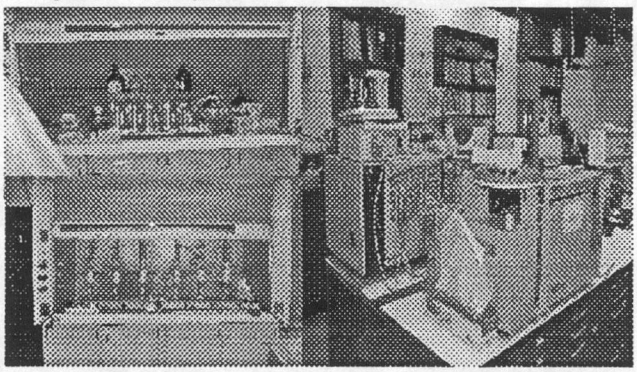
Instrumented Car



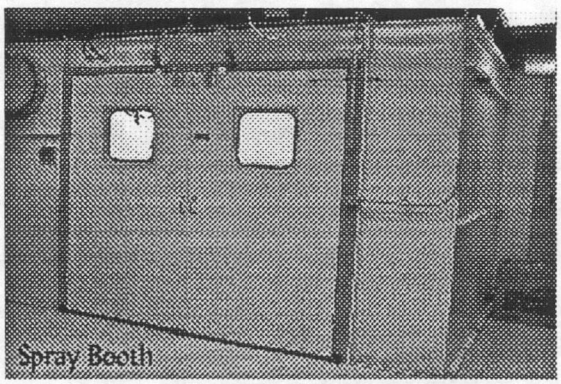
Laboratory Facilities (Partial List)

- Organic Analysis
- Coatings
- Biomass
- Mercury
- Small Environmental Chambers (Indoor Air)
- Metrology
- Inorganic Analysis

Organic Analysis

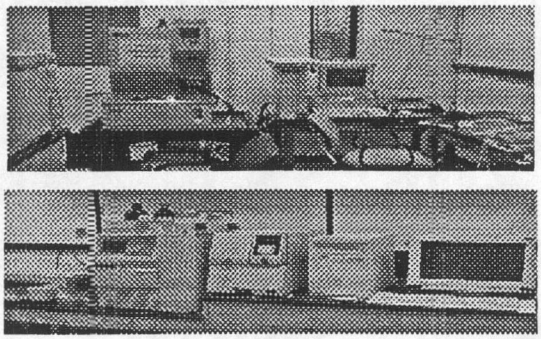


Coatings Laboratory

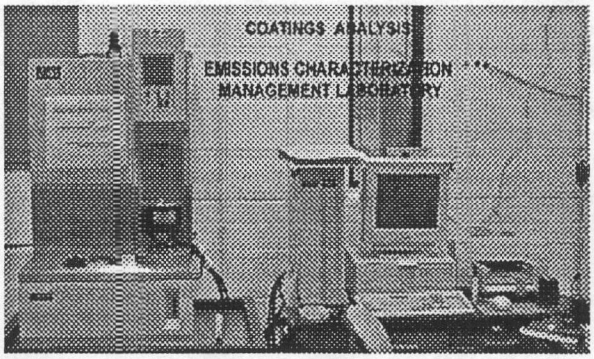


Spray Booth

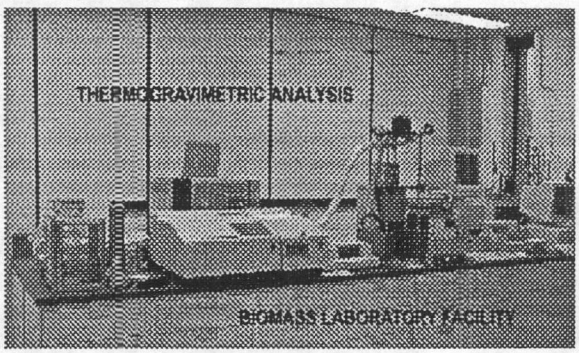
Coatings Sampling and Analysis



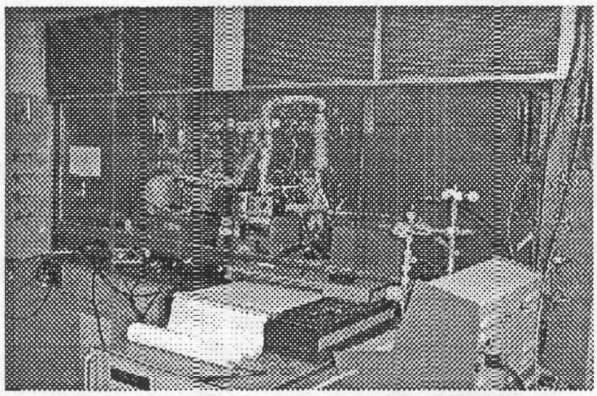
Coatings Laboratory



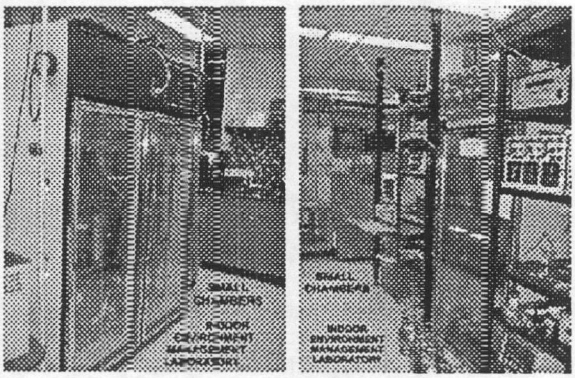
Biomass Laboratory



Mercury Laboratory

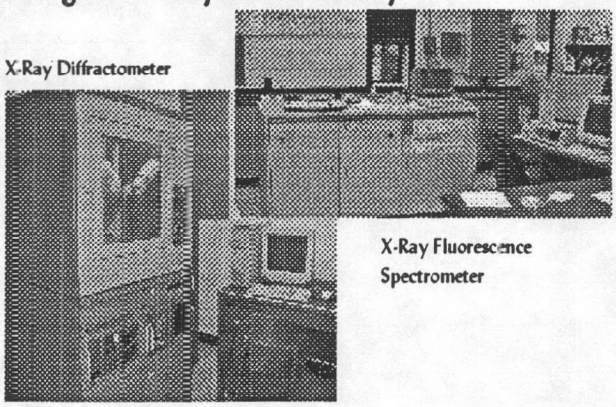


Small Environmental Chambers



Metrology Laboratory

Inorganic Analysis Laboratory



Why Prepare Facility Manuals

Research planning in APPCD is often different from that of other parts of the agency

- Planning is generally for smaller, cutting edge research projects
- Projects generally proceed in incremental steps
- Next steps build on results of preceding step
- QAD guidance documents address large projects
- Planning is different for mega-dollar projects

For Proof-of-Concept Research...

- Principal investigators say:
  - Full-blown "R-5 style" QA plan too complex
  - Priorities not compatible with small projects
  - Costs more time and resources to write the plans than to carry out the work
  - Individual plans contain repetitious material

Why Prepare Facility Manuals?

- Information generated only once
- Available in one document
- Once prepared, available for easy reference
- Citable in abbreviated Test/QA plans

Who Prepares and Uses Facility Manuals

- Facility Managers and Operators
  - Prepare manuals and procedures, keep manuals current
  - Train new personnel
- Project Managers, Data Users
  - Archive for facility layout, operations, procedures, quality assurance, calculations
  - Referenced in test/QA plans
- Auditors
  - Source of facility information

Preparation of Facility Manuals

- Phase I: Construction of Facility
  - Manual begins as task in statement of work
  - Document layout, engineering systems, instruments
  - Expense borne by construction project
- Phase II: Setup and Operation
  - Establish logbooks, documentation
  - Select software, modify as needed
  - Establish and document procedures
  - Expense borne by data collection projects

Maintenance of Facility Manuals

- Phase III: Concordance
  - EPA managed: EPA manager, QA officer, safety officer
  - Contractor managed: appropriate EPA approvals, plus Contractor task manager, QA officer, safety officer.
- Phase IV: Revisions
  - Managers and operators keep manual up to date
  - Hand-written entries, formal revision as necessary
  - In response to audits
- Phase V: Retirement
  - Kept for 5 years after decommissioning of facility

In Conclusion

- Facility manuals a useful tool in decreasing paperwork required in planning research projects
- Organization, layout, operating procedures, QA requirements collected in one document for project data users
- Provides archive of facility history
- Training tool for new facility personnel
- Source for auditing information

Auditing New Technologies: Issues and Approaches to QA in an R&D Setting

In the U.S. EPA's Office of Research and Development, many of the projects that quality assurance (QA) staff members audit involve novel methods, recently developed and not yet standardized. This precludes the approach of using standard acceptance criteria and well-established audit methods and materials. There is, however, a real and important need for QA support to the projects. This presentation illustrates some useful approaches to auditing research projects, using examples from new instruments and techniques for the measurement of fine particles.

The recently enacted National Ambient Air Quality Standard for fine (<2.5 micrometer) particle and ozone concentrations has accelerated the development of new methods and instruments for measuring fine particle concentration and size in air. However, several factors complicate the measurement of fine particles in air (aerosols):

- Different measurement methods are based on different particle characteristics (e.g., light scattering versus speed of migration of a charged particle in an electrical field). Sometimes it is unclear how the measured value corresponds to physical characteristics such as actual size and density; aerodynamic size, for example, is determined by inertial and viscous forces, but smaller denser particles could have the same aerodynamic size as larger particles that are less dense.

- Properties of specific particles affect their measurement (e.g., shape, density, charge, presence of volatile layers, chemical reactivity).

- Properties of the carrier gas affect particle measurement (e.g., relative humidity, flow, temperature).

- Size calibration standards, such as the widely used National Institute of Standards and Technology (NIST) polystyrene latex (PSL) spheres, may not accurately match the characteristics (e.g., shape, density, absorbance) of the aerosol to be measured. Many aerosol measurement systems assume that all particles are spheres.

- There are no widely recognized and readily available primary standards for mass concentration or number measurements, particle size distribution, or particle density.

- Mass measurements may be confounded by adsorption, desorption, or chemical reactivity. In cascade impactors, under some conditions, particles can bounce from the stage in which they would properly be collected to a subsequent stage in which smaller particles would be collected; this particle bounce phenomenon distorts size distribution measurements.

- Particle count measurements, as well as size distribution measurements, may be confounded by the number of particles in an airstream. A stream overloaded with smaller

Nancy Adams , U.S. EPA, APCD/NRMRL, Research Triangle Park, NC

particles may show "phantom" large particles, due to coincident smaller particles in the sensing portion of the counter. Likewise, in some systems, a large particle can create a signal that is also counted as several smaller particles.

- Particles can be lost in the inlet or transfer lines.

Given these complex problems in measuring aerosols and given the lack of primary standards, this presentation discusses some practical approaches to ensuring aerosol measurement quality, using traditional QA methods: planning (using the Data Quality Objectives process to establish how good the measurements must be, preparing a QA/Test Plan), QC (checks of flow measurements, checks of specific measurement characteristics), quality assessment (appropriate types of assessments and timing of assessments), analyzing and reporting data (software and electronic interface checks, data qualifiers), and quality improvement (using information gained in the conduct of the assessment and the measurement program to develop better procedures, to design better instrumentation, and to improve quality checks).

Auditing Aerosol Measurements: QA for R&D

Nancy Adams
ORD/NRMRL/APPCD/TSB

Presented at the Annual EPA QA Meeting, April, 1999

Increasing Interest in Aerosol Measurements

- Revision to NAAQS
  - Measure < 2.5 micrometer particles
  - New instrumentation
- Health effects research
  - Particles and mortality
  - Particles and lung function deficits
  - Particles and infectivity
  - Particles and asthma/allergic response

Differing Measurement Methods

- Light-scattering
- Light blocking (turbidity)
- Relative coloration of filter
- Migration in electric field
- Mass on filter or stage
  - ► collected by filtration
  - ► collected by inertial mass methods

Particle Properties Affecting Measurement

- Shape
- Density
- Charge
- Volatile coating
- Chemical reactivity

Properties of Gas Stream Affecting Measurement

- Viscosity
- Relative humidity
- Flow rate
- Temperature
- Turbulence

Other Confounders

- Agglomeration
- Precipitation
- Static attraction to walls, tubing
- Adsorption/desorption of volatile components
- Chemical reactivity
  - Particle-particle
  - Gas-particle

Measurement-Specific Confounders

- Particle bounce in cascade impactors
- Phantom particles (coincident small particles)
- Phantom small particles (misclassification of a large particle)

Available Standards

- NIST
  - PSL spheres
  - Glass spheres
- Variety of single size preparations
- Sold as liquid suspensions

Standards not available for:

- Mass concentration (micrograms/cubic meter)
- Number concentration (1,000,000/cubic meter)
- Size distribution
- Particle density

QA for Aerosol Measurements

- Planning
  - DQO process
  - QA/test plan
- Quality control
  - Flow measurements
  - Specific measurments checks
- Quality assessment
- Analyzing/reporting
- Quality improvement

Planning

- DQO process
  - State the problem
  - Identify the decision
  - Delineate inputs
  - Set boundaries
  - Establish a decision rule
  - Set error limits
  - Optimize design
- QA/test plan

Quality control

- Calibrations
  - Size
  - Flow
  - Temperature
  - Relative humidity
- Replicate measurements
- Instrument comparisons

Sampling QC

- Probe - Mechanical defects
- Transfer lines - Loss estimate
- Pumps - Operational
- Flow meters - Range of use

Sampling QC *(continued)*

- Instrument
  - Diameter of interest
  - Units
  - Concentration limits
  - Diluter calibration
- Particle collection substrate
  - Interactions
  - Loading limit

QC for Flow Measurement

- Mass flow controller (range varies)
  - Calibrate with NIST-traceable device
  - Calibrate over usage range
- Dry gas meter (>1L/min)
- Wet test meter (>5L/min)
- Roots meter (>5L/min)
  - NIST-traceable bell prover
- Orifice(>1L/min)
- Bubble flow meter ($1cm^3$-25L/min)

Quality Assessment

- TSAs
  - Early in project
  - May be done by project team
- PEs
  - Early in project
- DQAs

Data Analysis and Reporting

- Programs to check software
- Measurement of differing sample sizes
- Data descriptors
  - Bias, precision, MDL
  - Calibrations
  - Temperature, RH
  - Audits
  - Maintenance, repairs

Quality Improvement

- Documented methods
- Documented timeframes
- Modified SOPs
- Publishing of improved methods

References

- Factors Affecting Aerosol Measurement Quality, pp. 130-145, in *Aerosol Measurement*, K. Willeke and P.A. Baron

- http://www.epa.gov/ttn/amtic/qalist.html, Section 2.10, QA Handbook

Acknowledgements

EPA

- Les Sparks
- Richard Shores
- Paul Groff

Research Triangle Institute

- Dave Ensor

Quality Assurance Project Plan Development for the HSPF Model

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SUMMARY

The following is a condensed Quality Assurance Project Plan (QAPP) for the Hydrological Simulation Program - FORTRAN (HSPF) model. The model simulates surface water where diverse biota and wild rice grows and is critical to several Tribes, before and after construction of a proposed underground mine near Crandon, Wisconsin.

THE QUALITY ASSURANCE PROJECT PLAN - PROJECT DATA QUALITY OBJECTIVES

The formulation of the Project Data-Quality Objectives (PDQO's) includes the following seven steps: 1) Stating the problem to be studied; 2) Identifying the decision that will be made; 3) Identifying the information needed; 4) Specifying the boundaries to which the decisions apply; 5) Specifying how the environmental data will be summarized; 6) Specifying acceptable error rates; and, 7) Selecting the most resource-efficient study design that will achieve all of the PDQO's. A total of eleven questions evolved in the original QAPP, but then the focus was narrowed to five objectives that could realistically be answered (see below 1a through 1e). The five questions must be addressed by 1(a) hydrologists familiar with lake-level fluctuations in northern Wisconsin, 1(b) biologists familiar with the growth of wild rice, 1(c) biologists familiar with the flora, fauna, and habitat of interest, 1(d) is indirectly addressed by the model, and 1(e) hydrologists familiar with surface water flow in northern Wisconsin.

1(a) Identification of Surface-Water Bodies that Strongly Interact with Ground Water

Problem: According to the Environmental Impact Report (EIR) prepared by the mining company, a number of the lakes and ponds in the vicinity of the proposed Crandon Mine are poorly connected to the primary aquifer and, thus, would be minimally affected by drawdown resulting from mine operations. One lake is described as a **'perched lake'** with a silty clay lake bed above the water table through which little water percolates. Thus, the level of this lake is considered to be independent of the level of the primary aquifer. Others are described as **'ground-water-head-dependent'** lakes. The water levels in these lakes are affected by the ground-water levels. However, the lake beds limit percolation to the aquifer, maintaining a higher water level in the lakes than the surrounding water table. The water budget for a lake in HSPF is modeled as $\mathbf{\Delta S = P + I + GW - E - O}$, where P is the precipitation directly onto the lake, I is the surface and subsurface inflow from tributary areas and streams, GW is the deep ground-water inflow or outflow (which would have a negative value), E is evaporation from the lake surface, and O is surface outflow to a draining stream. Also, for the ground-water-head dependent lakes, the head difference between the lake level and the water table may be too small under natural conditions to result in substantial flows from the lakes to ground water. However, when the water table drops as a result of mining, the head difference could become large enough to result in substantial flows from the lakes to ground water. This issue cannot be evaluated because the available lake-level data do not reflect the effects of a substantially lower water table.

Decision: Are the lakes listed previously sufficiently affected by ground-water level fluctuations that lake levels and the overall water budget cannot be reliably simulated without considering ground-water interactions in HSPF? If lake levels cannot be simulated without consideration of ground-water interactions, then future large-scale, ground-water drawdown would be expected to have substantial effects on lake levels and water budgets. However, if natural lake levels can be simulated without consideration of ground-water interactions, the effects of future large-scale, ground-water drawdown on lake levels cannot be reliably evaluated because the HSPF model has not been developed and evaluated under such conditions.

Information Needed: A long series of measured monthly lake levels are needed to determine if lake levels can be reliably simulated without considering ground-water interactions.

Boundaries: The areas to which the decision will apply are Oak, Duck, Deep Hole, Skunk, and Little Sand Lakes.

Data Summarization: The simulated time series of runoff will be summarized as a series of monthly lake levels that will be compared with the measured series of monthly lake levels. If the average difference between the measured and simulated lake levels (error) is less than or equal to X ft and the maximum error in simulated lake levels is less than or equal to Y ft, then the hypothesis that the lake levels are not dependent on the surrounding ground-water levels is accepted. **The items underlined above must be specified by a hydrologist.**

Acceptable Error Rates: The acceptable error rate in the decision has been factored into the selection of the simulated lake-level-error tolerances given previously.

1(b) Effect of Runoff Changes on Wild Rice

Problem: Rice Lake holds the largest and densest stand of wild rice on an inland lake in Wisconsin. Wild rice is highly dependent on a limited range of flow velocities, flows, water levels, pH, dissolved organic carbon, metals, nutrients, and sulfate for reproduction and growth. It is of great cultural and economic value to the Sokaogon Chippewa Community. Therefore, changes in hydrology or hydraulics resulting from the construction, operation, and closure of the proposed Crandon Mine must not adversely affect the wild rice. This phase of the HSPF modeling project will focus on runoff simulation and, thus, HSPF simulation will be applied to determine if various phases of the mine development result in velocities and water levels substantially different from natural conditions.

Decision:

- Are water levels in Rice Lake maintained at a range of x inches to x feet in mid- to late-April when the grain begins to **germinate** such that the growth of the wild rice will not be impaired?
- Are water levels in Rice Lake maintained at a range of x inches to x feet during **emergent leaf stage** May to early July, and would the frequency of mid-summer flooding not substantially change such that the growth of the wild rice would not be impaired?
- Once the plants are in **midseason**, August to early September, will the frequency of water levels negatively affecting growth substantially increase such that the increase will cause the plants to topple and lodge?
- Once the plants have **completed growth**, mid-September, will the frequency of water levels negatively affecting growth substantially increase such that the increase will batter the stems, tangle the leaves and panicles and damage the seed crop? **The items underlined must be specified by a biologist familiar with the growth of wild rice.**

Information Needed: A long time series (20 years or more) of lake levels corresponding to hypothetical runoff from the Swamp Creek watershed under natural conditions are needed to determine the range in lake levels at key times in the growing season resulting from natural fluctuations in runoff.

Boundaries: Decisions will apply to Swamp Creek and Rice Lake.

Data Summarization: The simulated long-term time series of runoff for natural and mining conditions will be summarized as frequency distributions of lake levels during the key times of the growing season. The changes in the frequency of water levels negatively affecting growth and in high and low water levels during the growing season can be compared to the criteria previously given and a decision can be made regarding the magnitude of the effect of mining on wild rice.

Acceptable Error Rates: Because the lake levels will be simulated for a long time period, (20 years or more) and the simulated data will be analyzed utilizing a frequency distribution, the acceptable error rate should be factored into the biological criteria on the unacceptable frequency of stressful water levels.

1c). Will the changes in runoff and water levels resulting from mine construction, operation, and closure impair the health of flora, fauna, and habitat?

Problem: A land and water survey conducted around the proposed mine site observed a total of five endangered, five threatened, 40 special concern, and one proposed special concern species as listed by the State of Wisconsin. Further, in the project area 36 mammal species, 132 bird species, and 45 butterfly species have been identified. These and numerous other biotic components could be affected by changes in habitat resulting from changes in streamflow, lake levels, and groundwater levels. Clearly, it would not be possible to evaluate the potential effects of mining on all species, so certain key indicator species must be identified whose presence and population robustness indicate the general health of the ecosystem.

Decision: Are water levels or discharges in selected lakes, streams, or wetlands higher or lower, or the frequency of stressful water levels substantially increased at key times in the life cycle for selected species such that their health or habitat requirements could be impaired by the change in the physical parameters that comprise aquatic or terrestrial habitats? **The items underlined in the above decision must be specified by a biologist familiar with the habitat requirement for selected species in streams, lakes, and wetlands.**

Information needed: Same as above in 1b

Boundaries: The area to which decisions will apply consists of the surface water bodies for which the most significant effects on flora, fauna, and habitat from runoff changes resulting from mine construction, operation, and closure are expected. These include all the lakes, streams and wetlands within the modeling domain.

Data Summarization: The simulated long-term time series of runoff for natural and mining conditions will be summarized as frequency distributions of lake levels, wetland levels, and/or discharges during the key times of the life cycles of the indicator species. The changes in frequency of stressful water levels and/or discharges will be determined for mining conditions compared to natural conditions.

Acceptable Error Rates: Same as 1b.

1(d) Effect of Runoff Changes on Tribal Cultural Resources

Problem: The greatest socioeconomic and cultural impacts will be to the Tribes on established reservations in the area, including in order from greatest impact to the least, the Sokaogon Chippewa Community Mole Lake Band, the Menominee, the Forest County Potawatomi, and the Stockbridge-Munsee. The greatest impact of any adverse effects from the mining would be to the Mole Lake Band due to their proximity downstream from and directly adjacent to the mine, and because of the historic and current growing and harvesting of wild rice, *Zizania aquatica*, at Rice Lake on the reservation.

Decision: The decision to be made is whether the changes in stream discharge, water levels, or flood/drought frequency and intensity resulting from mine construction, operation, and closure will vary enough from the natural conditions in the watershed to have a deleterious effect on the water resources and related cultural resources such as wild rice, and hence the rice growing and gathering traditions of the people. The wild rice issue has been an historical focus, not just a recent response to the potential mining impacts.

Information Needed: More information is available than will be discussed for this model. The focus of this study is on the direct impact of the mine to the natural environment of the Tribal peoples, and will not expand to economics, demographics, infrastructure, or other historical mining data.

Boundaries: The watersheds that the reservations are part of must be recognized.

Data Summarization: A complete analysis of the impacts to the Tribal culture is available by Cleland, Nesper, and Cleland in a report prepared by Aurora Associates, Williamston, Michigan, under contract with the Sokaogon Band of Chippewa, the Menominee Tribe of Wisconsin, and the Forest County Potawatomi, in cooperation with the Great Lakes Indian Fish and Wildlife Commission (GLIFWC) on behalf of the Lake Superior Chippewa.

Acceptable Error Rates: as above in Data Summarization, not directly modeled.

1(e) Effect of Runoff Changes on Flood Frequency and Magnitude

Problem: The construction of the mine facilities will convert 550 acres of forested (main land cover), open space, and wetland areas into a mill for ore processing, a tailings-management area, a water management and treatment system, offices, maintenance shops, storage buildings, and parking . Surface runoff resulting from storms will be substantially higher from the constructed facilities than from the natural areas. It is also necessary to evaluate the changes in downstream flooding resulting from mine construction.

Decision:

- Are the frequency and duration of discharges greater than X ft^3/s at a key location along the streams substantially increased for runoff after mine construction relative to the frequency resulting for runoff under natural conditions? Has the magnitude for the Y-year storm at a key location along the streams substantially increased for runoff after mine construction relative to the frequency resulting for runoff under natural conditions? **The items underlined in this decision must be repeated as necessary to include all key locations along the streams, as specified by a hydrologist.**
- Is the frequency of water levels greater than X ft or Y ft on Little Sand Lake and Rolling Stone Lake, respectively, substantially increased for runoff after mine construction relative to the frequency resulting for runoff under natural conditions?
- If the answer to any of these questions is yes, then the mining company must redesign the stormwater-detention facilities such that release rates are sufficiently small to keep downstream flows and water levels within acceptable tolerances relative to flows resulting from natural conditions.

Information Needed: A long time series (20 years or more) of discharges and lake levels corresponding to hypothetical runoff from the watershed potentially affected by the mine under natural conditions are needed to establish a comparison baseline.

Boundaries: The area to which this decision will apply includes Hemlock, Swamp, and Hoffman Creeks and Little Sand and Rolling Stone Lakes.

Data Summarization: The simulated long-term time series for natural and mining conditions will be summarized as frequency distributions of discharges and lake levels. The changes in exceedance frequency for specified discharges and lake levels will be determined for mining conditions compared to natural conditions. Changes in the duration of discharges and lake levels above the specified targets also will be determined for mining conditions compared to natural conditions. Finally, changes in the magnitude of discharges of specified return periods will be determined for mining conditions compared to natural conditions.

Acceptable Error Rates: Because the simulated data will be analyzed utilizing a frequency distribution, the acceptable error rate should be factored into the criteria on unacceptable increases in high discharges, lake levels, or flood magnitudes.

PROJECT ORGANIZATION AND RESPONSIBILITY/QUALITY ASSURANCE OBJECTIVES FOR THE SIMULATION MODEL

HSPF calibration is performed in a stepwise manner primarily using data available at stream flow gages and matching the overall water budget, the annual water budgets, the monthly and seasonal water budgets, and finally, considering storm-runoff volumes and frequencies. In evaluating the monthly and seasonal water budgets and storm-runoff volumes, the relative proportions of high flows and low flows are considered. It is recommended by experienced modelers that **graphical and statistical means** be used to assess the quality of fit because trends and biases can be easily detected on graphs, and statistics provide an objective measure of whether one simulation is an improvement over another.

For the **overall and annual water budgets** only the percent error will be considered. Experienced modelers state that for HSPF simulation the annual or monthly fit is very good when the error is less than 10 percent, good when the error is between 10 and 15 percent, and fair when the fit is between-15 and 25 percent (Donigian and others 1984). **The target for acceptable calibration and verification for this study is simulation of the overall and annual water budgets within 10 percent of the measured values.**

Plots of observed and simulated runoff will be prepared for the **monthly water budget** and checked for periods of consistent oversimulation or undersimulation of runoff. The quality of fit for monthly values also will be examined using three statistics: (1) the correlation coefficient between simulated and observed flows, (2) the coefficient of model-fit efficiency between simulated and observed flows, and (3) the number of months for which the percentage error is less than a specified percentage. In areas where snowmelt is a major factor and meteorological data are sparse, it may be difficult to obtain the high correlation coefficients and coefficients of efficiency reported in the previously listed studies. **The targets for acceptable calibration and verification of monthly flows are a correlation coefficient greater than 0.85 and the coefficient of model-fit efficiency greater than 0.8.**

The **daily flows** will be checked graphically by comparing the observed and simulated runoff-duration curves and time series. General agreement between the observed and simulated runoff-duration curves indicate adequate simulation over the range of the simulated flow conditions. Substantial or consistent departures between the observed and simulated runoff-duration curves indicate inadequate calibration. Three statistics are utilized in the expert system for calibration of HSPF, HSPEXP (HSP Expert System) to numerically evaluate the high-flow/low-flow distribution indicated in a flow-duration curve. **The target criteria for acceptable calibration and verification for the high-flow/low-flow distribution in the simulated runoff relative to measured runoff are a mean low-flow-recession rate difference $\leq$ 0.02, an error in the mean of the lowest 50 percent of the daily mean flows $\leq$ 10 percent, and an error in the mean of the highest 10 percent of the flows $\leq$ 15 percent.**

The quality of fit for the larger storms will be measured graphically by the agreement between the simulated and observed partial-duration series of runoff volumes. The annual probability of exceedance of each storm will be determined . Also, the following criteria are utilized in the HSPEXP for storm volumes: (1) the error in total flow volumes for the sum of selected storms must be less than 20 percent, and (2) the error in total flow volumes for the sum of selected summer storms must be less than 50 percent. Runoff volumes are used in this study because changes in lake water levels are dependent on accurate simulation of runoff volumes. **The criteria for acceptable calibration and verification for storm-runoff simulation are (1) the error in total flow volumes for the sum of up to 36 selected storms must be less than 20 percent, and (2) the error in total flow volumes for the sum of selected summer storms must be less than 50 percent.**

Accurate simulation of lake and wetland levels is a vital component of evaluating the effects of the proposed Crandon Mine on surface-water resources in the vicinity of the mine. Therefore, calibration also will consider

accurate simulation of available monthly lake-level and well-level data in the Swamp Creek watershed. Verification will be done by spatial transposition of the calibrated model as well as temporal transposition of the calibrated model. Verification through **spatial transposition** involves application of the runoff relations calibrated for the Swamp Creek watershed to the Pickerel Creek watershed. Verification through **temporal transposition** involves application of the runoff relations calibrated for a given time period to a second independent time period.

The accuracy of the calibration and verification for monthly lake-level and water level in wells data will be evaluated using the correlation coefficient and coefficient of model-fit efficiency previously described. Maximum and average errors in water levels also will be considered relative to the range of water-level fluctuations for a given lake or wetland. **The targets for acceptable calibration and verification of monthly water levels are a correlation coefficient greater than 0.85 and the coefficient of model-fit efficiency greater than 0.8.**

The mine-affected area will be a combination of impervious surface and compacted open space, whereas the tailings management area is an unique land use/land cover. Ranges of parameter values will be established and sensitivity-analysis methods will be applied to determine the expected value of and ranges for runoff, lake levels, and water levels in wells for the watersheds affected by mine operations. The expected values and ranges will be used to determine which conditions result in substantial changes in runoff and water levels relative to baseline conditions.

CALIBRATION PROCEDURES

The water budget is simulated in HSPF on a continuous basis by subdividing the watershed into areas of specified land use/land cover and summing the runoff. In this project, verification will be done by spatial transposition of the model calibrated for runoff estimation on the Swamp Creek watershed to runoff estimation on the Pickerel Creek watershed. For the area of the proposed Crandon Mine, model-parameter values reflecting the current, natural conditions can be determined by calibration and verification utilizing runoff data at the Swamp Creek stream gages above Rice Lake and Swamp Creek below Rice Lake at Mole Lake, assuming adequate daily and hourly rainfall data and other meteorological data can be obtained. Flow from much of the immediate area, and representative of the remaining affected area in the Pickerel Creek watershed, is measured at the Swamp Creek stream gage above Rice Lake. The data from the gage below Rice Lake will be used to ensure flows and water levels in Rice Lake are correctly represented in the model.

The 9-year period of streamflow data will be subdivided into a **5-year calibration period and a 4-year verification period**. Verification also will be evaluated by applying the HSPF model with parameters determined for the Swamp Creek Basin to the Pickerel Creek Basin, simulating monthly lake and wetland water levels, and comparing the simulated values to the measured values. Initial values for model parameters will be selected from the results of previous studies on similar watershed characteristics and preliminary model simulations. The calibration process will then be facilitated by the use of the HSPEXP, though not exclusive of other methods. The basis of the HSPEXP is a compilation of more than two decades of experience with HSPF and similar models over a wide range of climates and topographies.

ANALYTICAL PROCEDURE TO EVALUATE CHANGES IN RUNOFF

Because the mine is proposed and not yet constructed, a procedure must be developed to estimate changes in runoff relative to natural conditions resulting from mine construction, operation, and closure. Runoff from natural conditions can be assessed on the basis of available data for the watersheds near the proposed mine. However, runoff from the modified conditions of mine construction, operation, and closure cannot be assessed on the basis of

available data for watersheds near the proposed mine. Therefore, a computer model that is capable of simulating runoff resulting from natural and mine conditions through physically defensible selection of model-parameter values must be used to evaluate changes in runoff. The model-parameter values corresponding to natural conditions can be determined by **calibration and verification** utilizing available data, including detailed water-table and stream-bed elevation data for the areas with high water tables and (or) wetlands.

In application of HSPF, each watershed studied is subdivided on the basis of rain-gage locations and land-cover categories. The primary purpose of **segmenting** the watershed is to divide the study area into land segments that are assumed to produce a homogeneous hydrologic and water-quality response.

INTERNAL QUALITY-CONTROL CHECKS

Quality-control checks are required for two aspects of the HSPF modeling effort: (1) the meteorological, streamflow, lake-level, and well-level data utilized to calibrate and verify the model, and (2) the assumptions and procedures utilized to calibrate and verify the model to the available data and to parameterize the model for mine construction, operation, and closure conditions.

MODEL-OUTPUT REDUCTION AND REPORTING/PERFORMANCE AND SYSTEM AUDITS

A manual procedure is used in HSPF model calibration even when the HSPEXP is applied. In this procedure, the model user decides which parameter values are changed and by how much for each calibration simulation. Thus, it is essential to keep an iteration log during the manual calibration process.

CONCLUSION

This is a progress report with no conclusion at this time. However, the objectives continue to be valid and viable goals for the project and the development and daily use of this QAPP are integral to completion of the project.

ACKNOWLEDGMENTS

As described in the Project Organization and Responsibility section, this project is a cooperative effort among three agencies: the USEPA, USGS - Illinois and Wisconsin Districts, and Aqua Terra Consultants. The Great Lakes Indian Fish and Wildlife Commission (GLIFWC), the US Fish and Wildlife Service (FWS), the US Army Corps of Engineers Waterways Experiment Station (WES), the Mole Lake Band of the Sokaogon Chippewa Community and the Menominee have made significant contributions to this project.

Appendix in original document entitled "Application of HSPF to the Upper Wolf river Basin for Evaluation of Hydrologic Impacts of Crandon Mine Simulation Plan" by Brian Bicknell of Aqua Terra Consultants.

REFERENCES/Furnished upon request, citations omitted from this article for brevity.

Cleland, C., Nesper, L., and Cleland, J. 1995. "The Potential Cultural Impact of the Development of the Crandon Mine on the Indian Communities of Northeastern Wisconsin", Aurora Associates, Williamston, Michigan.

Donigian, A.S., Jr., Imhoff, J.C., Bicknell, B.R., and Kittle, J.L., Jr. 1984. Application guide for hydrological simulation program-FORTRAN (HSPF): EPA-600/3-84-065, Environmental research, 177 p.

The United States Environmental Protection Agency (USEPA) is applying a hydrology and hydraulic model, Hydrological Simulation Program - FORTRAN (HSPF), for simulation of changes in a watershed in northern Wisconsin resulting from a proposed underground zinc and copper mine during construction, operation, and closure. The watershed is a forested wetland with many lakes and streams, including a shallow lake that supports a natural stand of wild rice on the reservation of the Mole Lake Band of the Sokaogon Chippewa Community. The entire hydrologic cycle will be simulated with HSPF with an emphasis on the surface waters (streams, lakes, wetlands), the water budget, and fluctuations of the water budget. These results will be compared to other models. Final and critical steps, still in a developmental phase, relate results obtained from HSPF simulation to the risk to habitat on a biological and cultural level.

The HSPF model will be used to complement the impact analysis for the water budget already in progress - the MODFLOW ground-water model completed by the mining company and being reviewed by the Wisconsin Department of Natural Resources (WDNR). The U.S. Army Corps of Engineers (USACE) is currently running a FEMWATER (Finite Element Mesh for groundwater) model to evaluate the mining impacts on the groundwater. The results of the FEMWATER model also will provide some input to the HSPF model. The results and interpretations from the HSPF model will be available to the WDNR and USACE for use in their respective Environmental Impact Statements (EISs) as they determine is necessary. The model can also be expanded or modified in the future for simulation of other parameters, such as chemistry or sediment, as data are available. The affected Tribes in the area may also modify the model. These changes can be simulated in HSPF, however, determination of appropriate model parameters for simulating the solute- and sediment-transport processes on the basis of limited data are complex and are deferred to a possible second phase of the HSPF modeling project.

The points that could effectively be addressed within this Quality Assurance Project Plan (QAPP) evolved from an all-encompassing total of eleven questions. Some of the commitments and the model itself had already been chosen, so the following Project Data Quality Objectives (PDQOs) greatly helped focus the overall endeavor based on the model, time and resource constraints.

a) Which surface-water bodies (lakes, creeks, wetlands) strongly interact with ground water and, thus, can be substantially affected by ground-water pumpage from the mine?

b) Will the changes in runoff and water levels resulting from mine construction, operation, and closure impair the growth of wild rice?

c) Will the changes in runoff and water levels resulting from mine construction, operation, and closure impair the health of other flora, fauna, and habitat?

d) Will the changes in runoff and water levels resulting from mine construction, operation, and closure substantially impact the culture or cultural resources of the various Native American Tribes in the vicinity of the proposed mine (with a particular focus on the Mole Lake Reservation)?

e) Will mine construction, operation, and closure substantially alter the frequency and intensity of flooding downstream from the mine site?

The HSPF model simulates the surface water balance with an input of precipitation, potential evapotranspiration, and meteorologic conditions, and outputs of actual evapotranspiration, streamflow (the sum of surface runoff, interflow, and base flow from ground water), and percolation to deep aquifers that do not contribute to the local surface streams. This water-balance simulation also will be valid only for a limited range of values for recharge to ground water. By comparing the valid ranges of values for recharge in HSPF to those for MODFLOW and (or) FEMWATER, the models can be used jointly to determine a recharge rate that yields reliable simulation of the surface-water budget and ground-water levels and flow rates. Since the model had already been utilized rather extensively, past projects using the model could help in deciding what calibration, verification, and other objectives could be reached and with what degree of confidence when comparing the simulated to the observed runoff-duration curves. "Correlation coefficients" and "Coefficient of Model Fit Efficiency" goals were established so that a "very good fit" could be achieved as several criteria had to be met within a "plus or minus" percentage of specified goals. These criteria include correlation of storm events, water budgets (overall, annual and monthly), high- and low-flow distribution, seasonal volume error, recession rates, and lake and well-water levels.

NELAC AND PBMS: THE GOOD, THE BAD, AND THE UGLY

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SUMMARY

NELAC and PBMS are both on the verge of implementation. We have the opportunity to create a new good program that will provide rugged, reliable, economical analyses with oversight by a sound accreditation process, to maintain our current bad program of a proliferation of trivial method requirements with little regard to data quality and inspections which focus on adherence to method details, or to create an ugly program with poor, biased, and unreliable analyses with no oversight.

NELAC and PBMS can work effectively together to bring a new era of environmental analyses, one where the data needs drive the laboratory analyses, where laboratories are held accountable for data quality, not method compliance, and where a sound accreditation process is used to judge laboratory competence.

INTRODUCTION

On January 14, 1999, the Environmental Laboratory Advisory Board (ELAB), a Federal Advisory Committee that provides advice and counsel concerning the systems and standards of accreditation for environmental laboratories, published a report with recommendations for implementing PBMS. ELAB recommended EPA incorporate 13 "Essential Elements" into their PBMS implementation plans, and that NELAC continue to establish a framework for incorporation of PBMS in their program. (ELAB 1999) The ELAB report provides a basis for establishing an effective PBMS program. NELAC can provide the independent oversight necessary for this program to be successful.

ELAB RECOMMENDATIONS FOR IMPLEMENTING PBMS

ELAB placed a great deal of importance on the fundamental principles of a successful PBMS program. These principles are referred to as Essential Elements (see Table 1). While all of the Elements are essential to PBMS, six were deemed vital to its proper implementation. The Essential Elements were developed using a "wide perspective" approach to describe key features while not becoming embroiled in details that could restrict its options. The report provides examples to clarify the intent and illustrate the main point of the Elements.

ELAB believes these Essential Elements are applicable to compliance monitoring independent of PBMS.

Table 1. Essential Elements for a Successful PBMS Implementation

A. Critical Elements

A-1. Legal Standing: Data generated in compliance with the PBMS framework must have the same legal standing as data generated using a promulgated EPA method.
A-2. Cost Effectiveness: Requirements for PBMS for method validation, demonstration of capability, and ongoing quality control should be consistent across all EPA programs and should also apply consistently to EPA published methods, modifications to EPA published methods, and new methods. Such requirements should be cost effective for small laboratories performing limited analyses, large complex laboratories working nationwide, and instrument manufacturers.
A-3. Scientifically Sound and Relevant Validation Process: Both the method validation and the PBMS documentation requirements should be based on principles that are widely accepted in the scientific community and on the intended use of the data.
A-4. Clearly Articulated and Appropriate Performance Criteria: EPA should develop and publish PBMS performance criteria appropriate to the anticipated regulatory use. PBMS performance criteria are the sensitivity, selectivity, precision and accuracy of the data needed to demonstrate compliance with the regulation.
A-5. Regulatory Development: EPA should employ or develop laboratory methods that have been demonstrated to be capable of achieving the regulatory compliance monitoring requirements. In order to assure the quality of the science used in the development of regulations, EPA should submit all the technical studies used to develop a regulation to peer review as part of the regulatory process, prior to finalizing any such regulation.
A-6. Documentation: The documentation required under PBMS must be sufficient for independent verification (i.e., auditing) and reproduction by another laboratory which is skilled in the art.

B. Important Elements

B-1. Flexibility: Regulated entities should have flexibility to modify methods, or use new methods, as long as the PBMS requirements are met.
B-2. EPA Optional Approval Process: The scientific community should have an effective system for an optional EPA approval of new analytical methods. There should be no unnecessary barriers to these approvals.
B-3. Consistency: Consistency in definitions, objectives and criteria for all aspects of PBMS among Program Offices, EPA Regions and States is essential.
B-4. Simplicity: The implementation of PBMS should be made as simple as possible without departing from the Essential Elements and the PBMS goals. Guidance developed for PBMS should be written with simplicity and clarity to ensure consistent interpretation and implementation.
B-5. Clarity of Intent: Performance criteria must be represented by unambiguous requirements or objectives, which can be easily understood, applied, demonstrated and readily auditable by the laboratory community (laboratories, data users, laboratory assessors).
B-6. Careful Implementation: Implementation of PBMS should consider how existing regulations and/or monitoring requirements will be affected.
B-7. Widely Available Reference Materials: Readily affordable reference materials should be widely available to assist in the method validation effort.

FRAMEWORK FOR AN EFFECTIVE PBMS

The ELAB report described the key features which must exist under PBMS. These activities can be organized into four broad categories: Performance Criteria, Method Validation, Laboratory Requirements, and Accreditation.

Performance Criteria refers to the quality of data needed. This term was used by ELAB in lieu of comparable terms such as Measurement Quality Objectives (MQOs) or Data Quality Indicators (DQIs). ELAB believes that the beginning of a successful PBMS program is the establishment of these data quality needs. ELAB described these needs in terms of the bias, precision, detection level, and confidence of the data. Ideally, these data quality needs would be described in the regulations, and, there would be at least one laboratory method whose documented performance can demonstrate compliance with the regulation. Alternatively, the data user can specify the measurement quality objectives.

Method Validation is performed to document that the required data quality can be met. ELAB believed there could be varying levels of validation, and various ways to validate a method. Conceptually, ELAB envisioned three levels of method validation. These levels relate to the degree of control over two critical aspects of laboratory quality control-ruggedness and sample variability. A laboratory who only analyzes one particular sample type (e.g. a municipal wastewater laboratory) has a lot of control over the quality system it employs, and the sample matrix has little variability. The validation performed by this type of organization could be less than that performed by a laboratory who analyzes many different types of samples. In this latter case, the laboratory still has control over the quality system, but not the sample types. Finally, a method developed for use by many laboratories for many different sample types, should have the most validation performed, as the method developer has no control over the laboratory's quality system.

In terms of the method validation activities themselves, there are several acceptable ways which could be used, including comparison to a Reference Method, analysis of a Certified Reference Material, and interlaboratory comparisons (Taylor 1983). Validation represents the activities required to show that a method has the capability to generate data of the quality needed and should be differentiated from those activities (QC) performed to document the ongoing quality achieved with routine sample analysis.

Laboratory Requirements refers to the activities needed to be performed by a laboratory. The laboratory must have a Quality System in place. The laboratory must document the method in a Standard Operating Procedure (SOP). It must perform some type of method start up activity such as an initial demonstration of competence, and, it must analyze quality control samples to document that the method was performed correctly. Finally, the laboratory must analyze data quality assessment QC samples (e.g. matrix spikes, field blanks) to document the data quality obtained on the samples.

If the activities above are performed, Laboratory Accreditation is then simply a review of the documentation to ensure that these activities were performed. If so, the lab is competent to perform analysis.

In summary, the regulations (or data users) establish measurement objectives, method validation is used to demonstrate method capability, laboratory QC is used to document data quality, and accreditation is used for laboratory competence, not data quality.

EXAMPLE PBMS PROJECT

As an example of how this new system would work, a hypothetical project was established. The sample was a sludge sample. Expected contaminants at the site are polynuclear aromatic hydrocarbons (PAH). The cleanup level established for these compounds is 200 ug/Kg. The project is a RCRA site and other compounds on the 40 CFR 264 Appendix IX list are of limited concern.

In my vision of a new framework, the first activity is to establish MQOs as follows:

- Accuracy of 70-130% for PAH at action level
- Accuracy of 50-200 % for other SVOC at 330 ug/kg
- <5% False Positive

In this "Good" project, the client request data to meet MQOs, not methods. The laboratory validates the performance of the method on a solid matrix, and accreditation is based on the quality system approach.

The Good Method

- Pressurized Fluid Extraction, methylene chloride/acetone
- 50 g sample
- GC/MS
- 5 point calibration for PAH, RSD < 15%
- Low standard equivalent to 100 ug/kg
- Single point standard at 300 ug/kg for other Appendix IX compounds
- Continuing calibration for PAH only, 15%D
- LCS at 400 ug/kg for PAH, 70-130%
- MS/MSD is PAH mix, spike level at 400 ug/kg

In the existing "Bad" system, the client specifies a method (e.g. 8270), the method cannot meet the MQO's, auditors audit from detailed method checklists, and laboratory competence is demonstrated on PE results on a water matrix (WS/WP). The laboratory does not establish that the method can meet the required project objectives and data validation is performed to assess method conformance, not data quality.

The Bad Method

- Soxhlet with methylene chloride
- 30 g sample

- GC/MS
- 5 point calibration for all, CCC RSD<30%
- Continuing calibration CCC %D<20%
- Reporting Limit of 200 ug/kg supported by MDL
- Low standard equivalent to 330 ug/kg
- LCS & MS at mid point, 8270 sub-list

A PBMS program implemented poorly, with no oversight, has the potential to decrease data quality. In this "Ugly" system, the client specifies a method, the laboratory modifies the method, but with no method validation and no documentation. There is no independent inspection, and no QC activities are performed.

The Ugly Method

- Shake with methylene chloride
- 10 g sample
- GC/FID
- Single point calibration at 500 ug/kg
- No LCS or MS; No Cal Check; No SS

CONCLUSION

If implemented correctly, PBMS can allow flexibility and improve quality. However, PBMS will only work if a rigorous oversight program such as NELAC exists. Together, NELAC and PBMS can provide a sound foundation for laboratory analyses.

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AUTOMATION IN LABORATORY INFORMATION MANAGEMENT SYSTEMS: MYTHS AND VIRTUES.

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SUMMARY

Recently, our laboratory undertook the project of substitution of old data management systems. The total project was managed independently in each Section (Organics, Inorganics, Sample Management) and a small "task force" served as link among them. After the installation of the new software, the need to expedite validation and final roll-out led to a realistic inventory of the contributions the LIMS would make (i. e., the lasting "virtues" that the laboratory would exploit), but it also revealed distorted expectations that had no support in valid, practical terms (i. e., the "myths" that were debunked).

One single system did not meet all our needs. We settled for a combination of Hewlett Packard's ChemServer and The Khemia Company's Omega. One single laboratory-wide approach to systematic field nomenclature did not work. The structure of tables within the databases was flexible enough, however, to accommodate correspondence of terms and field designations. The function of Quality Assurance could not be taken to limits of "full automation" because of the complex combination of method requirements within each analytical run. We had to settle for a sensible balance between LIMS-directed processes and effort-driven manual activities, i. e., computer power did not replace manpower. Finally, what we thought was the "end of the transition" simply indicated the beginning of a continuous evolution that still today makes our LIMS a living project.

Commitment to the integration of one LIMS product and one chromatography data system was a logical decision consistent with the strategic goals of the laboratory. Training proved to be the key ingredient to maximize the benefits of the LIMS. The high demand for electronic data deliverables (EDDs) led to expedient progress in database customization. The integrity of the LIMS structure turned it into a valuable repository of all lab-related information. Despite the crises that had to be overcome, having migrated to new, dependable data management systems has resulted into improved lab operations and renewed competitive advantage in the marketplace.

INTRODUCTION

In today's marketplace, the appetite for information and knowledge has not excluded the analytical data generated by commercial environmental laboratories. In order to compete effectively, the laboratory must commit time and money to the tools, resources and technologies

that support production and management of its data. Laboratory Information Management Systems (LIMSs), therefore, have become critical elements in any laboratory environment where processing of data and dissemination of information are indispensable.

The theory and the practice of LIMSs do not necessarily evolve at the same exact pace. The search for a "next generation", computer-based LIMS has become a major challenge, even though for many years the principles and guidelines for LIMS functionalities and structure have been well defined (Hinton 1995). The task can be overwhelming when the constraints of the implementation process must be made compatible with the demand for flexibility (if not stress) imposed upon the laboratory.

OUR LIMS SOLUTION

Beyond the dichotomy of vendor-generated vs. laboratory-developed LIMS, our initiative for migration to a new system began with the end in mind. We came to the conclusion that continuing support of the current system was untenable and unrealistic, we knew what we wanted changed; we knew what it was that we could no longer live with or without. We decided to screen and select an "off-the-shelf" LIMS product.

We had closely observed how, during the last three years, the LIMS industry had demonstrated incremental versatility in its products and increasing reliability in its services. At the same time the number of vendors more than doubled, and the product offering had been further specialized to the point of making available software packages specifically targeted to the commercial environmental laboratory. The major instrument manufacturers also had secured a strong presence in the LIMS market.

Our relationship with Hewlett-Packard was the first one to develop. Its chromatographic system combining a ChemServer network and Target software (CS/T) was a logical choice to revamp the entire data processing system in the Organic Section. The CS/T system, however, was not a LIMS. It could be (and, in our case, it was) integrated with a LIMS acting as a client-server application.

The choice of The Khemia Company's Omega was based on timeliness and fitness for use. It had just released a new version of Omega developed in MSAccess97, and we had just migrated company-wide to MSOffice 97; furthermore, we had established MSAccess97 as our "internal standard" for handling of databases. At the same time, the structure of Omega matched very closely the overall reorganization of workflow and data processing, started months earlier in preparation for the transition to a new system.

The implementation proceeded in a stepwise fashion with minor customization required to incorporate the sample registration (or "log-in") procedures. More extensive efforts were necessary during the steps of creation of tests and definition of method-specific variables. The most difficult obstacles were encounter during the customization of the invoicing capabilities.

Confronted with series of predictable and unexpected circumstances, the laboratory took a dual approach to managing the implementation process. The Organic Section remained independent

with exclusive use of the CS/T system. The Inorganic and Sample Management Sections focused on expediting the migration to Omega while still processing data in the "old LIMS". The old system was abandoned as soon as the "log-in" module of Omega was capable of sharing sample information with the CS/T system and of distributing accurate workload reports to the analysts.

During the evolution of the project, it became evident that some preconceived potential benefits of the LIMS would not be realized. The extent of the integration between the CS/T system and Omega was going to depend on our flexibility to reach consensus on customization of specific features. The uncharacteristic simplicity of the selection process had also raised expectations about the speed of delivery of the final LIMS product.

Our interest in expediting the final validation and full rollout of the system led to an inventory of the main contributions the LIMS would make (i. e., the lasting "virtues" that the laboratory would exploit). On the other hand, those expectations that would not be met began to take the shape of "myths" that we (with the evidence collected) would be in the position to debunk.

MYTHS

A. "One LIMS fits all."

One single system was not the solution to our problems and may not apply to commercial laboratories of characteristics similar to ours. Our LIMS is (and will continue to be) a true hybrid; the combination of the CS/T system and the Omega client-server application. The former is, unquestionably, a powerful chromatographic data system that centralizes the processing, reduction, validation and reporting of all the data in the Organic Section. It is not, however, an isolated network; it is directly linked to Omega through import/export routines that automate the retrieval of sample information and updating of analysis status. Omega, on the other hand, gave us the flexibility to handle log-in, invoicing and inorganic data without having to replicate the multiple features already present in the CS/T system.

B. "LIMS is a universal language."

Not all LIMS are created equal, and that is first revealed through the simple inspection of table structures in the databases. "Translation" is possible but it adds to the list of items to customize, to the list of training issues to resolve, and to the potential conflicts that may arise when the final product needs to be extracted by a third party who uses a different data system. The "language barrier" applies to field names and types and may also cover referential links among tables, the ability to export/import specific file types, or the structure of analytical runs.

C. "LIMS automates Quality Assurance."

The function of Quality Assurance (QA) is enormously benefited by a versatile LIMS but never replaced by it. The most sensitive area is the definition of tests, quality control (QC) samples and method detection limits (MDLs). The Quality Assurance Officer will be most

directly involved in the process of establishing test parameters in adherence to each method's standard operating procedures. Once in place, the tests incorporated in the LIMS will introduce automation to the extent that multiple samples will share the same test information and QA/QC requirements thus simplifying the data validation steps. The Quality Assurance function, however, must maintain an active role in the following areas:

(1) Verifying the timely incorporation of new test-related information or method-specific criteria; e. g., updating MDLs and quality control limits.

(2) Documentation of any deviation from key criteria; e. g., issuing Corrective Action Reports, judging the relevance of data points in control charts, generating Case Narratives for specific projects.

(3) Evaluating the integrity and completeness of data as they apply to specific projects with distinct regulatory drivers.

D. "Computer power will replace manpower."

Particularly in small commercial environmental laboratories, a good number of effort-driven manual activities find no substitute among alternative LIMS-directed procedures. Even the most sophisticated database features cannot replace the ability of the analyst to prioritize workload and assignments in order to maximize throughput and meet turn-around times. Computer power eventually replaces itself, i. e., every new generation of software and hardware introduces irreversible changes and guaranteed improvements.

E. "All good things must come to an end."

The end of the transition is simply the beginning of a long term LIMS project. For the sake of the laboratory and its clients, the LIMS must behave like a living organism. Assigning a "life cycle" to a LIMS, however, may be an oversimplification. With continuous evolution and improvement a LIMS may exceed the typical "life expectancy" of a software product. Before entering "maturity" and advancing into its "decline", the LIMS can pick up a new "life cycle" and revitalize itself. This approach may require investment in new hardware and customized programming but both can be incorporated within the same software architecture. In the foreseeable future, in fact, Y2K-compliance and throughput capacity may be the key limitations for extended life of an "aging" LIMS.

VIRTUES

F. Foundations of solid logic.

The more solid its internal and external logic, the more effective the LIMS solution will be. Internally, the logic of the LIMS refers to the integrity and validity of the database elements (tables, queries, forms, macros and modules) and its relationships. This logic is demonstrated by the flexibility of the application, by its ability to accept customization that maintains consistency in the programming code. Externally, the logic is reflected in the equivalency

between LIMS operation and laboratory procedures. A new LIMS will demand changes in some lab procedures and viceversa. This mutual influence should reinforce strengths. Any value-adding lab activity should find a counterpart in the LIMS structure.

G. The LIMS will be as good as its users.

Only through extensive and thorough training of all LIMS users will the system unleash its full potential. The training effort will also be the tool to transform compliance with new procedures into commitment to a long-term undertaking. Every user must realize the importance of each individual's contribution, the "big picture" of LIMS implementation, and the consequences of sub-standard performance.

H. Electronic deliverables and electronic clients.

The LIMS package includes the capability of generating multiple types of electronic data deliverables (EDDs). These EDDs have become the paperless equivalent of a full size data package. The clients' increasing demand for EDDs indicates a trend towards a more sophisticated level of data management. In fact, if all client-lab interactions can effectively focus on electronic exchanges, a "new breed" of electronic clients may lead to the mass customization of reporting formats submitted exclusively as EDDs.

I. LIMS as a virtual lab.

The LIMS is ultimately the repository of all the data generated by the laboratory. The proper management of data through the LIMS functionalities turns analytical results and sample descriptions into meaningful information. Through the dissemination of information, the LIMS becomes a surrogate for data-driven operators, i. e., a group of "virtual data analysts". The "physical" lab analysts interact with the LIMS as virtual clients. The virtual lab is then the collection of procedures that are automated through the LIMS and accessible by the virtual clients: acquisition, processing, validation, reporting and archival. The "external" lab clients interact not with the LIMS but with customized EDDs that the virtual clients generate.

J. LIMS as a laboratory's inflection point.

An industry's inflection point has been defined as the point in time when a serious threat dislocates all activities and demands a redefinition of paradigms, structures and goals (Grove 1996). Such are precisely the circumstances when a laboratory commits to the full implementation of a new LIMS. The strategies of the past do not work any more; the imminent threat is the loss of any advantage over the competition. The new LIMS brings about a new environment; the lab discovers new competencies and sets new goals consistent with them. The benefits of the new LIMS become visible in the bottom line but also generate a "return on knowledge" that enriches the expertise of the analysts and the value of the product delivered to the clients.

CONCLUSION

Every "LIMS project" may tell, in the details, a different story. The moral of ours is that, during the implementation process, myths and virtues will surface accompanied by clear evidence of their validity (or lack thereof). The lessons learned can be encapsulated in the need to fulfill three very important "C's":

- Communication: Its quality and depth will determine the overall pace of the process. It must incorporate the "voice of the customer"

- Collaboration: Everyone in the implementation team is a stakeholder, a knowledge worker and an owner of the process; the best results will derive from the best-concerted efforts.

- Customization: With a solid foundation of internal logic, any LIMS software can and must be intelligently customized to incorporate value-adding features.

ACKNOWLEDGEMENTS

All personnel at the Eckenfelder Laboratory contributed to the LIMS implementation process. Art Teter and Doyce Blair (The Khemia Company) provided vital assistance. Discussions with Rick Davis (Brown and Caldwell, Nashville) and Scott Bash (Brown and Caldwell, Atlanta) clarified perspectives on LIMS issues.

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The Use and Abuse of QA/QC Samples in Environmental Data Acquisition

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SUMMARY

The types and quantities of field quality control (QC) and quality assurance (QA) samples should be based on knowledge of the nature of the contaminant and the project data quality objectives (DQOs), rather than on protocol requirements (EPA 1993). DQO-based selection of project-specific QA/QC samples reduces the overall analytical cost of the project. During data validation field QA/QC sample results are usually discussed in terms of precision, sample handling and/or data comparability. Our experience shows that even when field sample results may be qualified based on field QC sample results, the overall data usability is hardly ever affected by out-of-control field QC samples. Other factors, such as the missed holding times, or poor analytical quality, usually govern the re-sampling and reanalysis decisions. This paper focuses on the misuse of soil QC samples, such as field duplicates, trip blanks and QA splits, however, many of the discussed issues are also relevant to QA/QC water sample use.

INTRODUCTION

The purpose of the plethora of QA/QC samples that are required by various protocols can be truly overwhelming even to seasoned environmental professionals. The use of these samples is recommended by the Environmental Protection Agency (EPA) and prescribed by the Department of Defense (DOD) branches. As Table 1 shows, QA/QC samples include trip blanks, field duplicates, QA splits, equipment rinsate and ambient blanks. These samples are collected and analyzed at a substantial cost to the project. The costs related to QA/QC samples may be as high as 30% of the total analytical cost. Collection and analysis of these samples are usually mandated by the protocol that is applied regardless of the project DQOs and intended use of the data.

DISCUSSION

The collection of field QA/QC samples has become a routine that is rarely questioned or revised to better meet the project needs. On many projects QA/QC samples are collected for the sake of satisfying the protocol requirements; the data obtained are rarely used to impact project decisions. The qualitative and quantitative acceptance criteria for field QA/QC samples are often arbitrarily selected and do not take into account the site-specific matrix variability or the nature of contaminant distribution. Meeting these acceptance criteria is of little consequence for the project execution. To reflect the current industry practice we flow-charted a prevalent process for soil samples acceptance shown as on Figure 1. One can see that the outcome of QA/QC sampling does not, in fact, affect project activities because cost and schedule considerations generally override the quality issues originating from the analyses of field QA/QC samples.

Table 1
Types of Soil QA/QC Samples

QA/QC sample	Army Corps of Engineers (USACE 1994, 1998)	Navy (NFESC 1996)	Air Force (AFCEE 1996, 1998)	EPA (EPA 1996)
Trip blank	Water and soil (clean sand)	Water blank only	Water blank only	Analyte –free media; no blanks for solid
Field duplicates	Homogenized or collocated for VOCs	Homogenized or collocated for VOCs	Homogenized or collocated for VOCs	Separate samples taken from the same point in space and time
Field replicates or QA splits	Homogenized or collocated for VOCs	Homogenized or collocated for VOCs	Sample divided into two equal parts	No reference
Rinsate (equipment) blanks	For all projects when sampling equipment is cleaned			
Ambient (field) blanks	Per DQOs	Per DQOs	Per DQOs	Per DQOs
Source water for rinsate blanks	No requirement or recommendation, however, this practice has been observed			
Matrix spikes	On project samples	On project samples	On project samples	Not project specific
Temperature blanks	Required	No reference	Required	No reference

VOC denotes volatile organic compounds

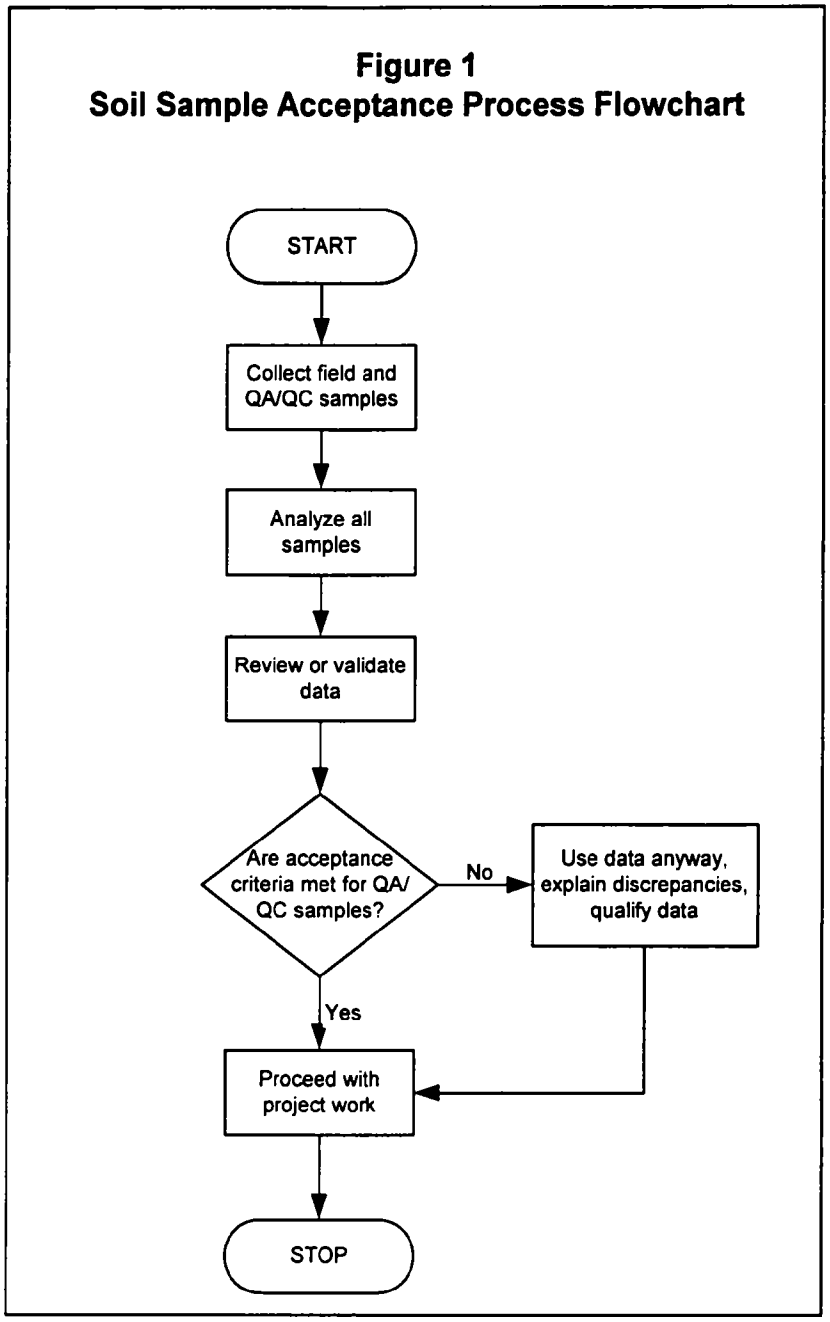
Field duplicates for Soil

Duplicate samples are usually collected and analyzed at a frequency of 10% of the field samples. The purpose of field duplicates is to evaluate the sampling precision as relative percent difference (RPD), with the RPD goal, depending on the protocol, varying from 30 to 50%. Sample results, as a rule, are not qualified during data validation based on the RPD criterion, and data sets are not rejected if this criterion is not met. In such cases, a token statement on "matrix inhomogeneity" usually satisfies all parties involved. Therefore, the main outcome of field duplicate analysis is some assessment of matrix inhomogeneity with no real consequences on data usability.

According to the Navy Laboratory Guide (NFESC 1996), field duplicate precision is affected by sample homogeneity/heterogeneity, precision of sample collection and handling, and analytical precision that is determined otherwise by use of laboratory control samples. Field duplicate precision calculated as RPD allows establishing the following parameters:

1. Total sampling and analysis precision
2. An indirect measure of matrix inhomogeneity
3. Representativeness of a sampling program or how well the samples represent the site

Experience shows that the third parameter is the most important and the most overlooked one. To substantiate this statement we offer some case studies.



Case Study 1.
Samples for VOC analyses cannot be homogenized due to contaminant volatility; therefore, collocated duplicate samples are commonly collected for VOC analysis. This type of sampling by its nature reduces the probability of good sampling precision, and the duplicate RPD for such samples depends on analytical precision and matrix effects.

Table 2 shows a comparison of the VOC results for collocated stockpile soil samples. The duplicate RPD ranges from 6 to 168. To complicate the matters further, collocated QA samples were collected from each location. Although QA sample results are comparable to the sample and duplicate results, the relative standard deviation (RSD) that ranges from 22 to 158%, confirms what we already know from the RPD data: there is a great variability of the contaminant distribution in the analyzed soil. These data had absolutely no impact on the project decisions.

Table 2
Unhomogenized Soil Duplicate Precision

	1,1,2,2-Tetrachloroethane concentration, mg/kg							
	No. 1	No. 2	No. 3	No. 4	No. 5	No. 6	No. 7	No. 8
Sample	0.010	28	87	74	1.6	0.2	4.2	0.2
Duplicate	0.024	51	56	66	1.7	2.3	0.64	0.18
RPD[1]	***82***	***58***	***43***	***11***	***6***	***168***	***147***	***11***
QA sample	0.081	20	71	46	0.67	2.4	3.5	6.3
RSD[2]	***98***	***49***	***22***	***23***	***43***	***76***	***68***	***158***

[1] RPD is the difference in two concentration values divides by the mean concentration
[2] RSD is the standard deviation divided by the mean concentration

These results raise more questions than they provide answers. Which one of these results represents the true concentration in a particular section of the stockpile? Don't we already know that the precision of unhomogenized collocated samples is likely to be poor due to one single major contributing factor, that is variability in contaminant distribution in soil? Why have we gathered this information in the first place, since it did not have any influence on project decisions? And finally, should we have collected more discreet samples instead of collocated duplicates to better estimate the overall concentrations in the stockpile.

Case Study 2
Homogenized duplicate samples were collected from a former ammunition demolition site. Field samples collected from surface areas were homogenized four-point composites, and their duplicates, subsampled from the same composite, were homogenized splits. The target analytes were metals and trace explosives. Thousands of samples were collected in this manner from excavations at the site. In this example we have randomly selected nineteen duplicate pairs with eighty-eight RPD values calculated for various detected target analytes. Table 3 shows that the RPD for a vast majority of duplicate pairs was below 30%, with the higher RPD values observed for such metals as lead and barium.

Table 3
Homogenized Composite Duplicate Precision

RPD Range	Number of Duplicate Pairs
0-30	68
30-50	12
Greater than 50	8

This information tells a story different from the one in Case Study 1. For this project, the collection and analysis of duplicate samples was useful for determining the sampling precision, i.e. the precision of compositing and homogenization. The RPD values for these samples truly represent the sampling and analytical precision. Reproducible results represent true environmental conditions; therefore, good sampling precision is a measure of representativeness.

Nonetheless, the 10% frequency of the duplicate sample collection at this site seems to be excessive. Once the homogenization procedure has been established for the project and

confirmed by analytical results, it would be sufficient to confirm it again only if the procedure changes.

Trip Blanks

Another example of QC sample misuse is the analysis of water trip blanks with soil samples. EPA and most of the DOD agencies do not clearly state whether trip blanks should be used for soil samples. Decisions related to this matter are usually made during the Quality Assurance Project Plan (QAPP) preparation. We have experienced significant difficulty justifying the DQO-based use of trip blanks.

Trip blanks are used to determine whether contamination could have been introduced into the samples while they are handled in the field and are in transport, i.e. in coolers with ice transported from a site to the analytical laboratory. Ambient contaminants or VOCs emanating from the samples would then travel through a Teflon-lined septum into a 40-ml vial filled with analyte-free water. These contaminants are usually chlorinated hydrocarbons, such as methylene chloride or Freon. Water trip blanks make sense only when they accompany water samples for VOC analysis, and low or unknown contaminant concentrations are expected.

Soil samples do not provide the same contamination pathway as water samples because they are not collected in 40-ml vials with Teflon-lined septa. In addition, soil matrix does not have the same transport mechanism as water does (adsorption *versus* dissolution). There are other differences that make the comparison impossible: different sample handling in the laboratory, a variety of purge and trap sample introduction techniques, and differences in soil and water detection limits. Comparison of low level trip blank contamination to low level soil concentrations is not conclusive and hence meaningless.

The same is true for the practice of monitoring cross-contamination between samples with trip blanks. This type of contamination is best controlled by such QA measures as sample segregation and proper packaging. Based on years of reviewing data packages one can come to a conclusion that the trip blank contamination most likely originates in the laboratory or in the source water used to prepare the blank, not in the field.

The use of clean oven-baked sand for soil trip blanks has been also proposed (USACE 1994, Lewis 1988). This cumbersome practice raises a different set of issues. For example, how does VOC transport in organic-free sand compares with VOC transport in soil of mixed lithological composition with organic carbon content? How can contamination of the sand blank with ambient laboratory VOCs be prevented?

Convincing an agency or a DOD reviewer to exclude a trip blank shipment with soil samples is not a trivial matter. Common sense does not always work, and often we are directed to analyze water trip blanks for soil samples on the projects where the action levels are orders of magnitude greater than the ambient levels that may be found in the trip blanks. With many sample coolers going to the laboratory the cost of obtaining this marginal information can be substantial.

QA Splits

QA splits are a valuable tool in detecting data quality problems, and as such, their use is recommended in Region 9 Best Practices for the Detection and Deterrence of Laboratory Fraud (EPA 1997). Homogenized QA splits have the most value as they serve as confirmation of results reported by the primary laboratory. Unless two laboratories employ the exact same procedures for extraction and analysis, results are usually not comparable. If samples are not homogenized or laboratories use different extraction and analysis techniques, comparison of results will not be meaningful.

QA splits are useful for making real-time decisions on data quality only when data comparison is conducted while the project is still in the field phase. Unfortunately, the reality is quite different, and data comparisons are usually made long after the field work has been completed.

CONCLUSION

The two case studies provide striking examples of the use and abuse of QA/QC samples. In our view, the data quality objectives of the Case Study 1 did not justify the collection and analysis of duplicate samples, because collocated samples are not true field duplicates and their precision reflects only matrix variability with respect to contaminant distribution.

Substantial sample variability is likely to be expected for any sample collection technique for VOC analysis (Vitale 1999). The same is true for many other contaminants. The analysis of eight duplicate samples increased the project analytical cost by 10%; however, the obtained data did not have any impact on the project decisions.

In Case Study 2, however, duplicate samples provided important information because they truly reflected the sample handling procedures that were susceptible to human error. These procedures were built into the sampling protocol, and therefore, if conducted improperly, would have produced unrepresentative site data. It is interesting to note that even when the RPD values were very high, no corrective action (re-sampling, additional excavation, etc.) was undertaken, and project activities were not impacted.

A wealth of experience exists today that equips us with the knowledge on contaminant transport in soil. Coupled with available information on site history and background, this knowledge allows us to make valid assumptions on contaminant distribution and variability in soil at the site. If the distribution is expected to be sporadic, to better characterize the site we should collect more field samples instead of duplicate samples or consider compositing as a sampling option. If the historic use of the site is completely unknown, a few duplicates collected early during remedial investigation will provide the information for making educated decisions related to the future sampling design process.

As we are moving towards implementation of the Performance Based Measurement Systems (PBMS), we need to re-evaluate the practices related to the collection of QA/QC sample data. Some of the recommendations that will significantly reduce project analytical costs without compromising the quality are as follows:

1. Collect trip blanks for water samples only when low level contamination is a matter of concern
2. Justify the type and frequency of collection of QC duplicates on the project DQOs; use the obtained data in sampling design process for further site investigation or remediation
3. Use QA samples only when justified by the sampling design and make decisions related to data comparability while the project is still active
4. Reduce excessive collection of equipment rinsate samples
5. Perform project-specific matrix spikes only if the obtained data will be used for project decisions

To reduce unnecessary costs QA/QC samples should not be collected if the obtained data are not used for project decisions. Justified by the project DQOs and meaningfully interpreted, these sample results can be used for developing representative sampling designs or for establishing the true sampling precision, otherwise their collection turns into an expensive yet unnecessary exercise.

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THE FLORIDA PERSPECTIVE - LESSONS LEARNED

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SUMMARY

Several programs in two different agencies administer the oversight of environmental data quality in Florida. Differences in objectives and an occasional conflicting requirement leave the regulated community and the data consumer with a sometimes confusing, slightly skewed concept of data quality. Recognizing that the existing system of programs resulted in inefficient quality assurance oversight, the Department of Environmental Protection and the Department of Health entered into a Performance Partnership Agreement with EPA Region IV to explore procedures that would make the most efficient use of all resources.

A list of quality management tools was identified through a series of focus groups, meetings with EPA and benchmarking exercises that considered programs in other states. In addition, electronic tools were developed to assist in many of the routine, repetitive, time consuming activities.

The result is a balanced mix of activities and responsibilities that takes full advantage of the growing NELAP program, electronic tools, information access and the concept that quality is a shared responsibility. The outcome should mean less intrusive oversight, and better informed data consumers who will in turn, have the ability to understand and utilize the data to make sound environmental decisions.

SETTING THE STAGE

Florida, to the rest of the world, has a strong quality assurance program, with requirements mandated by the Quality Assurance Section of the Department of Environmental Protection and the Department of Health's Laboratory Certification Program. Why, is it, then, that the DEP compliance staff encounters increasing incidents of data quality problems, shoddy laboratory operations and even data fraud. Part of the answer lies in a growing understanding of data quality by DEP program managers, but of greater concern is the manner in which Florida currently conducts business.

The oversight of data quality in Florida resides in two agencies. The Florida Department of Health Laboratory Certification Program (DOH LCP) certifies laboratories for testing drinking water and environmental samples. Participation in the program is mandatory for laboratories providing compliance data for drinking water and domestic wastewater; and is voluntary for all other laboratories. For most other environmental programs, except air, the Department of Environmental Protection's Quality Assurance Section (DEP QAS) requires that the sample collection and testing organizations submit a Comprehensive Quality Assurance Plan for

approval by DEP. These plans, while similar to Quality Assurance Project Plans, address all capabilities of an organization rather than those that might be selected for a particular project.
In addition to these programs, the DEP District staff conduct performance audit inspections (PAIs) as a part of an ongoing commitment to the NPDES program. These PAIs include audits of the laboratory that generates data for a given facility.

A laboratory in Florida has the potential of being audited by any of the above programs – sometimes concurrently, but more often than not, at separate times. Each program has a different set of objectives and requirements, which can, in some cases, impose conflicting requirements on the laboratory. Clearly, audits by three state programs are a poor use of resources, and create confusion in the laboratory community about which requirements to follow. This, in conjunction with the growing number of problem laboratories, led the Quality Assurance Section to conclude that the current system was inefficient and did not provide adequate quality assurance oversight.

IDENTIFYING RESOURCES

DEP began to assess the overall effectiveness of the quality management program in Florida. A series of focus groups, a performance partnership agreement with EPA Region IV and benchmarking activities sought to identify the basic principles and activities of an effective Quality Management Program.

The result of these exercises was the identification of four basic principles and a set of tools to be used in managing an effective quality assurance oversight program.

These principles are:

- Good decisions require good data;
- An effective quality management system is the basis for quality data;
- Quality of Science Reviews are necessary to determine if the Department's decisions are adequately supported by the collected data; and
- Data quality is a shared responsibility.

The quality assurance tools that are needed to implement an effective quality assurance oversight program include quality planning (the DQO and DQA process as well as quality plans), systems audits, proficiency testing and data validation.

THE CURRENT PROGRAM

In evaluating the current roles and responsibilities of the DOH LCP and the DEP QAS programs, it was determined that the programs emphasized three of the QA tools: systems audits, proficiency testing and quality plans. These activities tend to stress the importance of the process rather than the end product, focusing on a laboratory's potential to produce good data rather than assessing the generated results. Further, DEP and the data consumers (permittees, respondents, etc.) depended on the expertise and evaluations of the 15 professionals in the DEP QAS and DOH LCP programs to provide them with the answer to "How good are my data and my laboratory?", and the answer, based on the use of these three tools, provided a skewed, overly optimistic picture of laboratory data quality in Florida.

BACK TO BASICS

Recognizing the overemphasis on certain QA tools, the Department reevaluated the manner in which all the basic principles and quality assurance tools were being implemented. It was determined that data validation, which is based on the evaluation of actual data generated, and is a measure of an organization's routine performance, had been sadly neglected.

Also considered were the emerging national laboratory accreditation program, enhanced information access, interactive software programs to minimize tedious, repetitive tasks, and the current resources in the DOH LCP and DEP QAS.

THE NEW LOOK

The result of all the meetings and benchmarking exercises is a new look for data quality oversight in Florida, beginning with the realignment of responsibilities within the DOH LCP and the DEP QAS.

DOH LCP will be responsible for accrediting all environmental laboratories in Florida, and DEP QAS will concentrate its resources on evaluating the resulting data. While the new mix does not appear to be drastically different from the division of responsibilities, the difference is the National Environmental Laboratory Accreditation Conference (NELAC) and its associated National Environmental Laboratory Accreditation Program (NELAP). The NELAC standards effectively consolidate the currently separate requirements of DOH and DEP into a single program, making NELAP the logical step in consolidating Florida's laboratory oversight requirements in a single agency.

DEP will be able to concentrate on oversight of field activities as well as data validation and data quality assessments. By using industry's approach to quality control – routinely testing widgets from the assembly line for acceptability – the Department will be able to monitor routine data quality. The focus on the quality of the end product (data) as opposed to the initial specifications (QAP) will provide data managers relevant data quality information necessary for making sound environmental decisions.

Once the new roles and responsibilities were determined, it became apparent that neither the DOH LCP nor DEP QAS had sufficient resources to implement all the desired changes. Since the DEP program managers are responsible for making the environmental decisions, it was felt that they are in the best position to determine project objectives and data quality needs as well as deciding whether the submitted data met expectations – tasks that were often left to the DEP QAS who lacked in-depth knowledge of a given program. The success of the revised program lay in sharing the responsibility for data quality. However if the concept of a collectively shared responsibility was to become a reality, the program managers and data users needed access to the same information and tools that the LCP and QAS use in evaluating data or conducting audits DEP programs now have access to many of the data bases that provide information on the capabilities, certification status, and credentials of organizations. In addition the DEP Internet

and Intranet sites provide access to SOPs, guidances, checklists, rules, software and other tools that are used by QA staff in auditing and evaluating data.

The most significant accomplishments have been in the area of software development. These software packages minimize the amount of time required to perform tedious, often repetitive tasks.

DEP currently offers QA Planner, an interactive software that allows the user to develop a Quality Plan in the format required by DEP. It also evaluates the plan for completeness and approvability during the development process, and electronically reviews the plan when received by DEP. This process occurs in a matter of 10 minutes instead of 30 days and reduces the iterative process associated with manual reviews.

QA Planner is being transformed into the Florida Planner/Certifier, which will be used by the DOH LCP to accept electronic applications, as well as a means of managing the certification program.

The newest electronic tool is the Validator. In its current form, the program accepts manual or electronic data sets that are evaluated for permit/standard exceedances and data quality. The process concludes with a report that identifies problems, and recommends appropriate actions. A 200-page groundwater monitoring report is reduced to the critical problems in a matter of minutes instead of hours. As an added benefit, the resulting database is designed so that the information can be readily uploaded to the various department data repositories.

In order to determine if the changes in the QA program have a positive impact on the environmental decision-making process, the Department instituted the use of Quality of Science Reviews (QSRs) as a mechanism to evaluate whether the Department's decisions are truly supported by adequate and valid data. QSRs are large-scale program audits that review those program activities relating to data quality including identification and use of project/study objectives; selection of appropriate and sufficient parameters, methods and equipment; processes to evaluate the data in terms of quality and applicability; and mechanisms to manage the data. This process will identify the strengths and weaknesses in each program so that the overall efficiency and effectiveness of the decision-making process can be improved.

LESSONS LEARNED

- Accreditation doesn't necessarily ensure good data. Accreditation assesses the potential for generating quality data;
- Quality Assurance Plans don't guarantee quality. They are a statement of intent – a commitment to follow a document that should result in data that meets the expectations or data quality objectives of a particular project;
- There is a need to balance the use of the quality assurance tools, to achieve a realistic picture of data quality;
- Auditing – on-site audits of organizations, internal Quality of Science Reviews of departmental programs, and evaluation of submitted data – is crucial in determining if

organizations are functioning as expected, the resulting data are useable for its intended use and the Department is utilizing the data to make effective environmental decisions

EXPECTED OUTCOMES

The more effective use of the QA tools and QA principles in Florida will lead to a better understanding of data quality among the data consumers, and an improved product: environmental data. In addition, the Department expects that the process will result in:

- more effective use of the QA tools, and a more balanced, less intrusive approach to QA oversight in Florida as a result of realigning the responsibilities of DOH and DEP;
- a heightened awareness of the importance of quality data in environmental decision making through the promotion of the concept of shared responsibility. In addition, program managers, who are in the best position to understand the needs and goals of their programs, will have the resources and expertise available to them to take a more active role in determining the type of data quality that best fits their needs; and
- more efficient use of staff time through the use of electronic tools that have proven effective in minimizing the time spent on repetitive, but critical activities.

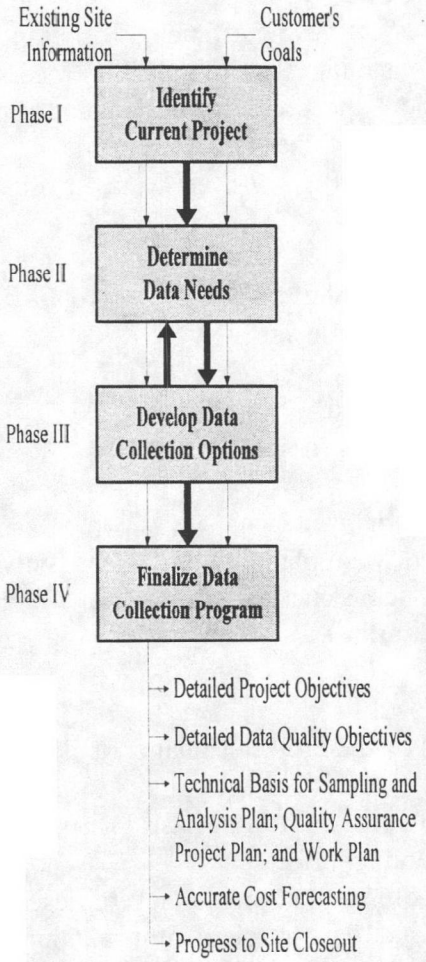
The end result will be data users who have a better understanding of the quality of data. They will also have the tools necessary to evaluate the usefulness of the data in making the types of decisions that will best protect the public health and the environmental resources in the State of Florida.

Larry Becker and Heidi Novotny
U.S. Army Corps of Engineers, Washington DC

US Army Corps of Engineers ®

Engineer Manual 200-1-2
(Download from http://www.usace.army.mil/inet/usace-docs/eng-manuals/em.htm.)

TECHNICAL PROJECT PLANNING (TPP) PROCESS



- ✓ Focused on site closeout!
- ✓ Useful for all sites (small/simple to large/complex)!
- ✓ Applicable when planning site investigation; design; construction; operation and maintenance; <u>and</u> long-term monitoring activities!
- ✓ Guidance for project managers, engineers, scientists, attorneys, customers, regulators, <u>and</u> other stakeholders!
- ✓ Use of TPP Process typically saves 10 to 15 percent of project time and costs!

This brochure provides only an overview of the TPP guidance provided in EM 200-1-2.

Phase I
Identify Current Project
Phase I activities accelerate protection of human health and the environment and expedite progress to desired future use conditions at a site.

- Decision makers and technical personnel are brought together;
- Current project is identified; and
- Project objectives are documented.

Phase I is designed to "front-load" conflicts and decision making. Resultant project efficiency more than compensates for the early commitment to proactive communications and detailed, site-specific planning.

Phase II
Determine Data Needs
Phase II activities involve an evaluation to determine if additional data are needed to satisfy the site-specific project objectives.

- Data needs are determined; and
- Data needs are documented.

Phase II is designed to support the detailed planning required to determine and document data needed for the current project, and subsequent

Who should use the TPP Process?
Project managers and their technical personnel should use the TPP Process to help satisfy a customer's expectations. The customer, regulator, and other stakeholders should also participate during the TPP Process to maximize the effectiveness of planning, implementation, and assessment efforts.

What is the TPP Process?
The TPP Process is a comprehensive and systematic process that involves four phases of planning activities. The TPP Process was developed for identifying project objectives and designing data collection programs for hazardous, toxic, and radioactive waste (HTRW) sites. Use of the TPP Process is consistent with the philosophy of taking a graded approach to planning that will produce the type and quality of results needed for site-specific decision making.

Why should the TPP Process be used?
Use of the TPP Process ensures effective and efficient progress to site closeout within all project constraints. Use of the TPP Process saves resources by reducing both the project duration and the project expenditures. Application of the TPP Process is also simpler and more complete than EPA's 7-Step Data Quality Objective (DQO) Process.

When should the TPP Process be used?
The TPP Process should be used as follows:

- To plan a new project;
- To review existing project plans; <u>and</u>
- To plan the next executable stage of site activities.

Where should the TPP Process be used?
The TPP Process should be used when planning any site activity (i.e., investigation; design; construction; operation and maintenance; or long-term monitoring).

How is the TPP Process used?

- Use of the TPP Process is lead by the Project Manager, and may be facilitated by an outside party;
- A multi-disciplinary team, identified during Phase I, uses the TPP Process to guide their planning efforts; and
- Use of the TPP Process requires that personnel represent decision maker, data user, <u>and</u> data implementor planning perspectives.

Phase III
Develop Data Collection Options
Phase III activities ensure the customer will have the information required for related business decisions.

- Sampling and analysis approaches are planned;
- Data collection options are developed; and
- Data collection options are documented.

Phase III is designed to support planning sampling and analysis approaches that will satisfy the data needs for a project.

Phase IV
Finalize Data Collection Program
Phase IV activities challenge a TPP team to discuss data collection options and finalize a data collection program that best meets the customer's short- and long-term goals for a site.

- Data collection program is finalized; and
- Data collection program is documented.

Phase IV is designed to provide guidance for documenting data collection programs with project-specific DQO statements. Many TPP products can also be attached to a project's management plan.

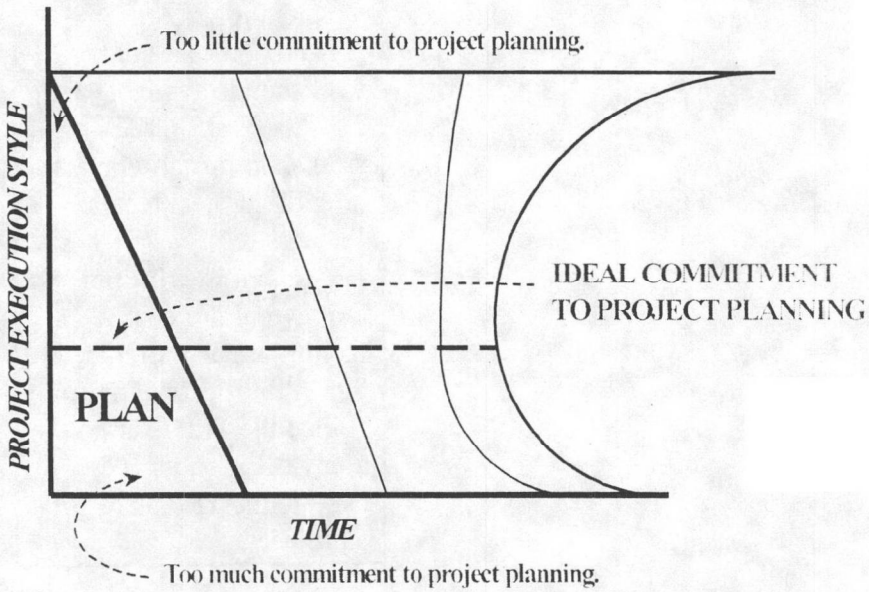
KEY CONCEPTS

- **Site Closeout** is achieving the "walk away goal," or final condition of a site, as envisioned by the customer. The team develops an effective site closeout statement after considering future land use; the site's regulatory compliance status and issues; and the customer's preferences for the final condition of the site.
- **Project Objectives** must be satisfied or resolved in order to progress from the current site status and condition to site closeout. Phase I efforts to identify and clearly document project objectives ensure that site-specific regulatory issues and environmental conditions are successfully addressed.
- **Basic, Optimum, and Excessive** are very powerful terms used for classifying project objectives, grouping data needs, and presenting data collection options for a customer's consideration.
- **Data Quality Objective (DQO)** statements are prepared during Phase IV, include nine data quality requirements, and meet EPA's definition of a DQO.

EFFECTIVE AND TIMELY PLANNING

A premise of the TPP Process is that each individual contributing to a project has his/her own project execution style. The systematic TPP Process enables a project manager to achieve an appropriate balance of project execution styles within a team, accelerate progress to site closeout, and reduce expensive time and efforts during the "do," "check," and "finish" stages of any project. As illustrated below, benefits of effective and timely planning include:

- Less time is expended to "check" and "finish" a well planned project; and



- Less overall time (and money) is expended when early efforts are focused and the team strives to optimally plan a project.

Applicability
The TPP Process applies to all HQUSACE elements and USACE commands responsible for HTRW projects.

Availability
Electronic copies of the TPP Process guidance and other USACE publications can be downloaded from http://www.usace.army.mil/inet/usace-docs/.

Points of Contact
- HQ Proponent Larry Becker, USACE (202) 761-8882
- Subject Matter Expert Heidi Novotny, USACE (402) 697-2626
- Subject Matter Expert Craig Willis, Black & Veatch (913) 458-6656
- PROSPECT Workshop Joy Rodriquez, USACE (256) 895-7448

Workshops
A hands-on case study workshop is available as a 2.5-day PROSPECT workshop for individuals or entire project teams.

On-Board Facilitation
On several projects, a facilitator has introduced the TPP Process and then helped the TPP team to apply the process and capture the TPP plans for a project.

TPP Process Guidance

Foreword	
Chapter 1	Identify Current Project (Phase I)
Chapter 2	Determine Data Needs (Phase II)
Chapter 3	Develop Data Collection Options (Phase III)
Chapter 4	Finalize Data Collection Program (Phase IV)
Chapter 5	Implement and Assess Data Collection Program
Appendix A	References
Appendix B	Abbreviations and Acronyms
Appendix C	Definitions
Appendix D	Outline of TPP Activities
Appendix E	Crosswalk to EPA's 7-Step DQO Process
Appendix F	Worksheets for Documentation
Appendix G	Verification of DQO Attainment

✓ The TPP Process is a critical component of USACE's quality management system that conforms to the American National Standard for planning the collection and evaluation of environmental data.

✓ The TPP Process supports development of management plans for projects as required by the Engineer Regulation governing program and project management.

✓ The TPP Process satisfies the systematic planning requirements of EPA's mandatory agency-wide quality system.

✓ Documentation tools provided within the TPP Process guidance encourage detailed data collection planning and contribute to maintaining institutional site knowledge.

Measurable Benefits of TPP Facilitation

USACE Project	TPP Facilitation	Cost & Schedule Effects	Qualitative Effects	Point of Contact
CELRB Luckey Site (FUSRAP)	3-4 February 1998 4 USACE personnel 2 USACE contractors TPP Contractor ($1,700)	Cost Savings > $150,000 Short-term schedule was met and long-term schedule was created to meet mandated milestones. Project costs and schedules were brought under control by CELRB.	CELRB personnel discovered where historical site data was stored and what site-specific contractor expertise existed. Resulting technical plans were better and much more defensible.	Jim Karsten, Project Manager 716/879-4245 Jim Thurn, Project Lead 716/879-4180
		Enabled CELRB to "develop an effective contracting strategy for the RI work." " The stream-lined contracting resulted in a more efficient RI."		
CELRB Painesville Site (FUSRAP)	4 February 1998 (only 2 hours) 2 USACE personnel TPP Contractor ($300)	Cost savings cannot be estimated because application of TPP Process and TPP facilitation was limited to identifying a realistic project schedule and the TPP tools and concepts to be used on the project.	Technical team was better prepared to use comprehensive and systematic process for reviewing and finalizing data collection plans. Technical roles were established.	Jim Karsten, Project Manager 716/879-4245

USACE Project	TPP Facilitation	Cost & Schedule Effects	Qualitative Effects	Point of Contact
CEMVS St. Louis Airport Site (FUSRAP)	25-27 February 1998 10-12 USACE personnel 6-7 USACE contractors 2-3 Federal and State Regulators TPP Contractor ($3,000)	$2,500,000 cost reduction when "excessive" data needs were deleted. $500,000 cost increase to include omitted sample collection and analyses needed for site decisions. Additional cost savings are not yet quantifiable. 19 specific action items were identified and directly linked to short-term project schedule. "Train wreck" schedule was met and Regulatory review cycles were significantly reduced.	Improved communications and technical relationships with Federal and State Regulators. Clear planning objectives enabled field personnel to further control costs and make good field decisions. Changed field conditions were well managed and acceptable data was acceptable data was collected on schedule and within budget. Regulators agreed that several existing technical evaluations were sufficient and that some data collection efforts could be deleted as "excessive" to the program. Legal Counsel issues related to future land use and other PRPs were resolved before field work.	Tom Freeman, Project Manager 314/331-8785 Don Meier, Technical Lead 816/983-3890
CEMVS St. Louis Downtown Site (FUSRAP)	25 March 1998 9-11 USACE personnel 5 USACE contractors 2-3 Federal and State Regulators 4 representing other PRPs TPP Contractor ($1,100)	Cost Savings > $180,000 8 administrative and technical constraints were recognized as critical path action items. These critical path items would have otherwise delayed the already demanding schedule. "Train wreck" schedule was met.	Resolved complex and contentious issues regarding background sampling within historic fill material. Gained Regulators' support for using available data from adjacent sites in lieu of some additional site-specific data collection.	Tom Freeman, Project Manager 314/331-8785 Don Meier, Technical Lead 816/983-3890

USACE Project	TPP Facilitation	Cost & Schedule Effects	Qualitative Effects	Point of Contact
CESWT AOC #34, Little Rock AFB (DERA)	3 November 1998 4-5 USACE personnel TPP Contractor ($2,400)	"Value-added is an intangible benefit that remains unseen by Customer. Lessons learned using TPP Process have subsequently improved project execution on several other AOCs." (Measurable cost savings are limited because Site Inspection samples had been collected, but not yet analyzed or interpreted.) Team recognized that site-specific "background" concentrations should be immediately obtained and tabulated to prevent subsequent schedule delay. Clear reporting of current and future project objectives was also realized as an important means to achieving the site's schedule.	Timely involvement of the Risk and Compliance Data User perspectives were determined to be critical to the project's success. Additional discussions with Customer and Regulator were planned to resolve several anticipated regulatory issues. Verification of future land use was identified as a critical action item to ensure team could develop a more specific site closeout plan.	Bob Thurman, Technical Lead 918/669-7170 Lloyd Lewis, Environmental Engr. 918/669-7172

USACE Project	TPP Facilitation	Cost & Schedule Effects	Qualitative Effects	Point of Contact
CESWT Tulsa Brownsfield Project (SFO)	4 November 1998 6-8 USACE personnel TPP Contractor ($2,400)	Cost savings are expected, but can not be estimated because project had not begun. Team determined that very precise project objectives would be needed to better define the current project and ensure $50,000 funding constraint was not exceeded. Strategy for dealing within limited funding was created to prepare CESWT for subsequent discussions with State and Federal Regulators, as well as City of Tulsa and other interested parties.	Team realized that the roles and responsibilities of all the decision makers and stakeholders needed to be better understood. Team determined that both Compliance and Responsibility Data User perspectives need to contribute to the project planning. Determined that evaluation of potential points of compliance and media of concern must be prioritized for efforts to remain within project's budget constraint.	Carol Wies, Project Lead 918/669-7519
CESWT Landfill #28, Fort Chaffee (BRAC)	5 November 1998 4-5 USACE personnel 2 USACE contractors 2 USACE Customers TPP Contractor ($2,400)	Cost savings are now being estimated. Potential schedule effects of new site operator, as well as technical review cycles were considered and factored into short-term schedule. An interim site closeout statement and schedule was drafted by the team to focus planning efforts.	Team realized that current role, responsibility, and authority of the future owner needed to be clarified prior to data collection. Need for Compliance and Responsibility Data User perspectives was realized.	Andrew McVeigh, Project Manager 918/669-4326 Susan Trussell, Technical Lead 918/669-7046

USACE Project	TPP Facilitation	Cost & Schedule Effects	Qualitative Effects	Point of Contact
CENWK Former Schilling AFB (FUDS)	12, 25 January 1999 1 February 1999 4-6 USACE personnel 1-2 State Regulators TPP Contractor ($4,400)	Cost savings are now being estimated. (Cost savings, pending Regulator approval of plans could exceed $230,000.) Inter-related tasks were identified and assigned to ensure that schedule for data collection efforts would not be delayed. Current schedule of activities will be very focused to ensure that IRAs are employed if appropriate and quickly verify if the site's relative risk score actually drops priority of site to a low level.	Assembled and activated an effective technical project team. Constrained technical resources will be able to selectively support the project and remain very focused because they contributed to documenting and prioritizing the project's objectives. Improved the Regulator's tolerance for the USACE's limited data collection plans within select OUs.	Judy Meier, Project Manager 816/983-3569 Amy Darpinian, Project Chemist 816/983-3897 Carol Dona, Environmental Engr. 816/983-3573
CENAB MOTBY (BRAC-Army)	22-24 February 1999 3-6 USACE personnel 1 USACE contractor TPP Contractor ($5,000)	Cost Savings >$1,100,000 (Cost savings, pending Regulator approval of plans and contractor negotiations, may actually exceed $1,500,000.) "Neck Breaking" schedule will now be met and all Customer's milestones can now be satisfied. Long-term schedule understood.	Technical strategies formulated for discussions with Regulators, local redevelopment authority, and active RAB. Technical and funding constraints and dependencies much better understood and addressed. Components produced for PMP and project plans should now pass AEC's Interim Technical Review.	Gladys Hester, Design Team Leader 410/962-2217 Margaret Martin, Environmental Engr. 410/962-3500

USACE Project	TPP Facilitation	Cost & Schedule Effects	Qualitative Effects	Point of Contact
9 USACE Projects	All Multi Disciplinary Teams! Only limited Customer and Regulator participation to date, yet tremendous savings and effects of TPP Process! TPP Contractor Costs < $23,000	Minimum Savings > $4,000,000 All Schedules Met! "Train wreck" and "Breakneck" Milestones Achieved!	Improved Project Focus! More Defensible Technical Plans! Increased Customer Satisfaction! Improved Regulator Relations!	**Note:** Each Point of Contact edited, reviewed, and approved this summary information. Contacts can also provide additional information as requested.

BEYOND ENVIRONMENTAL DATA:
Using the Malcolm Baldrige Criteria to Assess Organizations and Becoming a Certified Quality Manager

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SUMMARY -- Organizations today face significant challenges, and these challenges translate to new opportunities for the environmental data quality professional. As quality professionals, one significant opportunity to share quality information and knowledge is promoting the Malcolm Baldrige Criteria to assess and improve your organization. Becoming professionally certified is another opportunity.

Organizations today face significant challenges, these challenges translate to new opportunities for the environmental data quality professional that go well beyond the traditional tasks and responsibilities for environmental data. As specialists in quality management and quality systems, we are uniquely positioned to help the organizations we work for and with to improve processes and results affecting all key stakeholders. These stakeholders include customers, employees, suppliers, and the public. Two recent articles in *Quality Progress* illustrate the point.

In his regular Career Corner, Greg Hutchins' article "Padding like Crazy" (Hutchins 1998) translates not meeting the challenges and moving to new opportunities like standing still in a moving stream. The moving stream is organizational change like growth, downsizing, and reorganization. If we don't see the stream and effectively move with it, we might suddenly end up in the wrong spot. His challenges to the quality professional include getting a boat, which he suggests is lifelong learning. He then suggests what we should be doing, and the intensity by which he suggests is his term "paddling like crazy." His paddling includes actions like getting out of the box in our thinking, venturing into in-demand multi-disciplinary areas, becoming a vertical quality specialist and a horizontal business generalist, and becoming our organization's chief quality knowledge officer and the sharer of its quality information and knowledge. He also includes becoming professionally certified as one of his suggestions.

In her article "Quality Today, Recognizing the Critical SHIFT," Lori Silverman (Silverman 1999) outlines five trends in the quality field. First, she points out that quality is going softer in that business success cannot be achieved without attending to needs of the employees. This includes factors like working in teams and measuring employee satisfaction. Secondly, she points out that quality went into disfavor or hiding in the early 1990's as prior quality efforts like total quality management were discontinued. Third, she points out that many U. S. businesses

implemented quality tools and methods without appreciating an overall system. She says that quality must be integrative such that tools are used in concert with each other. Fourthly, she says that quality is far-flung, with interest in quality reaching to the far corners of the world. Finally, she points out that quality has gone technical in that highly sophisticated, technical, statistically based tools are needed.

An example of applying much of what Hutchins and Silverman suggest and moving beyond the traditional quality system for environmental data is promoting the Malcom Baldrige Criteria to assess and improve organizations. The term "manage by Baldrige" is being heard more frequently as thousands of U. S. organizations apply Baldrige. The Baldrige criteria are even being used by government organizations such as the Naval Sea Systems Command, the Air Force Air Mobility Command, Brookhaven National Laboratory, and Los Alamos National Laboratory.

The Malcom Baldrige criteria are accepted widely in U. S. and around the word. More than a million copies of the criteria have been distributed since 1988. The criteria are goal-focused, delivering improving value to customers and improving overall performance. The criteria address approach, deployment, and results, and the focus is on key processes, business results, and mission effectiveness. It also supports the Government Performance and Results Act.

In the program being used by the Naval Sea System Command through its Inspector General's office (IG), the organization being assessed competes a Self Assessment based on the current Malcom Baldrige criteria. The IG team competes a validation visit to validate and assist rather than just verify compliance. The IG team is made up of assessors from other organizations within the Naval Sea Systems Command, and I personally served as an assessor for seven inspections using both traditional and Malcolm Baldrige techniques. The organization being assessed then develops an improvement plan based upon their self-assessment and the IG's validation report. Responses to traditional compliance-based inspections were just in response to each specific finding, while a Baldrige-based improvement plan has a total business focus.

The Baldrige criteria for business are founded in seven categories, leadership, strategic planning, customer and market focus, information and analysis, human resource focus, process management, and business results. Now, there are also criteria for education and health care. The criteria are evaluated on the dimensions of approach, deployment, and results. *Approach* is how one addresses the Baldrige requirements -- the methods used. *Deployment* is the extent to which an approach is applied. *Results* describe the outcomes in achieving purposes of an item, such as *customer focused results.* Results are based on current performance, performance relative to comparisons and/or benchmarks, and rate, breadth, and importance of improvements. The criteria also have scoring guidelines. A maximum of one thousand points is distributed over the seven categories. Nearly half of the total points are in the business results category.

The benefits realized with the Naval Sea Systems Command's new inspection process include the IG assuming a new role of a business consultant rather than a compliance inspector. The process reinforces the Naval Sea Systems Command's Strategic Plan. There are a total command

commitment, increased awareness and interface with customers, an opportunity to improve processes and business results. Since the inspections by their new nature identify best practices, these are then widely disseminated.

Finally, we as environmental data quality professionals have an opportunity to become professionally certified. I personally support certification because the quality system itself promotes training and qualification, and because it promotes verification and objective quality evidence. Being certified presents a verification that we have, in the words of the American Society for Quality criteria, "demonstrated a proficiency within and a comprehension of a specified body of knowledge." Furthermore, the body of knowledge for the Certified Quality Manager helps us become a vertical quality specialist and a horizontal business generalist. It positions us to become our organization's chief quality knowledge officer and the sharer of its quality information and knowledge.

As an environmental data quality professional, becoming certified as a quality manager requires a fair amount of reading, study, and experience beyond that based upon American National Standard ANSI/ASQC E4-1994. The body of knowledge includes understanding: quality standards (like the Malcolm Baldrige criteria), organizational assessment, customer satisfaction surveys, project management, statistical analysis, control charts, quality control tools, team management, and training needs analysis.

CONCLUSION

Yes, we are in a time of significant change. I believe that we as environmental data quality professionals can and must take advantage of lifelong learning. Promoting effective programs that go beyond environmental data quality like the Malcolm Baldrige Criteria can prove a significant win-win for you and your organization. Finally, when you become certified, you gain a much greater appreciation for how everything fits together.

ACKNOWLEDGMENTS

I wish to thank the Commander, Naval Sea Systems Command's Office of the Inspector General for providing me the opportunity to participate in the Malcolm Baldrige Command Performance Inspection (CPI) Process and for providing me with material for this paper.

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OPERATIONAL QUALITY ASSURANCE - COMPLETING THE END STATE

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SUMMARY

Environmental program decisions developed and implemented through planning processes like the Data Quality Objectives (DQO) process define unacceptable contaminant levels, site status after cleanup, and verification/monitoring procedures. However, these decisions and their time lines often lack consideration for other regulators, such as the Department of Transportation (DOT). Frequently missing are the realities of packaging, shipping, and waste acceptance. A decision capable of implementation requires early integration of these and other considerations into the planning process.

PROJECT DESCRIPTION

The Project Description, as developed through various planning processes, can focus data collection on a well-defined problem. However, details necessary for implementation of solutions are not necessarily part of initial considerations. DOE, working with the EPA, developed a process called the Streamlined Approach for Environmental Restoration (SAFER) to integrate intermediate remediation decisions earlier in the decision process, thus saving time, reducing duplication of effort, and using resources efficiently. Other activities, such as expedited site characterization, have focused data collection to meet immediate needs to direct actions. These approaches can adequately address project implementation for most environmental programs. They work because a quantitative decision rule exists. Project definition establishes acceptable confidence and assesses monitoring options. Flexible documentation and moving the decision closer to the field are actions that have been completed safely and efficiently.

However, environmental program activities with higher risk and visibility have more obstacles to implementation. One potential obstacle is satisfying multiple regulators, as described by the EPA (40CFR, 1999). For example, DOE is responsible to "make hazardous waste go away," or, in the case of onsite storage, at least minimize the exposure. When this goal or end point is defined and accepted, programs will be designed to consider how to achieve the end state. Critical components to reach the end state often are not adequately emphasized to ensure availability consistent with end state time commitments. To address this kind of environmental project, early involvement of expertise outside the scope generally associated with DQO-like

planning is essential. The traditional process lists specific expertise necessary to formulate the problem and to design data collection appropriate to reach a decision within defined acceptable limits. However, additional, more specific expertise is necessary to ensure an acceptable approach can be implemented immediately. An example of specific expertise is knowledge in transportation and packaging regulations and options.

Some relatively complex decisions necessary for project implementation include onsite vs offsite storage, existence of acceptable packaging, mode and route of transport, and acceptance of waste for treatment/storage/disposal. These decisions are largely outside the scope of EPA/state environmental regulations, falling primarily under jurisdictions listed in Table 1. The degree of jurisdiction and how it is shared is dependent on waste classification. Waste constituents dictate packaging requirements, transportation requirements, material disposal options, and regulatory responsibility. The EPA and state governments control the RCRA constituents but not radioactive material.

Table 1. Regulatory Authority for Path to End State (radioactive material)

Activity	Department of Transportation	Nuclear Regulatory Commission	Department of Energy
Packaging	X	X	X
Transportation	X	X	X
Waste Acceptance		X	X

This summary is incomplete, since it does not include the authority of states and tribes to affect transportation routes and emergency capabilities along potential routes. The summary indicates that commitments are very much in hands other than DOE or EPA. Additional stakeholders should often be considered during early planning phases.

Definitions affecting waste classification (49 CFR part 171.8)

Radioactive material (YES, there is a de minimis) – Has a specific activity greater than 70 becquerels per gram (0.002 microcuries)

Hazardous Waste - Anything subject to EPA manifesting requirements (40 CFR part 262)

Hazardous substance - Listed in tables, quantity > reportable amount (weight per package)

Hazardous material - Mostly hazardous waste and hazardous substance

Transuranic waste - Atomic number >92; half-life > 20 years; activity > 10 nanocuries / gram - definitions are not exactly standardized

Three basic considerations are:

- EPA regulations are based on concentration; DOT regulations are based on contribution to package weight.

- EPA regulations referenced (40CFR-Parts 260-265) mean that the regulation directly applies to RCRA. Constituents regulated by other programs, such as PCBs and asbestos under TSCA, aren't directly considered.

- A high percentage of radioactive waste is mixed.

Based on these and other terms and considerations, significant potential for confusion exists. Examples include the following:

1) Solid Waste ~ free flowing liquid

   DOT considers these terms mutually exclusive. Packaging, transport, and disposal assume absence of free liquid in a solid material. This distinction is a basic decision element relating to physical protection of the driver and as a factor increasing exposure.

2) Ignitable - D001 (liquid) 60°C (140°F) for EPA, but less than or equal to 60.5°C for DOT

DOT and EPA have different primary drivers resulting in significantly different concerns. DOT needs details because the primary reason for regulation is protection of the transporter and, to a limited extent, to facilitate emergency response. For this reason, information to meet DOT regulatory requirements is similar to environmental data but often not identical. In addition to basic RCRA distinctions, DOT considers parameters and cut points listed in Table 2.

Table 2. Class 3 – Assignment of Packing Groups (from 49 CFR 173.121)

Packing Group*	Flash Point (Closed Cup)	Initial Boiling Point
I	***	≤35 ° C
II	≤23°C	35°
III	≥23°C, ≤60°C	35°

* Packing Groups relate to how dangerous the material is. Packing Group I is a robust package for very hazardous materials. Packing Group III is for least dangerous materials.

A timely example of confusion is the concept of corrosiveness as measured by EPA and DOT. EPA Corrosive - D002 is pH ≤2; or ≥12.5; or corrodes steel >6.35mm/yr @ 55°C

Table 3. DOT Corrosive - Class 8

	Group I	Group II	Group III
Exposure Time	≤ 3 min	>3 min, ≤ 60 min	> 60 min, ≤ 4 hr
Observation Time	≤ 60 min	≤ 14 days	≤ 14 days
Corrosion Rate on steel/aluminum	----	----	>6.25 mm/yr at 55°C

Packing Group I - Causes full-thickness destruction of intact skin tissue with an observation period of up to 60 minutes starting after the exposure (3 minutes or less)

Packing Group II - Causes full-thickness destruction within 14 days of exposure (3 minutes but not more than 60 minutes)

Packing Group III - Only for these materials: general range of environmental samples and most environmental level waste; only corrosion level that is at all comparable to DOT criteria

These discrepancies are both good and bad. On the good side, EPA concerns about sending corrosive samples are probably not a problem. The matrix and contaminants would most always fall under these limits for corrosion and for limited quantities.

On the bad side, recent interlaboratory comparisons (Vitale, etal, 1998) indicate that classification for RCRA determination of flash point may be a relatively low confidence measurement. Extrapolating this to DOT requirements would likely make the situation worse. This is problematic because this hazard is likely the biggest single DOT regulatory concern.

In transportation, a third significant figure in concentration is not as important as "can it blow up" or "how long will it burn." These basic questions or problems are much different from the traditional DQO statements for remediation of average concentrations, maximum exposure, or specific contaminant. DOT regulations can work with limited classification data by assuming the worst case. In many cases, this assumption provides an approach at a lower total program cost than would come with complete constituent identification (very expensive characterization).

Although these examples involve relatively simple packaging and transportation issues, even at this level, potential for confusion exists. Potential difficulties can be eliminated early in the decision process with no or minimal additional data collection. Parallel situations exist for transportation and waste acceptance; starting over to collect data or continuing a project on the assumption that specific activities are not important is a poor approach.

For example, at Rocky Flats (see reference 5), Restoration Programs and Safeguards and Security are evaluating additional options for onsite storage because neither packaging, transportation, nor an appropriate disposal site is available for various waste materials, including 111,000 cubic meters of rubble.

These oversights are major contributors to missing programmatic milestones; a commitment to move material must be based on thorough planning and realistic considerations, and not just on regulatory/legal requirements. Make sure a mechanism is in place to package and ship before making long-term, legal commitments on waste transfer. Without responsible planning, the commitment may not be feasible, and, in turn, may not happen!

The concept of expedited response and moving the decision to the field has considerable merit in making programs more pragmatic. However, the flexible work plans should consider specific packaging and transportation cut points to ensure that transportation requirements are met. For example, package limits and external dose requirements still apply. Expediting an environmental program action while introducing a DOT violation may not be a good trade off. Opportunities to improve communication and program functionality include:

- Incorporate additional regulatory expertise in planning of complex cleanup and waste management projects, e.g., transuranic / mixed waste;
- Recognize inconsistent use of the same term, e.g., solid waste (recognize because unique character not bad and standardization probably impossible); and
- Work cooperatively to meet human and environmental health needs across project life cycle, e.g., generation, storage, transportation, disposal, etc.

SUMMARY

Neither characterization, packaging, nor transportation is THE "environmental project end point." However, all three elements are critical and ultimately relative to successful project implementation. A guiding premise should be:

DON'T DIG IT UP UNTIL --

- You can get it there (packaging and transport); and
- They will accept it (waste acceptance criteria).

On occasion there may be additional, urgent health and safety concerns; but these can be responsibly managed with proper consideration and preparation.

Project Perspective:

- Waste is defined by a regulatory process (RCRA, CERCLA).

- Waste is packaged and shipped to be compliant with DOT/DOE/EPA (waste designation).

- Waste is accepted for treatment/storage/disposal to be compliant with waste acceptance criteria or commercial contracts (NRC/DOE/EPA/states).

Characterization Needs

- Qualitative identification recognizes that specific concentrations are important at defined decision points.

- Transportation requirements are more often based on mass than concentration.

- Mass and physical / chemical state dictate packaging requirements, amount of material per package, and the amount of material per shipment.

Examples of how these factors affect implementation:

- There is essentially no way to send large shipments of radioactive waste with moisture >5 percent except with small volumes of limited quantities, such as test samples.

- For plutonium, ~40 grams can be put into a single package. A 250-kg shipment of mixed contaminated material can result in more than 6,000 expensive little packages instead of a partially filled 55-gallon drum. Don't make this kind of commitment too quickly, since the packages may not exist.

CONCLUSION

For most CERCLA decisions, acceptable packaging exists. Transportation options are available and waste acceptance generally is not a problem. However, for mixed waste, the problems can become more complicated.

For projects involving mixed waste transfer, quality planning requires early consideration of packaging availability, transport options, and acceptability of waste. Expertise to help identify alternatives should be directly involved with the initial project scoping activities. These considerations are basic to determining the lowest total project cost end state and to ensuring the established goal can be implemented in an acceptable time frame.

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THE SIGNIFICANCE OF ANALYTICAL ERROR IN PROJECT PLANNING, IMPLEMENTATION AND ASSESSMENT

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SUMMARY

Considerations of error and its control are important in project planning, implementation and assessment. Analytical results are affected by errors in both sampling and analysis, which need to be taken into account in the data quality objectives (DQO) and data quality assessment (DQA) processes. Recommendations are made for reducing analytical bias before decisions are made based on the data.

INTRODUCTION

When projects involve acquiring environmental data, the U.S. Environmental Protection Agency (EPA) has described a systematic process involving three phases: planning, implementation and assessment (U.S. EPA 1998). The Water Research Centre (WRC) in England has described a systematic approach to analytical quality control (Cheeseman and Wilson, 1989). Both are concerned with controlling errors originating during sampling and analysis. This paper examines the significance of analytical error in relation to total error, and how the WRC approach to controlling analytical error can be incorporated into the project level of EPA's Quality System.

NATURE OF ERRORS IN ANALYTICAL RESULTS

The term analytical result denotes a numerical estimate of the concentration of a determinand (i.e. analyte) in a sample, and is obtained by carrying out once the procedure specified in an analytical method. Note that a method may specify analysis of more than one portion of a sample in order to produce one analytical result (Hunt and Wilson 1986).

The error, E, of a result, R, is defined as $E = R - T$, where T is the true value. Accuracy is defined as the total error of a result; that is, accuracy represents the combined random and systematic errors of a result and is said to improve as the total error decreases. Note that, in this definition of error, there is no implication that anyone has made a mistake, though of course mistakes may cause error (Hunt and Wilson 1986).

It is common experience that, when a stable homogeneous sample is analyzed repeatedly, the results of those analyses are not identical. The results obtained generally differ among themselves and are more or less scattered about some central value. The scatter obtained is attributed to random errors, which are so named because the sign and magnitude of the error differs from one result to another. There are many possible sources of random errors in analyses.

Example sources of random errors in analyses include slight variations in the volumes of reagents added to samples, variations in the times allowed for chemical reactions, variable contamination effects, fluctuations in instrument response and temperature variations. Random error in sampling can occur when there are variations in the concentrations because of the way the samples were taken or because of the way the samples were preserved, transported, and stored prior to analysis.

The errors due to sampling and analysis are therefore the two major contributions to the total error of a result. Of course there is also variability of the analyte in the environment, but the error in estimating this variability, corresponding to the sampling design error as defined by EPA, cannot easily be quantified.

Systematic error is present when there is a consistent tendency for results to be either greater or smaller than the true value. In statistical terminology, the mean of n analytical results from the same sample approaches a definite value, μ, as n increases indefinitely. When μ differs from the true value, T, results are said to be subject to systematic error of magnitude B, where $B = \mu - T$. In this paper, the term "bias", B, is used synonymously with systematic error. The term accuracy is sometimes used to denote bias, but this ignores the fact that random error also affects the accuracy of a result (Hunt and Wilson 1986). Many methods refer to "precision and accuracy" but, since accuracy includes precision, this expression should be discouraged. Note that any test or experimental design used to estimate bias will include a component of random error in the estimate.

It has been stated that there are six possible sources of bias or systematic error in water analyses (Hunt and Wilson, 1986):

- Unrepresentative sampling
- Instability of samples between sampling and analysis
- Interference effects
- A biased calibration
- A biased blank correction
- An inability to determine all forms of the determinand (i.e.analyte)

A seventh, mistakes by the analyst, could be added to this list, and cannot be overlooked, but should be controlled by proper organization, training and procedures.

The first two sources in the above list correspond to bias originating prior to analysis (i.e. during sampling or between sampling and analysis), while the last four correspond to bias occurring during analysis. Representative samples imply that there is a good sampling design as well as good execution of that design during measurement. While recognizing the importance of taking representative samples and assuring that the analytes in these samples remain stable until they are analyzed, the emphasis in this paper is on the analytical error.

EPA APPROACH TO ESTIMATING AND CONTROLLING ERRORS

EPA has described a Data Quality Objectives (DQO) Process which consists of seven iterative steps, starting with a clear statement of the problem and ending in an optimum design to obtain data. Part of the DQO Process involves the development of a decision rule and the specification of limits on decision errors.

EPA has defined the total study error as being equal to the combination of sampling design error and measurement error (U.S. EPA, 1994). Sampling design error is said to occur when the sampling design is unable to capture the complete extent of natural variability that exists in the true state of the environment. Measurement error refers to a combination of random and systematic errors that inevitably arise during the various steps of the measurement process (for example, sample collection, sample handling, sample preparation, sample analysis, data reduction, and data handling). Measurement error is therefore synonymous with the total error of a result as defined by the WRC, since both include sampling and analysis as causes of error. Since we cannot know the true state of the environment, it is impossible to quantify the sampling design error, which occurs either because of poor judgement in making the design or because of limitations in resources. In the latter sense, it is more of a choice than an error. Measurement error occurs as a result of samples being taken and analyzed and therefore the results of these analyses, along with the results of analyses of quality control samples, can be evaluated to estimate its magnitude.

According to EPA, since it is impossible to eliminate error in measurement data, basing decisions on measurement data will lead to the possibility of making a decision error. And, since there is uncertainty in measurement data, there must also be uncertainty in the decisions based on that data. The quantitative statement in the Data Quality Objectives (DQO) process includes developing a decision rule as an "if...then..." statement that incorporates the parameter of interest, the scale of decision making, the action level, and the action(s) that would result from resolution of the decision (U.S. EPA 1994). The decision rule is then used as the basis for specifying statistical limits on decision errors. EPA recommends guarding against making the decision error that has the greatest undesireable consequence by setting the null hypothesis equal to the condition that, if true, has the greatest consequence of decision error. Thus, the site manager may decide that a site is contaminated (null hypothesis) in the absence of strong evidence (study data) that indicates that the site is not contaminated (alternative hypothesis).

It is noteworthy that only random measurement error is directly considered in deciding whether the action level has been exceeded. According to EPA, the analytical error determination measures the precision of the analytical method (U.S.EPA 1993). Thus, the data used in judging whether or not decision errors are present are assumed to be unbiased and evaluated statistically, assuming a normal distribution. This means that bias in sampling and analysis must be eliminated or reduced significantly before the mean concentration of the results can be considered to be a good estimate of the true value and evaluated using a Design Performance Goal Diagram (sometimes called a Decision Performance Curve).

WRC APPROACH TO ESTIMATING AND CONTROLLING ERRORS

The WRC has described a recommended approach to analytical quality control (Cheeseman and Wilson 1989). Like EPA's DQO Process, it involves a stepwise iterative process, but the emphasis is on estimating and controlling analytical error affecting results, while recognizing that sampling can be an important source of error in results. While the WRC approach is designed for water samples, many of the principles included in the approach can also be applied to other matrices.

There are some parallels in the EPA and WRC approaches. EPA's DQO Process starts with a statement of the problem and includes the development of a quantitative decision rule and quantitative limits on decision errors, while the WRC approach starts with a definition of analytical objectives which include quantitative targets for accuracy (i.e. precision and bias). EPA's DQA Process includes statistically based judgements regarding whether the data quality objectives have been met, while the WRC approach includes statistically based judgements regarding whether targets for accuracy have been met. In the WRC approach, most of the work is done prior to collection of samples for routine analyses, and control charts are used to verify that targets for precision and bias are met on a continuing basis (Kirchmer 1983). The EPA and WRC approaches complement one another, since in the EPA approach there is no direct examination of the existence or causes of analytical error and in the WRC approach analytical error is examined in detail to assure that the targets for accuracy are met. Meeting targets for accuracy helps meet the data quality objectives, as expressed through the decision rule and the limits on decision errors.

Targets for accuracy are set in the following manner. In percentage terms, the total error of individual analytical results should not exceed 2p% of the result. If the total error is partitioned equally between systematic and random error, it follows that the systematic and random errors should each not exceed p% of the result.

The magnitude of random error can be defined only with respect to a chosen probability level, and the 0.05 probability level (equivalent to 95% confidence limits) is considered reasonable for most purposes. Since this probability level corresponds to approximately two times the standard deviation, it follows that the standard deviation should not exceed 0.5p% of the result.

At very low concentrations, the relative error increases and it is not possible to meet the percentage targets. In this case, the total error of results should not exceed the lowest concentration of interest, C_L.

In summary, therefore the systematic error should not exceed $0.5C_L$ or p% of the result, whichever is the greater; and the total standard deviation should not exceed $0.25C_L$ or 0.5p% of the result, which ever is greater. Table 1 (Cheeseman and Wilson, 1989) shows the effect of these recommendations, for a range of values of the concentration of primary interest (e.g. water quality standards).

Table 1 Calculation of Maximum Tolerable Errors in Analytical Results

Maximum allowable concentration*	Smallest concentration* of interest, C_L	Maximum tolerable error		
		Standard deviation, σ_t†	Systematic error†	Total error†
100	10.0	2.5 or 0.05C	5.0 or 0.1C	10.0 or 0.2C
50	5.0	1.25 or 0.05C	2.5 or 0.1C	5.0 or 0.2C
10	1.0	0.25 or 0.05C	0.5 or 0.1C	1.0 or 0.2C
5.0	0.5	0.125 or 0.05C	0.25 or 0.1C	0.5 or 0.2C
1.0	0.1	0.025 or 0.05C	0.05 or 0.1C	0.1 or 0.2C

* All expressed in the same concentration units: e.g., if the maximum allowable concentration is expressed in units of μg/L, the smallest concentration of interest and the maximum tolerable errors are also expressed in units of μg/L.
†In the quoted numerical values, C denotes the concentration of analyte in the sample. Of the two values tabulated for each error, that one applies which has the larger value for a given analyte concentration.

To determine whether the targets for precision and bias have been met, an experimental design is used to estimate within-laboratory precision and some sources of bias. The experimental design includes 5-10 batches, each batch including the duplicate analyses of blanks, standards, samples and spiked samples. The following information is obtained from the data: estimates of standard deviations for analyses of blanks, standards and samples, and an estimate of bias due to interference in samples. Duplicate analyses are done in order to estimate both within-batch and between-batch components of standard deviation. The within-batch standard deviation of the blank can also be used to estimate the limit of detection. Calibration data can also be evaluated to determine if there is a biased calibration.

If resources prevent the implementation of an experimental design prior to sample collection and analysis, estimates of within-laboratory precision and some sources of bias can be obtained by including duplicate analyses of blanks, standards, samples, and spiked samples along with routine sample analyses. However, in this case, if corrective actions are needed, it will not be possible to make them prior to routine sample analysis.

PERFORMANCE CHARACTERISTICS OF ANALYTICAL METHODS

An important step in the WRC recommended approach to analytical quality control is to choose analytical methods with satisfactorily small sources of bias and capable of adequate precision.

Some performance characteristics for analytical methods, that are useful when choosing a method, are: the substance determined, the type of sample, and the basis of the method; the range of application; the calibration curve; the total standard deviation; the criterion of detection (based on the within-batch standard deviation of the blank); the sensitivity; bias; interferences; and the time required for analysis. With respect to the the quantitative targets for accuracy,

performance characteristics of standard deviation, criterion of detection, bias, calibration, and interferences are most important.

Calibration is seldom recognized as a common source of bias in analytical results. A principle of analytical quality control is that standards and samples should be analyzed the same way, and that failure to do so can result in calibration bias (Wilson 1974). Calibration is a very common source of bias for labs analyzing trace organics (Kirchmer and Schupp 1986). For example, in the analyses of water samples for organics, standards are usually prepared in pure solvent whereas samples go through an extraction step and sometimes also a cleanup step. The analyses of aqueous standard solutions containing the target analytes often shows that the "recovery" of the target analytes is considerably less than 100%. Low "recovery" for analyses of standard solutions means that the bias can only be due to calibration. In other words, if the calibration standards had been taken through the same process as the samples, the recovery would be close to 100% and the bias due to calibration would be low. This assumes that sufficient standards have been analyzed so that the random error in calibration is also low, since random error in calibration becomes a systematic error when the calibration curve or factor is used to quantify sample results.

Table 2 summarizes some results for 8 interlaboratory studies done by EPA (U.S. Environmental Protection Agency, 1984). The results of these studies show that poor recoveries were obtained for the analyses of organics in pure (distilled) water. It is worth noting that recoveries for some specific compounds of interest were significantly less than the mean recoveries given in Table 2. Thus, for example, the recovery for phenol was only 43% and that for N-nitrosodimethylamine was only 37%. The studies also included recoveries for compounds spiked in tap water, surface water, and wastewater, but only the results for pure water are included in Table 2 since they would not be affected by interference or matrix effects. Any bias would have to be due to the differences in the procedures for calibration and analysis, namely that samples go through extraction and cleanup steps while calibration standards do not. Bias due to calibration was found to be significant for these methods. Interestingly, there was little evidence in these studies for any significant bias due to interference, which is commonly believed to be a more significant source of bias.

Table 2. Results for Interlaboratory Studies of some Organics Methods (U.S.EPA 1984)

EPA Method	No. Compounds	Mean Recovery*	Calibration Bias
604 – Phenols	11	67.6%	-32.4%
606 – Phthalates	6	65.6%	-34.4%
607 – Nitrosamines	3	65.9%	-34.1%
608 – Organochlorine Pesticides	24	86%	-14%
610 – PNAs	16	61.5%	-38.5%
611 – Haloethers	5	82.2%	-17.8%
612 – Chlorinated Hydrocarbons	8	76.3%	-23.7%
625 – BNAs	65	74%	-26%

* Percent recoveries are for 100 μg/L of compounds in pure (distilled) water

In some cases, however, interference can also be an important source of bias, especially for complex samples such as hazardous wastes. Spiked samples are often analyzed to determine if interference or matrix effects are present. But the power of the spike recovery test to detect interference is low. It is much more effective to estimate bias due to interference by implementation of an experimental design than by routine spiking of samples. Experimental designs can include an examination of the interference effects of specific substances (Hunt and Wilson 1986).

Other sources of analytical bias may be significant for some projects. For example, if the concentration of interest, C_L, is near the limit of detection, biased blank determinations or failure to blank correct may result in bias. This source of bias may be critical, for example, in trace metal analyses. Finally, one must be certain that the chosen method is able to determine the forms of the analyte that are of interest. For example, one may need to determine only dissolved orthophosphate when other phosphates (e.g., undissolved orthophosphates, condensed inorganic phosphates) are also present (Wilson 1974).

On the other hand, method performance can be characterized by low bias and high random error. An example of this would be EPA Method 624, for the analysis of purgeable organic compounds in water by gas chromatography-mass spectrometry. A method validation study for EPA Method 624 found that overall recoveries for the volatile organic compounds were very good, with an average recovery of 100%, indicating no calibration bias. This is to be expected, since calibration standards and samples are analyzed the same way. But the median percent relative standard deviation at 100 µg/L was 24%, indicating a large degree of imprecision. In this case, accuracy for individual analytical results could be improved by basing results on the average of several replicate analyses, since the standard deviation of the mean is equal to $s/\sqrt{n}$, where s is the standard deviation for the individual analytical results and n is the number of results used to calculate the mean. This illustrates that random error, unlike systematic error, can always be reduced by replicate analyses of samples, and this should be taken into account in reducing the analytical measurement errors.

ERROR DUE TO SAMPLING

It is difficult to quantify error due to sampling, although there are ways to optimize the frequency and time of sampling and to reduce bias and random error arising from the way samples are taken, preserved, transported and stored prior to analyis.

Replicate samples can be taken both to reduce the random error in sampling and to obtain estimates of the magnitude of that random error. For example, duplicate samples can be taken in the field to estimate the contribution of sampling to the total standard deviation of a result. If one of those samples is split in the laboratory, estimates of total and analytical standard deviation can be obtained. This is usually applied to grab samples, but could also be applied to composites if two composite samples are taken simultaneously. It can be thought of as the variability of a sample representing a particular combination of space and time. The equation for additivity of variances is used to determine the contributions of the standard deviations due to sampling, s_s, and analysis, s_a, to the total standard deviation, s_t. That is, $s_t^2=s_a^2+s_s^2$. So if duplicate samples,

sometimes called collocated samples, are taken, the total standard deviation can be estimated from the equation $s_t=D\sqrt{2}$. This is a poor estimate of standard deviation, however, since there is only one degree of freedom in the estimate. In order to get a better estimate, several duplicate samples can be taken from a location and a pooled estimate of standard deviation obtained using the following equation: $s_t=\sqrt{((\Sigma D^2)/2m)}$, where D is the difference between two sample results and m is the number of pairs of sample results.

CORRECTION OF ANALYTICAL BIAS

Bias due to calibration has been identified as a significant source of bias for some methods of analysis, particularly for organic compounds. This bias needs to be corrected before using EPA's Decision Performance Curve to decide if an action level has been exceeded. The preferred correction would be to choose another method or modify an existing method so that calibration bias is eliminated. Some methods, such as EPA 504.1, do not exhibit calibration bias because calibration standards and samples are analyzed by the same procedure, and should be selected whenever possible. EPA 504.1 states that "Aqueous calibration standards are extracted and analyzed in an identical manner as the samples in order to compensate for possible extraction losses." Isotope dilution methods, such as EPA 1625 for BNAs, also do not exhibit calibration bias, since the isotopically labeled internal standards are added to the samples and carried thru the extraction and cleanup procedure. If it is not possible or permissible to change to a less biased method, results can be mathematically corrected, based on the recoveries found for analyses done on analytes spiked into pure matrix (e.g. pure water).

Bias due to interferences are best corrected by using a method less subject to interferences. For organics analyses, isotope dilution mass spectrometry is less subject to interferences. For metals analyses, the method of standard additions can often be used to reduce interferences, but it should be remembered that interference effects that are independent of the concentration of the target analyte are not corrected by this procedure.

A change in the procedure for determining the blank or in making blank corrections will be necessary if either of these are a source of bias. Any changes should be documented in the written procedure.

PERFORMANCE BASED MEASUREMENT SYSTEMS

EPA's proposal for performance based measurement systems defines acceptability of alternative methods in relation to a reference method. When that standard method exhibits bias, (calibration bias, interference, or failure to blank correct), it should be permissible to define acceptability in relation to the true value, and not just in comparison to a reference method.

NATIONAL LABORATORY ACCREDITATION PROGRAM

In the National Laboratory Accreditation Program (NELAP) laboratories are audited to determine if they are performing analyses correctly. As performance based methods are increasingly used by laboratories, it will be the auditor's responsibility to verify that the proper documentation is present to demonstrate that the alternative method is as good as or better than

the reference method. The auditor should be permitted to approve alternative methods if they exhibit less bias than the reference methods.

CONCLUSION

At the project level of EPA's Quality System approach, steps are included to identify and control errors that may keep one from being able to meet the DQOs and thus avoid decision errors. The approach effectively deals with random errors of sampling and analysis, but systematic errors in analysis are assumed to be negligible when in fact they may be significant. The WRC approach to AQC complements EPA's approach through a series of iterative steps that include the definition of analytical objectives, selection of methods, estimation of precision and bias, and routine control of precision. Sources of analytical bias that may need to be controlled are bias due to calibration, bias due to interference, biased blank corrections, and the use of inappropriate methods. Random error can often be reduced by specifying the analysis of more than one portion of a sample to produce one analytical result, and it is important that random error be considered in the definition of DQOs and targets for accuracy. Finally, it is important to estimate random errors for both sampling and analysis. Too much effort should not be expended to reduce analytical error if the random error of sampling is much larger and cannot be reduced.

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Pitfalls in Performance Auditing

Volatile organic compounds (VOCs) and aldehydes have been implicated in sick building syndrome in new office buildings. My organization, the Air Pollution Prevention and Control Division (APPCD) of the National Risk Management Research Laboratory, participated with a private sector "verification partner" in an Environmental Technology Verification project to test emissions from low-emitting office furniture. The purpose of this project was to produce methods to verify performance, based on manufacturers' claims that their furniture did not emit significant levels of VOCs, including aldehydes and other VOCs, into the indoor office air environment.

A standard protocol exists for measuring VOCs emitted from materials placed in large environmental chambers. The procedure involves placing newly manufactured furniture into a large environmental chamber, passing clean air over the furniture, and collecting any emitted volatiles on sorbent cartridges, which are subsequently analyzed in a laboratory, following the standard protocol. The QA Team in APPCD needed to assess the capabilities of three analytical laboratories to analyze the compounds emitted by office furniture.

The plan to audit was straightforward: We would spike several sorbent tubes with two levels of some compounds emitted by furniture and send these spiked tubes to the analytical laboratories. At the same time, we would spike some tubes for analysis by our reference laboratory, to confirm spiking levels and to determine the inherent variability in the method. We would assess results from the participating laboratories by comparison with the reference laboratory.

The illusion of simplicity was short-lived. Each laboratory uses a different sorbent, and each laboratory uses tubes of different size, none of which were compatible with our reference laboratory's equipment. None of the laboratories wished to change their system. In addition, the laboratories wanted to begin with known compounds and unknown quantities, testing only VOCs. There were scheduling problems and problems with the proprietary nature of data from prior tests done on furniture emission, used to determine spiking levels. The solvent used in preparing the spiking solutions was not compatible with one of the sorbent systems.

A sequential description of problems encountered in conducting this audit and solutions reached is presented in the hope that others conducting performance assessments can glean helpful suggestions.

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Pit al s in Performance Auditing

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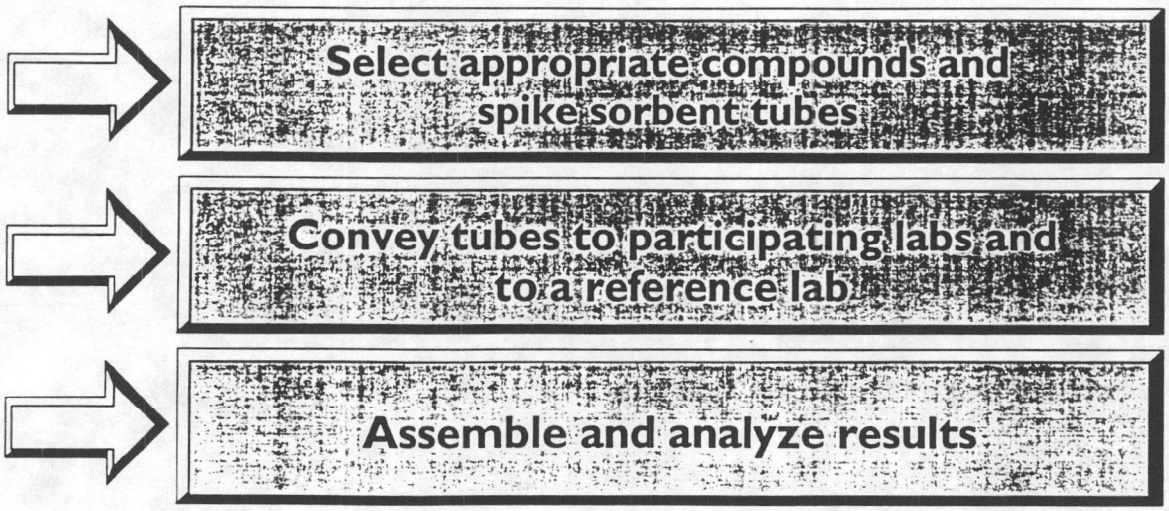
Presented at the Annual EPA QA Meeting, 1999

Background:

- Sick building syndrome
- ETV project on IAQ
  - Verification partner
  - Stakeholders
- "Green" office furniture manufacturers
- Verification of performance
- SOP for VOCs/aldehydes
- Audits to verify capabilities of labs

Performance Audit Procedure



Issue: Proprietary data

Solution: Discussion of purpose of study

Issue: Audit materials
- VOCs and aldehydes?
- Unknowns v. knowns

Solution: Plan for multiple rounds of audits

Issue: Participants

Solution: Two labs withdraw, one added

Status:

- Three labs
- Four known analytes
- Two unknown levels plus blanks
- 23 tubes
  - 7 high level - 3 reference tubes
  - 7 low level - 3 reference tubes
  - 7 blanks - 3 reference tubes
  - 2 spares

More Issues:

- Labs can't spare 23 tubes
  - Use 11 tubes (3+3+3+2)
- Each lab uses a different sorbent
  - Assume similar and assess data
- Each lab uses different size tubes
  - Incompatible with reference lab
  - Participants can't change
  - Ref. lab can't purchase equipment
    - Ref. lab can't validate spikes
    - Ref. lab will validate own sorbent

(continued)

- Different calibration ranges
  - Adjust spiking levels
- Scheduling problems
  - Wait
- Concerns with proprietary procedures
  - Encourage sharing of knowledge

Status (with more issues):

- Spiked samples prepared
  - One lab's tubes inconsistently packed
    - Use the best tubes; inform lab.
  - One lab's tubes were metal and heated too rapidly
    - Modified spiking procedure
- Shipment to labs, with instruction for reporting results

Status (with more issues): *(continued)*

- Validation with reference lab's sorbent tubes
  - Ref. lab forgot to run TVOC standard
  - Can't assess TVOC levels

More issues:

- No response from two labs after expiration of time limit for analysis
  - Phoned
  - E-mailed
  - &*#%$!
- Verification partner scheduled conference call
  - Labs submitted results at the last minute

Still more issues:

- One lab's data unacceptable
  - Accusations!
  - Rebuttals!
  - Technical solution proposed (incompatible solvents)
    - Remade spiked tubes
    - Reanalyzed, with delays due to instrument problems
    - Acceptable results

Lessons Learned:

- Nothing is completely standardized
  - Look for possible areas of difference
  - Work with smart and experienced people who can solve problems!
- Expect the unexpected, especially in scheduling

Lessons Learned: *(continued)*

- Maintain constructive relationships
  - Noone likes to be audited; show respect.
  - Everyone wants to do well; show appreciation.

- Remember that performance audits are the only way to verify analyses

Acknowledgements:

- Dr. Roy Fortmann and Libby Beach, Arcadis Geraghty & Miller
- Shirley Wasson, APPCD liaison for IAQ studies
- Dr. Les Sparks, APPCD Project Officer
- Dr. Dave Ensor and Debbie Franke, Research Triangle Institute

SUPERFUND QA OVERSIGHT– WHERE DO WE GO FROM HERE?

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Extended Abstract

Background:

Introduction: EPA's Superfund program has emerged, over its approximately 19 years of existence, from a program of mainly site assessment and characterization – as its National Priorities List of sites was continually growing - to one having a larger focus on design and construction of remedial actions and actual cleanup. This is true both for "Fund-lead" projects and, on a growing basis, for Potential Responsible Parties (PRPs) and Federal Facilities. As the Superfund "pipeline" status was changing, so was the Agency perspective on how to do business – changing from a prescriptive to a performance-based approach where possible. This combination of paradigm shifts stimulated the Superfund Headquarters QA personnel to set up a series of visits to the 10 EPA Regions (and ERTC) to review current practices being carried out for QA oversight of Superfund activities, regardless of lead.

Justification for these visits was strengthened by the March 1997 report by the Office of the Inspector General. The ultimate goal of the Regional reviews is to develop *relevant* guidance on the minimum elements needed for QA oversight for all Superfund environmental data collection activities (planning, implementation, and assessment). The guidance will take advantage of the information gained during the reviews to identify and share the best and most innovative practices being followed and to identify the areas of weakness that will benefit from guidance. Both global/program level (e.g., Regional QA staff and, in some Regions Superfund QA staff) and project level [e.g., Remedial Project Mangers (RPMs), On-Scene Coordinators (OSCs), and Site Assessment Managers (SAMs)] QA oversight was reviewed and will be covered. Some perspective on Regional Superfund Program management was also gained. The Agency policy defined in EPA Order 5360.1, change 1 and its accompanying 5360 Quality Manual will provide a valuable framework for the upcoming guidance

Approach: Separate questionnaires were used for interviewing Regional QA staff and Superfund staff (the QA staff questionnaires are being used also for Superfund QA personnel) because of the importance of assuring that there is an adequate Regional QA program in place as the underpinning for individual project level QA oversight. The questions for both audiences covered the gamut including systematic planning through determination of whether project goals were met, roles and responsibilities throughout the process, and adequacy of experience/training

of those performing program and project functions. In addition, the more fundamental project level review looked at oversight of contractors (for both Fund and non-Fund lead) because of the high dependence on the commercial sector for support. Many Quality Assurance Project Plans (QAPPs) were collected and reviewed according to a very detailed checklist based on EPA's R-5/G-5 QAPP documents.

General Findings:

It is important to reiterate that our reviews were not intended in any way to provide a "report card" or focus on problems that would demand formal corrective action – such as an OIG audit/report or a Management Systems Review (MSR) by QAD. Rather, they were intended to gather information to learn about the good practices, share innovation, and provide a pointer to the areas most needing improved guidance. It is also important to understand that the findings that follow are not all encompassing for all Regions. Each Region has high points and weaknesses scattered throughout. The Regions were very gracious about giving up their time to us and candidly sharing both their descriptions of how they carry out their roles and their overall feelings about currently-needed "help" from Headquarters (e.g., guidance, training, involvement), even when negative, and how they can better be helped. General findings follow.

- Project management personnel were sincerely interested in doing a good job and believed that decisions were supported by adequate and appropriate data.
- Regional Superfund senior management was interested in QA and supportive of QA efforts. The level of this management support varied across the Regions.
- There is a major gap in QA training – it is not mandatory in most Regions, and when it is provided by the Regions, not usually well attended. A large number of interviewees had no QA training, though were interested in acquiring basic QA knowledge.
- Most personnel interviewed (QA and program staff) indicated that QA training should be mandatory. The general recommendation from Superfund project managers was that QA training should be more relevant to their jobs and several people recommended that it should be presented by program staff (especially true for DQO training – as noted by many RPMs).
- The DQO process is rarely used according to the national guidance (G-4). There is general lack of understanding of step 6 (establishing the limits on decision error) and skepticism on the value of going through a complex exercise of null and alternate hypotheses, etc., and statistical planning.
- Many QAPPs reviewed were quite good, though it was difficult to evaluate them against the R-5 requirements since many of the R-5 elements are found in other project documents (e.g., Work Plans, Sampling and Analysis Plans, Field Sampling Plans, to name a few). Since R-5 is still an interim document, some Regions did not require that it be followed.
- Generally, the project managers felt that they had good contractor support for their activities. There was some indication of lack of oversight of contractor activities and, in some cases, a possibility of too much trust without oversight activities in place to verify performance.
- There is great variability across the Regions in how much involvement Regional QA staff have in project planning and implementation and even global oversight. There is a pattern of "personality-based" involvement, and often little structure to obtaining QA support or formal policy for when QA staff involvement should occur.

- There is strong feeling from QA staff that they could provide much valuable support to project managers in planning, QAPP review, field oversight, and data acceptability determination – these roles being successfully carried out in some cases.
- There is still some perception of the role of QA as a burden and obstacle.
- A Superfund QA function/staff is on the rise.
- The Removal program staff often feel that it is not well understood and that their data collection must be less stringent (e.g., emergencies/time critical removals).
- Many interviewees said the QA documents should be "requirements," not "guidance."

Next Steps:

Regional profiles have been developed and are being reviewed by Regional QA and Superfund staff as to their representativeness of overall Regional practices. Those profiles are be the basis for the National Summary which highlights exceptional practices and highlights areas of weakness for focus on improvement recommendations. Lastly, the "Superfund Guidance on Minimum QA Oversight Program Elements" (proposed title) will be developed, with anticipated strong input from the Regional Superfund programs and QA staff. It will be a clear interpretation of "5360" for Superfund activities, regardless of lead. The guidance will incorporate any Interagency Data Quality Task Force (IDQTF) products, either by reference or appendix, in order to assure that no contradiction or redundancy in products occurs and interagency buy-in is more likely.

QA oversight guidance elements likely for inclusion cover: systematic planning for data collection, generation of planning documents needed for carrying out data collection (e.g., QAPPs, SAPs, FSPs), oversight of the data collection process (e.g., adherence to the sampling (and other relevant) plans and documentation of deviations, equipment decontamination, field record-keeping, field measurements, sample packaging and shipment), evaluation of data for suitability for use, laboratory QA oversight, sample and field QC practices (e.g., types of quality assessment samples to use), appropriate training for various roles (program and project management and QA staff, communications (up, down, and sideways) and feedback mechanisms, and data management. Needed flexibility and a performance-based approach will be retained – at the same time making QA and management goals clear.

Conclusion:

The Regional reviews were very useful as a starting point for guidance document development. There are many fine examples of good project management and oversight and many examples of weaknesses that will benefit from guidance. There appears to be enthusiasm for a single, new, concise, and user-friendly set of minimum QA elements for Superfund activities – with the hope that the myriad of existing guidance can be declared obsolete. Management understanding and support for QA should be enhanced.

Audience participation will be requested on related questions.

AN ALTERNATIVE APPROACH TO QUALITY ASSESSMENT SAMPLE ALLOCATION

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SUMMARY

An alternative approach to the determination of the type and number of field quality assessment samples such as collocated samples, field splits and a variety of blanks (rinsate, field blanks and trip blanks) has been developed as part of the Los Alamos National Laboratory Environmental Restoration Project. This approach is designed to reduce the burden associated with the collection and analyses of these samples, while maximizing the benefit, and hence value. The alternative approach starts by recognizing the overall objectives of collecting field QA samples and the problems associated with traditional approaches. The process involves assigning QA samples to aggregates of sites and focuses on representing specific environmental media and analyte classes of interest. The process has wide spread applicability to Federal Facilities or industry where large clean up or monitoring programs require the collection and analysis of vast quantities of environmental data, and has the potential to save vast sums of moneys while improving the quality of the product generated.

INTRODUCTION

A great deal of time, money and effort associated with large environmental data collection efforts is devoted to the collection and chemical analysis of a variety of field quality assessment and quality control samples. Until recently, the Los Alamos National Laboratory (LANL) Environmental Restoration (ER) Project followed the same approach as that taken at many facilities across the country -- to routinely collect field duplicates (either collocated samples or field splits), and a variety of blanks at a set frequency. For example, the standard procedures followed by LANL from 1992-1996 called for field QA sampling (field duplicates; rinsates, field and reagent blanks) at the 1 in 20 or 5% rate for soil sampling. In practice, this approach (in combination with the QA/QC samples used in the laboratory) resulted in 40-60% of the sampling and analytical budget being spent on this ancillary data, rather than on field samples. It is no wonder that the value of QA/QC samples has begun to be called into question.

Recognizing these issues, LANL initiated an effort to develop a rigorous QA Oversight program. As a first step in this process, a decision was made to download and assess all historical QA data to learn about the overall performance of the measurement systems that have been in place and to determine the relative value of different sample types and the information in general. The following were stated as the products that the QA Oversight program were to produce:

1. A method to determine what measurements are most critical for generating quality measures.
2. Estimates of precision and bias for the entire measurement by media (matrix), analyte, methods, (analytical, sample preparation, field sampling), field season, year, or groups of years, and lab
3. Estimates of the performance of field data including completeness (in data base), and precision and bias
4. Data to evaluate the comparability of methods

5. Summary of how frequently different validation flags are put on data by: lab, analyte, and matrix
6. Relative contribution of measurement variability to total study variability

Efforts to generate these products based on the historical review were impeded for a number of reasons. First, attempts to access the data were fraught with difficulties due to historical problems in coding QA data that interfered with the ability to query the data base, multiple codes used to identify QA samples, and missing entries for QA results. In addition to data base related problems, duplicates that were identifiable frequently contained numerous non-detects for constituents of interest, or the number of duplicates related to any particular site was inadequate to generate a meaningful estimate of variability.

Early conclusions of the QA Oversight effort were twofold: 1) the recognition that numerous changes in the data recording and management systems would need to be made, and 2) the recognition that the information obtained from the current allocation of field QA samples was of questionable value to the decision making process and the process for determining the type and number of samples should be reconsidered. In the interest of doing more with less, an evaluation was made of the types and numbers of field QA and other samples that should be introduced by LANL during the sample collection and handling operations. Emphasis was placed on (1) identifying QA samples that provide information that is *necessary* to assess data quality for decision making, and (2) establishing a minimum standard for use across the ER Project. An alternative process for designing the QA sampling program was developed, and over time has evolved to a new SOP. This process, and its basis, is presented in this paper.

GOALS AND OBJECTIVES

The goal of this effort was to come up with an alternative process to follow in determining the minimum number of each type of field QA sample. The specific objective established for QA data was to augment normal field samples in such a way that would support estimates of total measurement system precision and bias[1], by media, analyte and to some extent, sampling method (e.g., surface soil methods versus subsurface soil methods). It is the total measurement system performance in combination with statistical sampling error that directly impact the probability of making a decision error. The number and allocation of field samples should be adequate to support the decisions of interest. The role of the QA samples is primarily to support the evaluation of the performance of the measurement systems used; not to improve the quality of data being generated.

THE ALTERNATIVE APPROACH

The approach presented herein reflects recent EPA guidance on the use of field assessment sampling contained in (EPA 1998a, and EPA 1998b). These documents emphasize the importance of integrating

[1] Total measurement system error is the sum of all errors associated with generating an individual result including error introduced through the processes of sample acquisition, handling, transport and storage, preparation and analysis. An estimate of total measurement system variability can be obtained through the use of collocated and/or field split samples. Whenever practical, use of collocated samples are recommended, since in that way the sample acquisition process is repeated. This is typically impractical when dealing with subsurface cores, where samples should be split. Total bias is usually estimated by analyzing matrix specific PE samples and blanks. Additional lab procedures utilizing spiked samples, surrogates and reference materials will also provide some useful estimates of analytical bias.

field assessment sampling with the sampling and analysis plan (SAP) and the overall project objectives, rather than achieving a specified ratio of field assessment samples to field samples.

The alternative approach is designed to support an aggregate-level evaluation of the performance of the measurement system, rather than assessment for a single project or sampling event. Aggregation is essential, since many studies at LANL (as well as other facilities with multiple sites) involve a small number of samples from a given matrix at a given site, analyzed for a focused set of analytes. Using the traditional methods, these sites would be allocated one duplicate and one or two blanks. Analyzed alone, one duplicate or blank sample provides almost no information of value for interpreting the field samples, or in designing future studies. Project aggregation is therefore the first step of the procedure for allocating QA samples.

A project aggregate is defined here as a set of individual projects (e.g., small sites) for which one series of QA samples will be collected and evaluated. A project aggregate should meet a number of criteria: it addresses a defined geographic area; it is under the control of a common manager and has a single point of contact; sampling should be performed within a set time frame, typically a calendar year or field season; aggregate sampling effort should generate a minimum of at least 50 field samples (more than 150 samples are preferred); and either sampling should be performed by a single contractor, or QA samples representative of each applicable matrix and analyte suite should be collected by each contractor (which may increase the number of QA samples required). By defining aggregates in this way, an adequate number of QA samples can be collected to generate some valuable information, without overburdening individual sampling efforts. This approach should be easily adaptable to other large Federal Facilities, as well as large industrial areas, where the majority of the nations environmental data collection efforts are ongoing.

Identify the Field Samples to be Collected by Projects in the Aggregate

This step in the process requires the project aggregate manager to project how many samples of each matrix will be collected during the time period to be represented by the QA samples taken (e.g., calendar year or field season). In addition, if at least 20 samples within a matrix are to be collected using two or more different sampling techniques (that may affect total measurement error), they should be separated, so that QA samples specific to that technique can be allocated. Once this has been done, the next question to answer, is how many of these samples will be analyzed for each of the analyte suites of interest, and what method(s) will be used to perform the analyses. If two or more analytical methods are to be used to perform a suite of analyses, these groups should be separated and QA samples allocated to each group. In addition, any unusual methods that are to be employed should be identified. The results of this exercise should be recorded in a table like that shown below (Table 1) which includes the analyte and matrix classes that pertain to the LANL ER project.

Table 1. Example format for recording the number of field samples and types of analyses to be taken within an aggregate

	Aqueous Liquid	Gas/vapor	Soil/Sediment	Tuff	Other (e.g., sludge, debris)
High Explosives	0	0	85 (45 lab analyses, 40 field screening methods)	35 (all lab analyses)	0
Inorg/metals	0	0	85	35	
PCBs/Pesticides	0	0	10	10	
RAD	0	0	85	35	
SVOCs	0	0	10	10	
VOCs	0	0	0	0	
Special					

Allocation of Field Duplicates

To begin the process of determining the number and type of field duplicates, the first step is to highlight the matrix/suite pairs in Table 1 that contain enough samples (usually more than 20) to make it worth while assigning some number of field duplicates to the cell. Also cells for which information is required because a novel or difficult sampling or analytical method is to be used, should be identified, even if they contain less than 20 samples. Other cells are generally viewed as being too small to warrant allocation of QA samples.

Having completed the table, the project aggregate manager and site experts then contribute their best judgment regarding what to expect from the sampling campaign in order to decide whether to collect collocated or split samples. Collocated field duplicate samples are recommended if site heterogeneity is potentially significant (such as when contaminants are expected to be particulate or chunky in nature). Spatially or temporally collocated samples are also required where field splits are impractical, e.g., when collecting samples for volatile analysis. Either field splits or collocated samples are acceptable for other situations. Slightly different components of the total variance are estimated if field splits are used, compared to what is estimated using collocated samples (see Table 3).

For each highlighted matrix/suite combination, the next step in the process is to determine the number of field duplicate pairs required using Table 2. Project aggregate area managers will notice that as the number of field samples goes up, the proportional burden goes down. The numbers of field duplicate pairs listed in Table 2 are the minimum recommended numbers, and reflect practicality considerations at least as much as statistical considerations. Managers will be motivated to form larger aggregates to keep the cost of QA sampling to a minimum. Additional duplicate pairs are recommended when unfamiliar sampling or analyses methods are used, or when the estimate of measurement error is an important outcome of the study (e.g., when conducting a Phase I study that will produce variance estimates used to determine the number of Phase II samples required).

Table 2. Minimum Numbers of Field Duplicate Pairs

Number of Field Samples	Number of Field Duplicate Pairs
<20	0
20-45	3
45-75	4
76-120	5
121-180	6
181-245	7
>245	8

Having determined the number of duplicate pairs, the remaining step is to determine which field samples will be duplicated to obtain the required numbers for each highlighted matrix/suite combination. In general, field duplicates should be distributed evenly across the project in both space and time. However, to maximize the value of these samples, more duplicates should be taken from locations that are likely to yield detected results for the analytes of interest. By incorporating QA sampling design into the overall QA and SAP planning, sample locations for duplicate pairs can be identified that achieve these goals.

Allocation of Equipment Rinsate Blanks and other Types of Field Blanks

Other types of field assessment samples are required only for certain types of sampling and/or analysis and no minimum numbers are required. These other types of field assessment samples should be carefully targeted to anticipated problems associated with novel or difficult sampling and analysis methods. For may routine sampling situations, no equipment rinsate blanks are recommended, however if equipment is not being immediately reused, such as when equipment is decontaminated in bulk at the conclusion of a project, a single rinsate blank may be collected prior to equipment reuse. Other situations where rinsates may be deemed appropriate include: use of an analysis procedure with especially low detection limits, collection of samples of relatively low analyte concentration following the sampling of areas of high concentration, or collection samples after equipment has been in contact with relatively adhesive materials such as asphalt. Action levels that would trigger a change in sampling procedure or resampling if exceeded must be specified. Rinsate blanks are most useful as a QC tool, but this requires scheduling the collection early in the field season and the use of quick turnaround analysis to provide results prior to collecting the majority of field samples. Problems found after the fact (when rinsates are used as a QA tool) may lead to rejection of field data and potentially expensive resampling, while problems found during the field season can be corrected. If appropriate (i.e., if methods of adequate specificity and sensitivity are available), rinsate blanks may be analyzed by field methods or quick turnaround methods; it is not necessary that the methods used for the routine samples be used.

Other types of blanks such as field blanks are most useful at sites where VOCs are known or strongly suspected to be present. Contaminated sampling containers and reagents are very rarely a problem for routine sampling and analysis methods. If required, the appropriate analyte free matrix should be used for the blank. For example, distilled or deionized water for liquid or solid matrices, and unexposed filters for gas samples. Blanks can be opened at the site during the sample collection process to determine if cross contamination is likely due to volatiles (e.g., open field blanks), or can be kept closed (e.g., trip blanks) to evaluate the potential for cross contamination during shipping and storage. Like

rinsate blanks, if field blanks are used, they may be concentrated near the beginning of a project if contamination problems are suspected, or inserted at the rate of one per site or round of sampling. Again, an action level, that if exceeded would trigger changing sampling methods or resampling, should be set ahead of time.

Table 3. Quality Assessment/Quality Control Samples

Sample/Data Type	Parameter Estimated	How Data Are Used [pool the results for media/analyte classes]
Field Split Field sample homogenized and subdivided in the field, then individual portions submitted for analysis.	**Variance.** Provides estimate of total measurement variance, excluding the effects of sample collection and small-scale site heterogeneity. Useful for estimating sum of handling, storage, preparation and analysis variances and for estimating effectiveness of sample homogenization protocols.	Compare observed concentration difference between split and original sample with differences between lab duplicates, and reported laboratory precision. Look for outliers and trends. Calculate RSDs. Evaluate the effect of analyte concentrations on RSD.
Collocated Sample Sample collected as near in space and time to the original field sample as the sampling equipment and procedure allows.	**Variance.** Provides estimate of total measurement variance, including the effect of population (site) heterogeneity on scale of sample. (e.g., differences that actually exist in the field on the scale of the collocated sample.)	Compare observed concentration difference between collocated and original sample with variability among field samples, differences between lab duplicates, and reported laboratory precision. Look for outliers and trends. Use to estimate overall sampling variability. Calculate RSDs. Evaluate the effect of analyte concentrations on RSD.
Rinsate Blank Blank material poured over decontaminated equipment, collected and submitted for analysis.	**Bias.** Indicates potential for contamination of field samples (positive bias) through contact with contaminated sampling equipment.	Compare observed concentrations to action levels. Exceeding action levels indicate potential for sample contamination. [inadequate ñ We want to know if we have detects in the blanks ñ that alone might be indicative of a problem. If found, then evaluate against decision criteria (e.g., action levels) to see if it matters. Similar to field blanks in this regard.] Corrective actions may include revision of decontamination procedure or resampling.
Field blank Analyte-free matrix transported to field in closed sample container. Optionally, container opened in field. Appropriate reagents added and sample submitted for analysis.	**Bias.** Indicates potential contamination of field samples from: exposure to site conditions (if opened in field); contact with reagents; field and laboratory storage/shipping/handling.	Compare observed concentration to detection limit. Use comparisons to indicate potential for sample contamination. Corrective actions may include revision of sampling procedures or resampling.
Performance Evaluation Sample Sample of prepared and certified performance evaluation material collected and analyzed in the field.	**Bias.** Provides estimate of bias of field analytic method relative to method by which the performance evaluation material was certified. **Variance.** Provides estimate of variance of field analytic method.	Compare measurements to certified values. Estimate the bias and variance of the measurements. Measurements with large bias or variance may indicate the need to modify decision rules that use the field analyses in order to

		compensate for the limitations of the field method.

Table 3 summarizes the different types of duplicates, blanks and performance evaluation samples that should be considered when designing a SAP. By applying some of the methods described in this document we believe these samples will provide greater value to a project.

CONCLUSION

An alternate procedure for allocating field QA samples to environmental data collection efforts during the design of data collection efforts has been developed. This procedure will increase the value of those samples collected by ensuring that all important matrices and analyte classes are represented in a manner that will facilitate pooling data for assessment purposes. The procedure encourages managers to build QA sampling into their overall SAP, to create meaningful aggregates of sites that will result in a large enough number of field samples to generate a meaningful QA data set without overburdening a project. By focusing on the important objectives associated with QA samples, and recognizing upfront how they will be used, the likelihood that they will in fact be assessed will increase. Therefore, not only will the burden of collecting the samples go down (especially as aggregate sizes increase), the amount of useful information obtained will go up.

ACKNOWLEDGMENTS

The alternative procedure discussed herein has been developed as LANL ER-SOP 1.05 by Katherine Campbell. Paul Black, Wendy Swanson, Dean Neptune and Kristen Lockhart (Neptune and Company), Tom Johnston (formally of Neptune and Company), and Larry Souza (LANL) played an important role in developing the concept. Terre Mercier, Wendy Swanson, Paul Black and Kristen Lockhart (Neptune and Company) and Catherine Smith (LANL) contributed by pursuing QA Oversight, and Brad Martin and Alison Dorries (LANL) encouraged the search for a more efficient and meaningful approach to QA sample collection.

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MEASURING THE COST OF QUALITY— ANALYTICAL PROGRAM CONSIDERATIONS

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SUMMARY

When the USEPA buys data, the Agency pays for "defect-free" data, plus the costs of imperfect data. The USEPA pays for sampling, and the bid price for laboratory services. Laboratory services include analysis, reporting, bottles, and built-in lab internal QC checks and reanalysis fees. The USEPA also pays third party contractors such as Contract Laboratory Analytical Support Services (CLASS) and Quality Assurance Technical Support (QATS) to review work, check invoices, provide reports, etc. It is to the government's advantage to use quality costs to identify cost savings, and work with the Contract Laboratory Program (CLP) labs to reduce appraisal and failure costs.

Laboratories are evaluated on a number of factors, including completeness/compliance and data turnaround time, results of PE samples and audits, etc. Laboratories performing better on these indicators are candidates to receive additional work, with the expectation that the labs will continue to perform at a high level. If these appraisal costs are quantified, the results can be factored into an analysis of quality costs. This paper examines the various costs and proposes evaluation tools to lower total quality costs.

INTRODUCTION

The Quality Cost Improvement Philosophy is simply stated:

PRIVATE SECTOR: Every dollar saved in the total cost of quality is directly translatable into a dollar of pretax earnings.

PUBLIC SECTOR: Every dollar saved in the total cost of quality may be translated into increased ability to meet public needs (protect human health and the environment)

Quality improvements and quality cost reductions cannot be dictated by management—they must be earned through the process of problem solving. The first step in the process is the identification of problems. Every problem identified by quality costs is an opportunity for profit improvement. Quality improvement results in cost improvement. Designing and building a product right the first time always costs less. Solving problems by finding their causes and eliminating them results in measurable savings.

BASICS OF QUALITY COSTS

J.M. Juran developed the cost of quality (CoQ) technique more than 40 years ago. There are two kinds of costs: those incurred because of a lack of quality (nonconformance to specifications) and those incurred in the achievement of quality (conformance to specifications). Costs due to a lack of quality are further divided into costs of internal failures and costs of external failures. Costs of achieving quality are divided into appraisal costs and defect-prevention costs (see Table 1, Cost of Quality Categories).

Table 1, Cost of Quality Categories

Category	Definition	Typical Examples
Internal failures	Quality failures detected before providing a service or shipping a product to the customer	Rework, retesting; costs of scrap, reinspection
External failures	Quality failures detected after delivery or shipment of the product or service, to the customer	Rework, retesting, resubmission, liquidated damages; costs of processing customer complaints; cost of lost or reduced business, liability costs
Appraisal	Costs associated with measuring, evaluating or auditing products or services to assure conformance to quality standards and performance requirements.	Checking and screening activities, product reviews, incoming and source inspection of purchased material, audits, calibrations
Prevention	Efforts to ensure product quality	Inspections, process studies, metrics collection, training, equipment maintenance, quality planning, supplier capability surveys, process capability evaluations, quality improvement projects

The Total Cost of Quality is the sum of all these costs of failure, prevention, and appraisal. They represent the difference between the actual cost of a product or service and what the reduced cost would be if there were no possibility of substandard service, failure of products, or defects in their manufacture. To improve or maintain quality involves cost. Product or service must be inspected to assure bad output does not reach the customer. Control systems must be established and maintained. Workers must be trained.

Each participant working with or supporting the CLP—the laboratories, the contractors supporting EPA (sampling team, CLASS, QATS), and the Regions—incurs the three classic categories of quality costs—prevention, inspection, and failure (see Tables 2 and 3). CLASS, the Regions, and the labs each have their own QC programs that monitor internal performance.

Table 2, Example Activity-Based Quality Costs for the EPA (with CLASS, QATS)

EPA Activity	Costs	Quality Cost Category
Planning, Scheduling, Training	Data Quality Objectives, EPA and field contractors' costs, Quality Assurance Project Plans, Health & Safety Plans, Sampling & Analysis Plans, program-wide standardized methods and deliverables	Prevention
Sampling	Packaging and shipping expenses, QC sample costs, review costs	Prevention and appraisal
Review/Validation	Semi-automated and manual hardcopy validation, pre-and post-award on-site audits, blind and quarterly PE samples, data package and tape audits	Appraisal
Rework	Resampling, corrective actions	Failure

Table 3, Example Activity-Based Costs and Quality Costs for a Laboratory

Lab Activity	Costs	Quality Cost Category
Planning, Scheduling, Training	Peer, management, and QA reviews	Prevention
Receipt/Login	Check paperwork, preservation, custody	Appraisal
Prep/Analysis	QC checks, calibrations, Standard Reference Materials, traceability, maintenance, review	Prevention/Appraisal
QA Program	SOPs, audits, PE samples, training, reports	Appraisal
Reporting/Customer Service	Initial report, answering questions	Appraisal
Rework	Re-prep, re-analysis, re-reporting, corrective actions, Liquidated Damages, potential lost business, reduced receipts	Failure

ESTIMATED SAVINGS USING QUALITY COSTS

The following questions are worth asking when considering the possible savings that could be realized in using a quality cost approach:

- To minimize the total of these costs, how should they be measured and used?
- How can managers use them to identify areas where small increases of resources can mean substantial quality increases, and large quality cost decreases?
- Can they be compared using cost/benefit procedures, or by standardized accounting criteria such as Net Present Value (NPV), or Return on Investment (ROI)?
- Can they be compared using a simple "Hassle Factor" (HF), with the combinations causing the fewest problems equated to the lowest quality cost?

CLP EXAMPLES OF QUALITY COSTS

Assume a situation in which purchased material rejections (i.e., failed data deliverables) are the Agency's biggest problem. Pareto analysis can be used to determine which suppliers cause the most problems, based on Contract Compliance Screens (CCS) and the need for manual data reviews. Then the Agency can focus on these suppliers and take appropriate action. The Agency might convince them to institute quality cost programs. Improved profitability for the supplier may eventually result in lower prices for the Agency in a competitive market. The supplier quality costs can be incorporated into a supplier rating system. A ranking of suppliers by quality cost performance index can be constructed. What information could be used in such a rating system? CCS is designed to work on a consistent and fast-turnaround basis. To achieve this, systems have been implemented to perform the following tasks:

- Track the progress of deliverables through all parts of the CCS system.
- Examine and report on the presence of defects, completeness of variables, and compliance specifications of the data reported on the electronic diskette deliverables.
- Generate reports summarizing the full compliance status of deliverables in terms of summary sheets and approved defect statements.
- Generate CCS records containing coded compliance status and error records summarizing details of detected defects.
- Report compliance status and trends across time, laboratories, Regions, and/or CCS criteria.

The following are examples of CLASS routine CCS reports that measure supplier performance:

- Failed Sample Delivery Group report
- CCS Defect report and Resubmittal report (semi-automated)
- CCS Defect report and Resubmittal report (full manual)
- Compliance Analysis and Late Trend Data Report (each SOW)
- SDG Completed Monthly Report
- Weekly CCS Updates
- Diskette Deliverable Compliance Analysis for Contracts
- Data Acceptance/Rejection/Reduced Value (DARRV) Forms

As an example of the magnitude of quality failure costs (lab's external failures), the following figures in Table 4 for FY98 show liquidated damages for all SDGs:

Table 4, FY98 CLP Liquidated Damages Charges

SDGs based on Data Receipt Dates	2540
Total SDGs with Liquidated Damages	1480
% of SDGs with Liquidated Damages	58%
Total Liquidated Damages	$233,000

(Note: Figures are rounded)

HASSLE FACTOR REDUCTION

"Hassle Factor" is a term applied to the amount of effort and aggravation necessary to solve a problem. For CLP data, a hassle factor can be quantified in terms (such as "What easily-avoidable failure category items take the most time to deal with?"), and are consequently the most aggravating types of problems handled? A simple example is when labs don't call to report discrepancies in sample identification/labeling. A lab may "guess" which sample numbers are correct, based on information on the bottle labels or Traffic Reports and Chain of Custody forms. If the lab is incorrect, the sample numbers on the diskette deliverable will be unacceptable, since the information provided from the sampling team doesn't match what was anticipated from the laboratory. When the diskette fails in the CCS, the CLASS Environmental Program Coordinator must talk with the lab and the Region to determine the correct sample numbers and institute changes in the appropriate documents. The electronic information must then be corrected and the electronic data screen repeated. If the problem is not resolved within 5 days, and a manual screen of the data is performed, review costs are much higher for the EPA. A small amount of prevention (calling about discrepancies) causes a large cost of quality with this failure (failed screen, corrective action, costs of second screen, and possible manual screen, liquidated damages, etc.). Diskette failures that trigger manual screening cost the Agency more than $1500 per SDG, even if there are no problems with the analytical data being reported. The lab incurs additional expenses in resubmitting the diskette, too.

RETURN ON INVESTMENT (ROI)

Consider a lab's investment in software to pre-screen Organic SOW diskettes using CCS software checks. The software performs the same screening function as the Agency's software, and can help the lab identify and fix problems before they are reported. A few thousand dollars invested could save many thousands in late fees, liquidated damages, reduced value, etc. Assume $2,000 expenses for software in the first year of a three-year analytical services contract. If the software check prevents 2 SDGs from being manually screened by the CLASS and the Regional customer, this is a savings of about $3000 that could have been charged to the lab for liquidated damages and reduced payments. The present value of saving $3000 each year of the contract, assuming a 15% cost of capital to the lab, is $6849, giving a Net Present Value (determined from statistical tables) of $4849 for the ROI in the software. (This calculation doesn't account for the cost of training lab staff in its use, and possible software licensing fees. It also doesn't account for the extra costs to the lab of reprocessing the diskettes of the failed SDGs, and the loss of client goodwill.)

COST/BENEFIT COMPARISON

Another simple example compares the difference in quality costs and performance for individual labs. Two labs may each receive the same number of samples and SDGs, but a lab with problems will have a higher cost of quality than one without. It is spending more money to correct failures than to detect and prevent them.

IMPLEMENTATION OF A QUALITY COST PILOT PROGRAM

Economic benefits of CoQ are usually reported in terms of productivity gains, improved product quality, reduced cycle time, total cost and effort savings, or return on investment. Managers want to know that money spent on better practices will yield good returns, and they want to see numbers that show a positive impact on the bottom line. Convincing management of the value of tracking CoQ is often the first hurdle. The main purpose of the initial CoQ effort is to show the opportunity for cost savings. Juran and Gryna (1980) suggest that the following relationships have the greatest impact on management:

- Quality costs as a percent of sales
- Quality costs compared to profit
- Quality costs compared to the magnitude of the current problem

Campanella (1999) says "The real value of a quality program is determined by its ability to contribute to customer satisfaction and to profits." The payoff, or monetary gain, to a company in seeking better customer satisfaction is Gain in Contribution Margin: Cash flow from the incremental gains in revenue due to additional repeat sales from more satisfied customers, less the costs of those sales. For most organizations, the principal investment in the entire quality cost program is the expense of the quality cost collection system.

The strategy for using quality costs is simple: (1) attack failure costs in an attempt to drive them to zero; (2) invest in the "right" prevention activities to bring about improvement; (3) reduce appraisal costs according to results achieved; (4) continuously evaluate and redirect prevention efforts to gain further improvement. If the basic quality measurement system of a company cannot provide the identification of defects or problems to which quality costs can be attached, the first corrective action required is to establish a system that does. If failure costs are collected in a defect-tracking system, the most expensive defects can be identified for root-cause analysis. This strategy is based on the premise that

- For each failure there is a root cause.
- Causes are preventable.
- Prevention is always cheaper.

All department representatives should be encouraged to make program suggestions from their expert viewpoints. Ask them to prepare a list of those tasks or functions performed by their departments that can be considered quality costs—work that would not have to be performed if quality were and always would be perfect.

Steps in an effective implementation of a Cost of Quality program are (Houston, 1999):

1. Obtain management support for a CoQ assessment.
2. Select those parts of the organization to be assessed.
3. Establish an assessment team from work groups, management, and accounting.
4. Define the various CoQ components within each of the categories.
5. Collect data on each CoQ component for a given time period and convert into $.
6. Compare with a base (e.g., total sales, cost of services sold).
7. Analyze the CoQ cost components into drivers, symptoms, and root causes.
8. Determine the investment and impact to eliminate root causes of poor quality.
9. Do a cost/benefit analysis.
10. Present to management the anticipated improvements in product or service quality, the associated savings, the required investment, and the time period for realization.
11. With approval, select and train the improvement team, develop an action plan, and implement the improvements.
12. Continually assess progress of the improvement projects and continually monitor and report Quality Costs.

CONCLUSION

Investment in a Cost of Quality program will produce lower overall costs for the Agency and its suppliers. By focusing management attention on the costs of failure and appraisal, root causes of problems will be identified, corrected, and ultimately prevented. The Agency and the public benefit from improved performance and cost savings, completing scheduled work on time and within budget. Laboratories receive more revenue with less costs, and can demonstrate improved quality leads to higher profits. They perform more efficiently, allowing them to perform additional analyses and maintain customer satisfaction. There are clear advantages for the Agency to work with the laboratories to apply the Cost of Quality principles.

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Efficient QA Through Consolidated Metrology

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EPA order 5360.1 requires that all environmental data be of known quality. When obtaining environmental measurement data, "known quality" requires calibrations of the instruments obtaining such data to be of known quality, usually traceable to an accepted standard. Using "factory" calibrations usually requires returning the device to the manufacturer, which necessarily means taking it out of the system. The device is then tested in the "factory" setting, which may not be the same setting as the researcher will be collecting data with it. To obtain on-site calibrations can be extremely costly. Performing your own calibrations requires the researchers to train someone to do the calibrations and to obtain the required calibration instruments and standards. What this all can boil down to is excessive time and resources spent on calibrating instruments when compared to the amount of usage the instruments receive. APPCD researchers recognized this and consolidated their funds to enable a metrology laboratory to support APPCD's calibration needs.

The following presentation shows the cost savings associated with operation of the metrology laboratory; additionally, the improved data quality, record keeping and measurement system improvements have contributed to enhancing many projects. Many of these improvements are documented in this paper and shown to be effective both from the Q/A prospective and the researcher's point of view.

QUALITY ASSURANCE REVIEWS AT THE ORD, NHEERL, MID-CONTINENT ECOLOGY DIVISION

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EPA policy requires that each Research Project be documented in a Research Plan and associated Quality Assurance Project Plan (QAPP). This is then implemented by the research team. The Division Quality Assurance Program is then tasked to assess the implementation of the QAPP. This assessment is accomplished through the review process, its implementation at MED will be explained.

Principal Division Research Tasks are targeted for review on a three year rotation. Under this plan these tasks should be assessed at the beginning and again just before the research has ended. Thus, the review is to assist the team in understanding the requirements of the Quality Assurance Program before the project becomes too involved and again to document that the Quality Assurance/Quality Control procedures as explained in the QAPP were followed.

Materials available at this presentation will provide the participants with a format for interactive, user friendly, documentation of a Research Work Plan, Quality Assurance Project Plan, Health and Safety Plan, and Animal Control and Use Plan,available on Wordperfect Disk at the presentation) as well as a simple format for the basic questions asked in most QA Reviews (see following). The specific detail of the review is based on the Research Plan and the Quality Assurance Project Plan. This detail is added to this form by the interview team following their review of the Work Plan and QAPP prior to the scheduled interview with the research team.

STANDARD NHEERL/MED QA INTERVIEW

TEAM LEADER/PRINCIPAL LEAD:

AUDIT FOCUS:

AUDIT TEAM MEMBERS:

DATE OF AUDIT:

PERSONNEL INTERVIEWED:

NAME	POSITION

OPERATIONAL AREAS THAT WERE OBSERVED:

	Laboratory Facilities and Equipment		Internal QA/QC procedures
	Methods and QA documentation		Review of QA/QC or Performance Evaluation Data
	Sample Receipt and Storage		Data Management Capability
	Sample Compositing and Sorting		Data Entry and Review Operations
	Sample Identification and Enumeration		Data Verification and Validation Activities
	Sample Tracking within Laboratory, between Agency and Contractor		Data Base Documentation, Reporting and Transfer Activities

STANDARD NHEERL/MED QA INTERVIEW QUESTIONS

Based on general Environmental Protection Agency requirements as described in EPA QA/R-2 and specific requirements described in the Research Projects - Quality Assurance Project Plan (QAPP)

ITEM	QUESTION	RESPONSE
PLANNING DOCUMENTS AND BACKGROUND		
1	Is there a written and approved protocol. research plan, or workplan for this study? If yes, how is it identified and has the most Current version been distributed to key study personnel? If there is not one, briefly describe how/where the study plan is documented.	
2	Describe the internal process (team/branch) for preparation. review, and approval of Research Plan or other similar document (QAPP).	
3	Are there deviations from/to the QAPP? What are they? How are they noted?	
4	Are written and approved standard operating procedures (SOPs) used in this study? If yes, list below and note whether they have been distributed to key study personnel and are available to all users in this study. If not, briefly describe how/where study procedures are documented.	
5	List known SOPs here: List tentative/planned SOPs here:	
6	Are there additional planning documents (Agency Guidance/Intraagency Agreement)for this study? If yes, list below and note whether each has been distributed to key study personnel.	
7	How are the QA resources set and allocated for your team? Who has input and what is included? What is the current resource level ($, FTE) and is this adequate to meet your QA needs?	

8	How is the fulfillment of existing Agency, NHEERL, and MED QA requirements confirmed? Describe QA processes within the team (e.g. planning, experimental design, data review, documentation) and external to the team (e.g. research plan approval, peer reviews, audits).	
9	What portion of your project is subject to the Agency QA mandate (5360.1 CHG 1., 07/16/98) regarding environmental data/programs? What are Agency's requirements for these studies? Are there additional QA requirements?	
QUALITY OBJECTIVES AND PERFORMANCE CRITERIA		
10	Identify the clients for the research with which you are involved. How are their needs addressed in the research planning process?	
11	Briefly describe the intramural research planning process and your role in it.	
12	Is the anticipated use of the data known and documented?	
13	Have study quality objectives, consistent with anticipated data use, been established and documented?	
14	Have performance criteria for measurement data (e.g., detection limits, precision, bias) been established and documented?	
15	Are there established procedures for assessing whether quality objectives and measurement data criteria have been met? If yes, briefly describe. Are these assessments documented?	
16	Are QC analysis being performed at required frequencies and within acceptance criteria stated in the QAPP? Are QC responsibilities and reporting relationships clearly defined? Does the lab maintain a QC manual? Are all QC data up-to-date and accessible? Is there a mechanism in place to analyze QC data for trends?	
STUDY ORGANIZATION AND PERSONNEL		

17	Describe the organizational structure of your project. Who on your team is responsible for quality assurance duties? What portion of their time is devoted to QA? What are their principal responsibilities with respect to: - research planning? - project monitoring? - project management or oversight?	
18	Do all of the principals on your team have in their performance agreement an "environmental data quality" statement as directed by the EPA Senior Leadership Council in FY 96? (Probably as part of a research standard).	
19	What are the primary QA related duties and responsibilities of the individual team members and how are these communicated to them and to others? Does each team member regularly attend team meetings? Is QA a discussed topic at these meetings or are additional meetings held to address QA issues? How are these discussions documented and related to the rest of the team?	
20	What are the primary research tasks, both intramural and extramural, in your team? How are these research tasks documented? How are these tasks allocated among team members?	
21	Are there standard forms for use in this study? If yes, list below and note whether these are available to all anticipated users. -	
22	Does the team have ready access to a copy of the current approved Quality Assurance Project Plan as well as MED's Quality Management Plan? Where are they kept? Are you familiar with both?	
23	Are there any extramural projects involved in this research? How are QA/QC issues addressed in planning the extramural studies? How is extramural QA compliance monitored? If contracted: How do you ensure that EPA is directing the research activities (i.e. control against contractor performance of inherently government function) without violating rules against personal services?	

24	How and by whom are your studies identified for QA reviews and audits? What is the frequency of these reviews?	
25	ORD employs a hierarchical QA approach which reflects the intended use of the data and the type of work being done. To what Category (I-IV) does your project belong? How does this affect your team QA requirements?	
26	How do you measure the overall success of your QAPP and the success of individual components, and how is this information communicated to Laboratory or Division management?	
	TRAINING REQUIREMENTS	
27	How does your team identify training needs?	
28	Is needed training provided? How?	
29	How are training records maintained?	
	FACILITIES EQUIPMENT AND SUPPLIES	
30	List below any key facilities used in the study (e.g., research laboratories, analytical support laboratories, exposure facilities, animal care facilities), identify the location of each, and briefly describe the major activities performed in support of the study. Indicate whether each facility is adequate. If not, briefly describe areas where improvements may be desirable or necessary. -	
31	List below key instruments or equipment used in the study. As appropriate for each instrument listed, indicate whether routine maintenance and calibration or calibrations checks are conducted. If yes, specify: -- frequency of routine maintenance -- frequency and range of routine calibrations or Calibration checks -- type of calibration standards/devices used -- persons or organizations responsible for performing routine maintenance and calibrations/calibration checks -- if procedures are documented in SOPs -- if maintenance and calibration logs are kept. -	

32	Is acceptance inspection or testing performed on any of the instruments or equipment listed above? If yes, list each instrument below and briefly describe inspection or testing procedures and associated acceptance criteria.	
33	Is acceptance inspection or testing performed on any supplies and consumables used in this study? If yes, list each supply/consumable below and briefly describe inspection or testing procedures and associated acceptance criteria.	
TEST SYSTEMS AND QUALITY ASSESSMENT		
34	What types of planning documents are used to address QA issues and who prepares these documents?	
35	What types of QA assessments are performed to evaluate adherence of intramural studies to approved plans, by whom are these assessments conducted and to whom are the observations reported?	
36	Does your team have an acceptance program for critical research supplies and services?	
37	What is the role of the Division QA Manager in dealing with this research?	
38	Have you been able to use the DQO process to your perceivable advantage?	
RECORD KEEPING AND DATA MANAGEMENT		
39	Are floppy disks, logbooks, and notebooks identified with the study/protocol number?	
40	Are there procedures to ensure the security of hand recorded and electronic data?	
41	What sort of document control process does your team use to help manage plans, logbooks, forms, records, QA guidelines, SOPs and software?	
42	What quality and security measures are taken to ensure the defensibility of data resident on network and stand-alone computers?	
43	Are provisions made for storage of both raw and reduced data?	
44	Are duplicate sets of electronic and hard copy data being stored?	
45	How do you identify and communicate the quality of the data?	
46	Are data calculations double checked by a second staff member?	
47	Is the data review and approval process documented and available?	

48	Is there an index list of all data, records, samples and specimens to be maintained for this study?	
49	Are all study records (e.g., floppy disks, log books, notebooks, instrument outputs, samples/specimens, correspondence) clearly cross-referenced (e.g., by protocol number, date, experiment number)? If yes, briefly describe	
50	Is there an individual responsible for compiling all study data and reporting to the principal investigator?	
51	Are study records maintained in a central file?	
52	Are standard forms listed above used to record and/or compile data?	
53	Are hand-written records recorded in numbered or otherwise uniquely identified notebooks or binders which are assigned to individual staff members?	
54	Are the initials of each person using a notebook or binder listed in the front?	
55	Is dark permanent ink used and are corrections made with a strikeover and initialed?	
56	Are there procedures for routine verification of the data collection and management activities listed below? If yes, briefly describe and note whether verifications are documented in study records.	
57	Are data reduction and analysis procedures clearly documented?	
58	Have data reduction and analysis procedures been validated? If yes, briefly describe. Is this documented?	
59	Are all data files and samples named according to a standard convention? If yes, briefly describe.	
60	Are all data records identified with a test/sample ID number and a protocol or study number?	
61	How do you ensure that specialized computer software is developed and documented in accordance with specifications or approved procedures, and that it performs as required?	

Modeling Quality Assurance Plan for the Lake Michigan Mass Balance Project

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SUMMARY

A quality assurance plan has been developed for all modeling aspects of the Lake Michigan Mass Balance Project (LMMBP). This has been a difficult, but the successful undertaking of a complex, multi-media project involving multiple organizations, investigators, and models is better ensured when concepts in these plans are implemented.

INTRODUCTION

With the ever increasing complexity and costs of environmental, ecosystem protection and remediation, the USEPA is placing more emphasis on ensuring the quality and credibility of scientific tools, such a models, that are used to help guide decision-makers who are faced with difficult management choices in these areas. The Agency has issued several documents covering broad requirements of the development and use of mathematical models and these are used in the formulation of the Modeling Quality Assurance Plan (MQAP) for the Lake Michigan Mass Balance Project (LMMBP). This is a stand alone document, separate from, but related to the LMMBP Quality Assurance Project Plan (QAPP). Because guidance for modeling QAPs is new and somewhat limited, the LMMBP MQAP could be viewed as a prototype particularly for projects that involve holistic, multi-media modeling approaches for large systems like the Great Lakes.

The LMMBP models include hydrodynamics, sediment transport, eutrophication, chemical transport and fate, and food chain bioaccumulation. In addition, the MQAP report (Richardson 1999) includes the quality assurance (QA) process for the development of atmospheric models used to describe the emission of the current-use herbicide, atrazine, from the agricultural lands in the U.S. and its transport and deposition to the lake. It also includes the quality assurance process for the estimation of tributary and atmospheric depositional loads for measured atrazine, as well as persistent, bioaccumulative chemicals including polychlorinated biphenyls (PCBs), trans-nonachlor (TNC), and mercury.

This plan does not cover the quality assurance process for field collection and laboratory analyses. These topics are covered in the LMMBP QAPP (USEPA, 1997a,b,c,d,e,f).

THE LAKE MICHIGAN MASS BALANCE PROJECT OVERVIEW

The LMMBP was initiated by the USEPA, Great Lakes National Program Office (GLNPO) in cooperation with the USEPA, Office of Research and Development (ORD) and other federal and state agencies. The project was initiated in response to regulatory mandates contained in the

Great Lakes Water Quality Agreement (GLWQA) between the United States and Canada and federal legislation that requires the development of "Remedial Action Plans" (RAPs) and "Lakewide Management Plans" (LaMPs). The purpose of the LaMPs is to restore and maintain the chemical, physical, and biological integrity of the waters of the Great Lakes Basin ecosystem. The USEPA also intends that the LaMP process serve as the basis for the development of State Water Quality Management Plans. This project also has implications and applications to the Great Lakes Binational Toxics Strategy (Virtual Elimination Strategy) and the Great Waters Program.

The primary goal of the LMMBP is to develop a sound scientific base of information to guide future toxic load reduction efforts at the federal, state, tribal, and local levels. Objectives include: (1) determination of relative loading rates of critical pollutants from major sources to the Lake Michigan Basin; (2) evaluation of relative loading rates by media (tributaries, atmospheric deposition, contaminated sediments) to establish a baseline loading estimate to gauge future progress and load reductions; (3) development of the predictive ability to determine magnitude of chemical concentration reductions in water, sediment, and biota due to specific load reduction scenarios and the time to realize those reductions; and (4) improving the understanding of key environmental processes which govern the cycling, dynamics, and availability of contaminants within relatively closed ecosystems.

BASIC MODELING CONCEPTS

As this paper is intended for a non-modeling audience, a few basic modeling concepts will be presented. All models of natural systems whether for air, water, groundwater, or sediment are based on one or more of the thermodynamic principles of the conservation of mass, momentum, and energy. Air and water transport models usually include all three. Mass balance models include conservation of mass with implied inclusion of the other two. Bioaccumulation models are usually based on mass conservation principles but if population dynamics are modeled, then energy conservation is included. In general for any media the modeling equations are solved to produce computed concentrations in space and time, which are functions of the sum of mass inputs, outputs, and transformations occurring in each model segment:

$$C(t,x,y,z) = f(\sum Mass_{in} - \sum Mass_{out} \pm \sum Mass_{reactions}) \qquad (1)$$

Figure 1 illustrates hypothetical model output as a function of time. The computed chemical concentration for a point (or spatial segment) in space is represented by the solid line. Field data representing that point in space and time are represented by the box with error bars. The error bars represent the data variance due to collection and analytical laboratory variability and any spatial and temporal averaging. Model credibility is determined in part by the ability to calibrate computed model concentrations to a set of measurements in time and space. Ultimately model validity can only be determined by comparing predicted concentrations to a set of measurements taken independent of calibration and under different environmental or loading conditions. When a model is deemed acceptable then it can be used to extrapolate concentrations in time and space. Also, a model can be used to determine the relationship between loading reductions and concentrations, at various times following the load reduction (Figure 2). As the last example of

mass balance utility, the model can be used to construct the mass budget of a system at any point in time (Figure 3). The mass budget quantifies the chemical-specific inputs, outputs, and transformations computed in the model, either for the entire system or for specific spatial segments of interest.

Figure 1. Hypothetical Model Computation (concentration vs. time at point x,y,z)

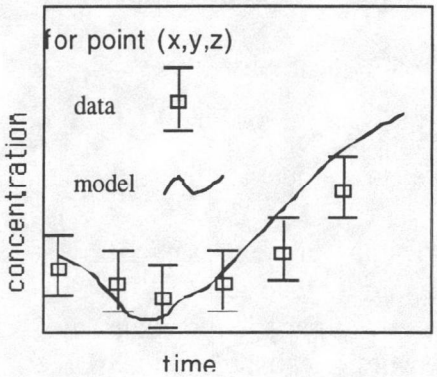


Figure 2. Hypothetical Load-Concentration Relationship at any time, t.

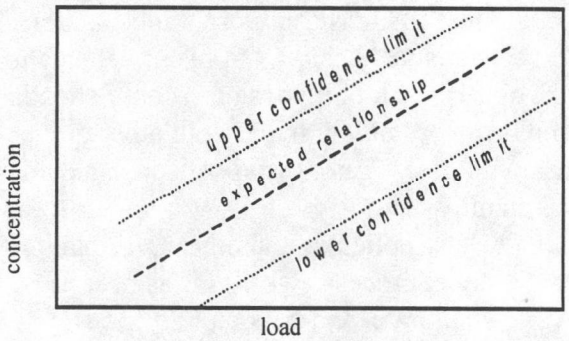
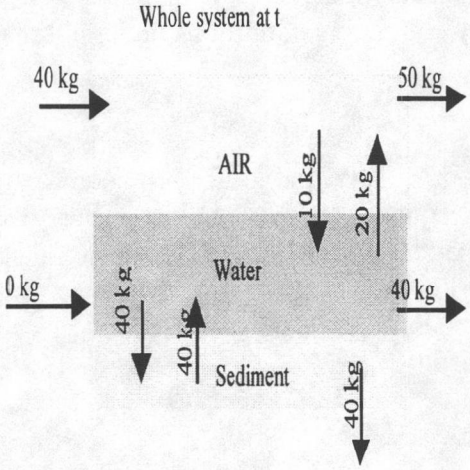


Figure 3. Hypothetical Mass Budget for whole system at time t.



GENERAL MODEL DATA REQUIREMENTS

In general models require three types of data: (1) input and (2) calibration, and (3) validation. Input data include such items as loads, initial conditions, boundary conditions, and process rates. Calibration data include chemical concentrations at strategic points in space and time. Validation data are obtained for the system under different loading and environmental conditions. Data collected to satisfy model requirements are usually better than "data of opportunity" collected for some other purpose. Synoptic (contemporaneous) information is also desirable and possibly necessary. In other words, data collected in the lake (or whatever media is of concern) should be collected during the same period as the loads and boundary conditions. It is also essential that modelers be directly involved with the designation of Data Quality Objectives (DQOs) and the design of the data collection program including the specification of data acceptance criteria, sampling locations and times, and frequency of sampling. This was the case for LMMBP.

MODELING APPROACH

A general approach to the multi-media modeling processes has evolved from modeling the Great Lakes that may be useful as guidance for others. The basic premise is to start with the problem and specific management questions and fit the model specifications to the problem. Otherwise a

wrong or inadequate model with no chance of really helping with the decision making process might be developed. This approach includes the following steps:

1) Determine specific management questions for the problems being addressed.
2) Define the appropriate modeling framework needed to address these questions.
3) Propose alternative modeling/project designs for management review to narrow the range of expectations and costs.
4) Using historical data and available computer programs, construct a preliminary screening model to test the sensitivity of various model components.
5) Perform statistical analyses of historical data to determine optimal sampling designs.
6) Make specific sampling design recommendations.
7) Maintain a continuing dialog with other groups involved with the project.
8) Work with investigators who collected and analyzed samples to conduct a joint "data quality assessment."
9) Evaluate data replicates and other QA notations to determine appropriate uses of data.
10) Update model process algorithms as necessary according to current theories.
11) Develop, calibrate, and validate the models. Testing includes comparison of calculated concentrations to field data and adjusting model parameters within realistic and justifiable ranges to obtain a model fit that satisfies the statistical criteria established in the MQAP. Ideally, models are confirmed by comparing predictions to results. However, this may not be able to be done until after decisions are made and implemented and is the primary reason that model uncertainty be defined.
12) Conduct uncertainty analysis to estimate reliability of predictions.
13) Provide answers to specific management questions by simulating conditions under alternative load management scenarios.
14) Document models and results.

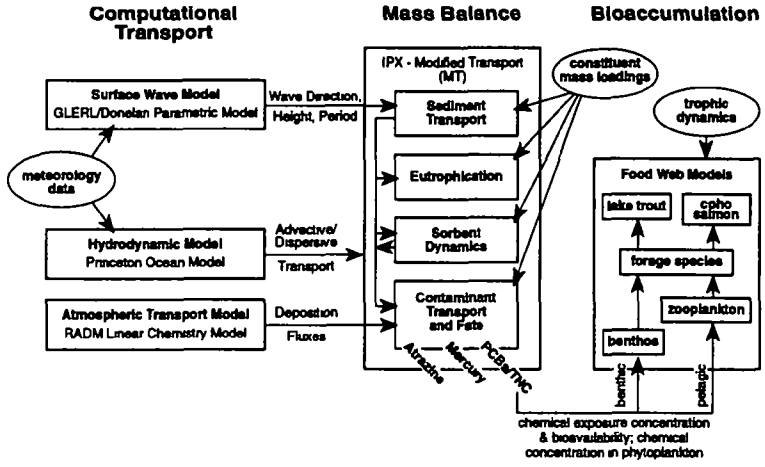
One important aspect of this approach is the use of a screening-level model for project design. This task may take a year or longer to complete and may require its own MQAP and review process. Sometimes the screening level model may be used for certain aspect of decision making before the project model is developed and applied. Model integrity can be improved by implementing screening models for various space/time scales and by using alternative approaches and computer programs and comparing the results.

LMMBP MODELING FRAMEWORK

The modeling framework for the LMMBP that resulted from the design process is shown in Figure 4. This framework is being applied to Lake Michigan at three levels of spatial resolution. The greater the level of spatial resolution, the more effort in terms of computational power/time and effort and time spent in calibration. Greater resolution can also mean more state variables and/or more complex process descriptions. A more resolute model can simulate the ecosystem in greater detail, but if the resolution is not properly constrained by observations, then the resulting model can be less reliable than a simpler model. The question that always arises is, "What is the optimal resolution?" Modelers and managers must reach some agreement about this. Usually, this is done by estimating the resources needed at different levels of effort along with the estimate of model uncertainty at each level.

Figure 4.

Lake Michigan Modeling Framework



GUIDANCE FOR PREPARING THE LAKE MICHIGAN MQAP

The mandate to prepare a MQAP for LMMBP was given to the LMMBP modeling workgroup from GLNPO management. The project was already well underway and GLNPO was undergoing a QA audit from which the mandate for the MQAP originated. At that time, project planning documents began to be formulated using some general guidance that was available (USEPA 1991, SUNY 1993, USEPA 1994, USEPA 1995, ASTM 1992). The most specific guidance was provided in the "Quality Assurance Guidelines for Modeling Development and Application Projects: A Policy Statement" (USEPA 1991). This policy applied primarily to development and application of relatively simple modeling projects, unlike the LMMBP involving numerous, linked multi-media models. This was used as a basis and included additional items provided by the other documents and by our own experience and history in developing and applying Great Lakes models over the past 28 years. Essential factors of a good modeling project include:

1) Qualified personnel including education, training, experience, expertise, integrity, and publication record.
2) Infrastructure, including laboratories and offices, computers, software tools, supporting administrative staff and progressive and supportive management.
3) Adequate extramural research budgets for acquisition of expertise beyond that of the in-house research staff.
4) The administrative means to include extramural researchers and contractors via cooperative agreements and contracts including the ability to build coordinated teams and partnerships directed at answering relevant scientific and management questions.
5) Interaction within the scientific and engineering communities at scientific meetings and workshops and through publication in journals to ensure the utility of most currently accepted scientific theory.
6) Professional engineering judgement.
7) Computer programming support to implement the theory into computer code.
8) Verification of computer code and calculations.
9) Evaluating and reporting uncertainties of calculations and stating assumptions, qualifications, and caveats which could affect research application to regulatory problem-solving.
10) Peer review of research including theoretical construct, computational methodology, appropriateness of application, assumptions, and interpretations.
11) Common sense and hard work.

LMMBP-MQAP FORMAT

Lacking any other guidance for actually preparing a written report, ORD's Handbook for Preparing Office of Research and Development Reports was used (USEPA 1995). The report evolved after several drafts into three main chapters with five appendices. Chapter 1, Introduction, presents information related to the mandate for preparing the MQAP, general considerations for modeling quality assurance, and background and history of the primary air and water modeling programs in EPA and NOAA.

Chapter 2 follows the Duluth policy outline (USEPA 1991), with some additions, and presents "common quality assurance topics as applied to all project models." Topics such as project description, quality objectives and acceptance criteria, products, and timetable, project personnel, and support facilities, general modeling approach, and data quality, peer review reduce redundancy in presenting information for individual models in Chapter 3.

Chapter 3 focuses on the individual models and each section was prepared by the principal modeler(s). These follow the Duluth policy guidance (USEPA 1991). Each model framework is described along with specific procedures for model calibration, uncertainty analysis, etc.

The appendices include: A) The original "Lake Michigan Mass Balance Project Modeling Work Plan" (USEPA 1995a); B) The LMMBP Modeler's Curriculum Vitae; C) description of the "Revision Code System" used by modelers in tracking versions of computer code; D) Project Approvals and E) Model Development and Progress. As the project evolves, modifications to the models will be included as either further appendices or as addenda rather than modifying the body of the report.

QUALITY CONTROL

The primary objective of QC for modeling is to make sure that the modeling theory is implemented correctly by the computer program. To accomplish this in practical ways, a list of requirements was developed and agreed to:

1) All modeling activities including data interpretation, load calculations or other related computational activities are subject to audit and/or peer review, so careful written and electronic records should be kept for all aspects of model development and application.
2) Written rationale will be provided for selection of models or versions of models like WASP4 or WASP-IPX, SEDZL, etc.
3) As modeling computer programs are modified, the code will be checked and a written record made as to how the code is known to work (i.e., hand calculation checks, checks against other models, etc.). This should include input and output, if appropriate, or results of external calculations used to confirm code.
4) If historical data are used, a written record on where this was obtained and any information on its quality will be maintained. A written record on where this information is located on a computer or server will be maintained.
5) If new theory is incorporated into the model framework, references for the theory and how it is implemented in any computer code will be documented.

6) All new and modified computer codes will be documented. This should include internal documentation, as revision notes in program headers, and external documentation, in user's guides and supplements.

Audits of each modeler's work will be conducted periodically by the Agency QA auditing team, the project QA officer, MED-Duluth QA officer or one or more of their designees

PEER REVIEW

The Agency has provided very clear guidance for peer review of modeling projects that are involved with regulatory decision making (USEPA 1994). Since the LMMBP will be used in the LaMP process and perhaps in establishing "total maximum daily loads" (TMDL), it was determined that the modeling activities should undergo an ongoing peer review process. A group of scientists and engineers were invited to become members of a "Science Review Panel" (SRP) and to participate in a series of reviews. It was thought that involving the SRP throughout the modeling process would result in a better product and would provide time to resolve problems in contrast to a peer review at the end of the project. The first review was held in June 1998. As a result of the review the SRP submitted a review report including a list of questions and concerns. Each of these was addressed by the modeling workgroup in a response report. It is expected that the SRP will meet at least once per year until the end of the project.

CONCLUSIONS

In the final analysis, the quality of the work and the reliability and credibility of the models will be enhanced by the preparation and implementation of the MQAP. But most importantly, the quality of the modeling work is determined primarily by the desire and integrity of the project personnel. History has shown the mathematical models of Great Lakes water quality have been reliable in predicting future events in making regulatory and remedial decisions, and have contributed to the success of these efforts. The Lake Michigan modeling efforts build on this long history of model development by the ORD's Great Lakes Modeling Program at Grosse Ile, Michigan; the Modeling Program at Research Triangle Park, North Carolina; the experience of the National Oceanic and Atmospheric Administration (NOAA) Great Lakes hydrodynamic modeling program at the Great Lakes Environmental Research Laboratory (GLERL) in Ann Arbor, Michigan; the Modeling Program of the U.S. Army Corps of Engineers at Waterways Experiment Station, Vicksburg, Mississippi; and several other federal, private, and academic organizations. Hopefully, the MQAP fulfills the requirements of Agency QA managers and will contribute to the overall success of the project.

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B. Michael Ray and Brenda T. Culpepper
U.S. EPA, NHEERL, Research Triangle Park

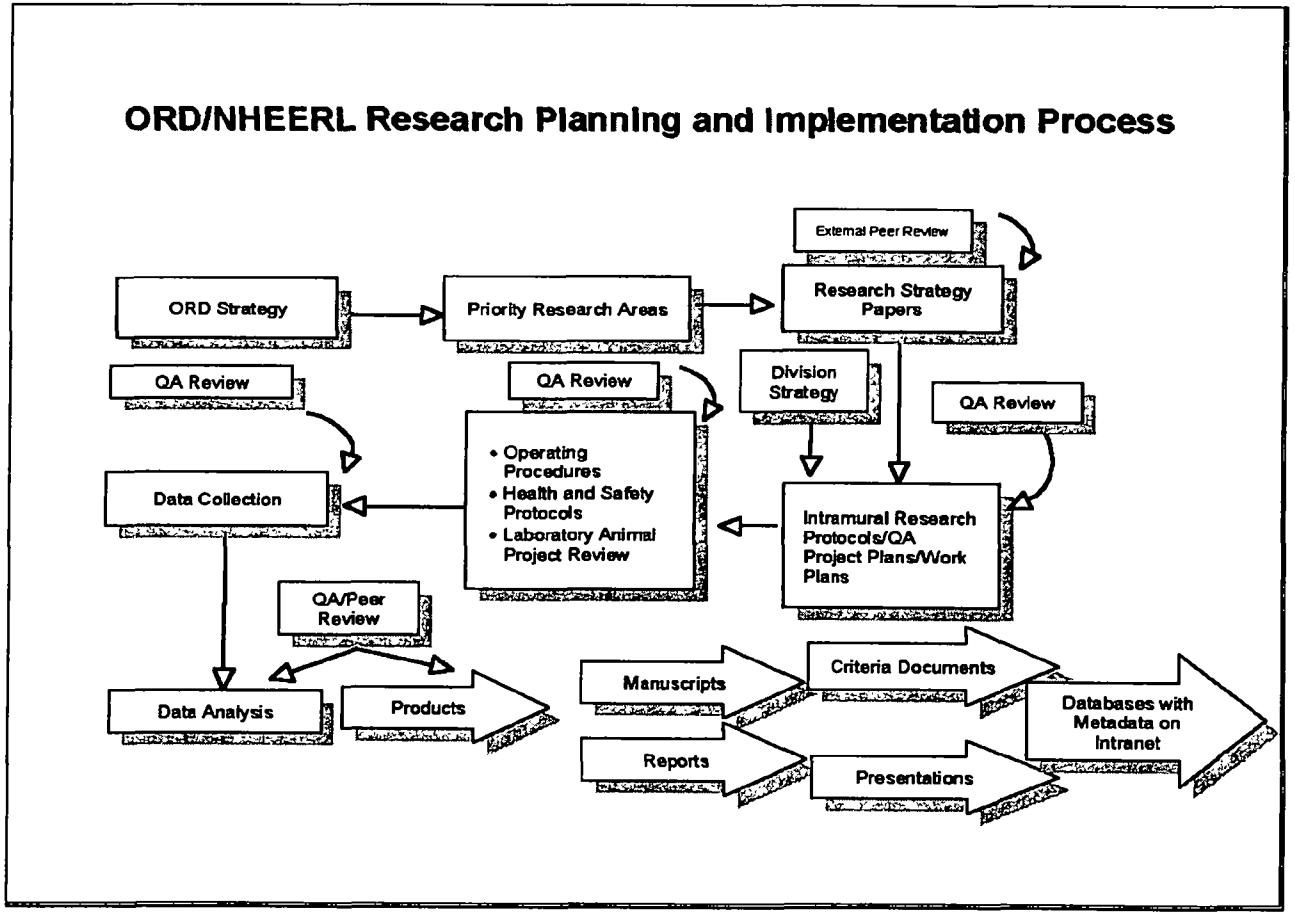
NHEERL APPROACH TO TECHNICAL SYSTEMS REVIEWS OF HEALTH EFFECTS STUDIES

Mike Ray and Brenda Culpepper

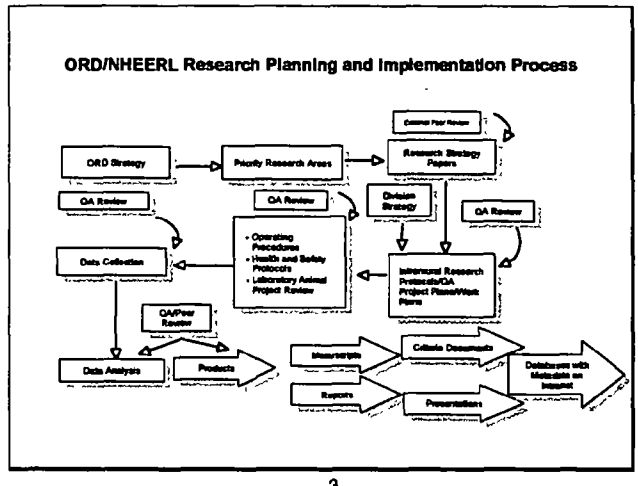
TSR Requirement

Agency mandate requires NHEERL to establish a Quality Management System designed to assure the quality and defensibility of all our environmental data. Integral to that System are elements that address the planning, implementation, and *assessment* of the research efforts that generate NHEERL's environmental data.

TSP THE ORD/NHEERL RESEARCH PROCESS



TSH IN THE ORD/NHEERL RESEARCH PROCESS



TSH Objectives

- Assess whether a group is likely to achieve results of sufficient quality to meet the stated objectives of a task or project
- Improve the understanding of the need to ensure the defensibility and reconstructibility of data

TSR Awareness Training

- Mandatory TSR Training
- 277 Scientists Attended 22 Training Sessions

Types of Studies and Facilities Reviewed

- Extramural and Intramural Epidemiology Field Studies
- Human and Animal Controlled-Exposure Studies
- Pathology Studies
- Bioassays
- GIS Modeling Studies
- GLP-Mandated Study

TSR PROCESS OVERVIEW

- Who's Involved?
  - Principal Investigator and Support Staff
  - NHEERL-RTP QA Staff
    - One primary QA reviewer
    - One primary technical reviewer
    - Branch Chief and/or Project Officer
- Frequency of TSRs
  - All Category I and II Studies — At Least Once
  - 10% of All Research Studies Annually

TSR PROCESS OVERVIEW

- Selection of Studies
  - Requests on the QA Review Form
  - Requests by Line Managers
  - Requests by QA Staff
- Use of Checklist

TSR CHECKLIST

Corel WordPerfect - C:\QADOCS\TSR-qapres OVR.wpd

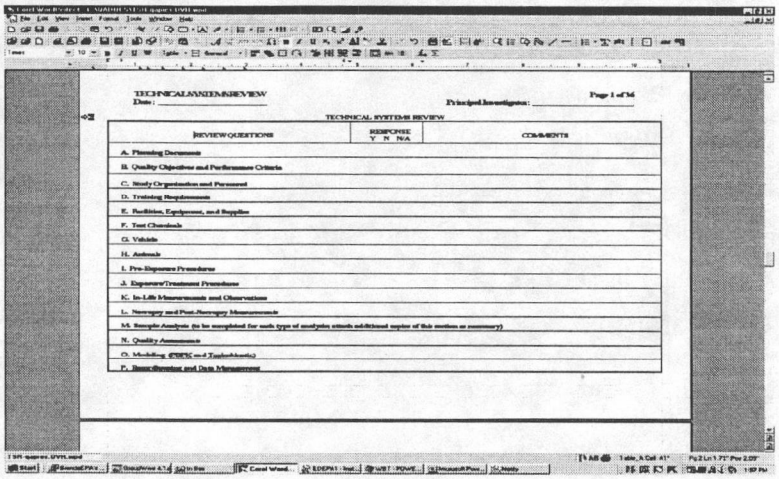
TECHNICAL SYSTEMS REVIEW
Date: _____

Principal Investigator: _____

TECHNICAL SYSTEMS REVIEW

REVIEW QUESTIONS	RESPONSE Y N N/A	COMMENTS
A. Planning Documents		
B. Quality Objectives and Performance Criteria		
C. Study Organization and Personnel		
D. Training Requirements		
E. Facilities, Equipment, and Supplies		
F. Test Chemicals		
G. Vehicle		
H. Animals		
I. Pre-Exposure Procedures		
J. Exposure/Treatment Procedures		
K. In-Life Measurements and Observations		
L. Necropsy and Post-Necropsy Measurements		
M. Sample Analysis (to be completed for each type of analysis; attach additional copies of this section as necessary)		
N. Quality Assessments		
O. Modeling (PBPK and Toxicokinetic)		
P. Recordkeeping and Data Management		

TSR CHECKLIST



TECHNICAL SYSTEMS REVIEW

REVIEW QUESTIONS	RESPONSE Y N NA	COMMENTS
A. Planning Documents		
B. Quality Objectives and Performance Criteria		
C. Study Organization and Personnel		
D. Training Requirements		
E. Facilities, Equipment, and Supplies		
F. Test Chemicals		
G. Vehicles		
H. Animals		
I. Pre-Exposure Procedures		
J. Exposure/Treatment Procedures		
K. In-Life Measurements and Observations		
L. Necropsy and Post-Necropsy Measurements		
M. Sample Analysis (to be completed for each type of analysis attach additional copies of this section as necessary)		
N. Quality Assurance		
O. Modeling (QSPR and Toxicokinetics)		
P. Data Reduction and Data Management		

Customize Checklist

- Based on the Following
  - IRP
  - QAPP
  - OP
  - Data Management Plan

CHECKLIST QUESTIONS FOR EPIDEMIOLOGY STUDIES

- Consent Forms
- Questionnaires
- Coded Data Entry
- Physiological Testing
- Blood, Urine, and Stool Samples
- Migration of Data
- Data Archival

CHECKLIST QUESTIONS FOR INHALATION STUDIES

- Test Atmosphere Generation
  - Aerosol vs. Gas vs. Particulate Matter
- Test Atmosphere Analysis
  - Safety and Quality Issue
- Medical Surveillance
  - Physical Exam
- Physiological Data Acquisition
  - Pulmonary Function Testing, Heart Rate Variability
- Environmental Conditions
  - Temperature, Humidity, pH, Sound Level

CHECKLIST QUESTIONS FOR PATHOLOGY

- Tissue Extraction, Preservation, Staining Techniques
- Labeling of Slides and Blocks
- Blind-Reading of Slides by Pathologist
- Use of Independent Pathologist when Warranted
- Archival of Slides and Blocks
- Incorporation of Pathology Findings in Study Report

CHECKLIST QUESTIONS FOR GIS MODELING STUDIES

- Secondary Data
  - Birth Certificates
    - Number of Full-Term Live Births and Premature Live Births
    - Birth Weights
    - Mothers' Residences
  - City Water Districts Information
    - Water Treatment
    - Extent of Piping Network
    - Water Analysis

CHECKLIST QUESTIONS FOR GIS MODELING STUDIES

- Validation of GIS Software
  - Modeling Results vs. Hydraulic Measurements
  - Modeling Results vs. Water Analysis

TANGIBLE BENEFITS OF TSRs

- Additional Field Staff Provided for an EPI study
- Additional Funding Provided for Vital Records Archival
- Backup Power to Sample Freezer
- Improved Storage and Chain-of-Custody for Test Substance
- Improved Extraction Methods for Air Sample Filters
- Support for Contract Negotiations

ANYTHING CAN HAPPEN DURING A FIELD STUDY!

- Robbery at Gun Point
- Unexpected Exposure to Nudity
- GI Distress—Green vs. Red
- Long Hours
- Delightful Test Subjects
- Nifty Thrifty

USING FIELD METHODS - EXPERIENCES AND LESSONS: DEFENSIBILITY OF FIELD DATA

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SUMMARY

One perceived obstacle to the use of field methods is the legal defensibility of field data. The standards which are used by the courts are quite different than the standards used in the environmental testing community. The rules on the acceptability of scientific evidence are different in federal courts than in some state courts. The federal rules were changed significantly by the *Daubert v. Merrell-Dow* decision handed down by the U.S. Supreme Court in 1993. In that decision, the Supreme Court gave judges considerable latitude to decide what evidence was relevant and reliable. California, on the other hand, still uses a standard based on "techniques which are generally accepted by the scientific community."

Neither the federal nor California standards for admissibility distinguish between analysis done in a fixed laboratory and analysis done in the field. Nor do the standards require adherence to methods approved by U.S. EPA or other standard-setting organizations. In one California case, *People v. Hale,* there were major deviations from the relevant EPA method, but an appeals court found that the deviations were harmless and allowed the data to be used.

In order for data to be accepted as evidence, whether the data come from a fixed laboratory or the field, the technique may need to generally recognized in the scientific community (state standard), and must be shown to be relevant and reliable (federal standard). Once evidence has been accepted, the weight which is given to the evidence may depend on a variety of factors, including the training and experience of the personnel, the accuracy of the equipment, and the reliability of the method. The rules for the defensibility of field methods are no different than those for fixed laboratory methods.

INTRODUCTION

A real obstacle to the wider use of field methods is the perception that field data are legally less defensible than fixed laboratory data. To actually examine this perception, it is necessary to examine the actual legal standards which are used for scientific data. Although environmental scientists have their own standards for analysis, the actual standards for the legal defensibility of scientific data involves the interaction of science and law. The courts have made significant changes in recent years to the rules for scientific evidence, which reached a climax with the U.S.

Supreme Court opinion in the case of *Daubert v. Merrell Dow Pharmaceuticals.*

FEDERAL RULES FOR SCIENTIFIC DATA

First, we must realize that the rules for scientific data may be different in federal courts than in state courts. This, however, does not necessarily pose an insurmountable problem. The federal rules changed in 1993 when the U.S. Supreme Court issued an opinion in the case of *Daubert v. Merrell Dow Pharmaceuticals.* Although the case involved allegations that a drug, Bendectin, caused birth deformities, the ruling had a broad application because it abandoned an earlier standard, based on *Frye v. United States.* In its 1993 *Daubert* ruling, the court established a more flexible and liberal test of admissibility of scientific evidence. The Supreme Court received a considerable number of briefs from scientific organizations, and this is reflected in their opinion, which even dealt with the definition of science.

> "...under the Rules the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable *(Daubert v. Merrell Dow Pharmaceuticals,* 4827)".

Readers who are interested in a thorough examination of the *Daubert* ruling may want to look at Foster and Huber's book, *Judging Science.* The question of what constitutes reliable scientific evidence is still subject to debate, but the impact of the Court's ruling was to give the judge considerable flexibility in deciding that question in a particular case.

STATE RULES FOR SCIENTIFIC DATA

Unlike the federal courts, California courts still maintain a standard based on "general acceptance" in the relevant scientific community (*People v. Kelly,* 1976). The three "prongs" of this standard are:

> 1) The scientific test's reliability must be established by its general acceptance in the relevant scientific community;
> 2) The testifying witness must be properly qualified; and
> 3) The proponent of the evidence must demonstrate that the correct scientific procedures were used.

Again, none of these standards would distinguish field methods from fixed laboratory methods. They also should not pose a significant barrier, with the exception of a "black box," which may operate using principles that have not been accepted in the scientific community.

CASE HISTORIES

People v. Hale, 1994: The first line of this California Appellate Court ruling reads:

> "SW-846 is not the name of some new gasoline additive marketed by an oil company. It is the title of a manual compiled by the United States Protection Agency (EPA) dealing

with the collection and testing of hazardous waste."

The case involved illegal dumping of 1,1,1- Trichloroethane into waste dumpsters. The appeal focused on major deviations from SW-846: no sampling plan was used, the lab had used Method 8015 (using a flame-ionization detector) instead of the accepted methods 8010 or 8240; the samples were frozen instead of cooling to 4°C.; and the 14-day holding time was exceeded. The court held that the deviations were harmless.

> "We discern no per se rule which does automatically precludes the introduction of evidence of disposal of hazardous waste just because the gathering of the sample does not follow every jot and tittle of the EPA manual."

People v. K&L Plating, 1997: Although this is not a case published by an appellate court, this case involved the use of field methods. This was a manslaughter case, in which a worker died after rescuing another worker who was cleaning out sludge in a waste treatment tank. The prosecution used results from a Draeger tube testing of head space in a jar of sludge and a hydrogen cyanide monitor as evidence that hazardous levels of hydrogen cyanide were emitted from the waste. The defense challenged the reliability of all of the data. Review of validation of the Draeger tube showed that a lower estimate of HCN concentration could be calculated even though the tube changed color on one stroke instead of the required ten strokes. The HCN monitor, the prosecution argued, used an accepted principle and provided an expert witness to support the data. The defendant plead guilty.

People v. Sangani, 1994: This case involved illegal disposal of hazardous waste into a sewer system. The defendant was convicted, but appealed, in part, because the lab which did the analysis was not certified by the California Department of Toxic Substances Control. The Appellate Court found that even if the Hazardous Waste Control Law required the use of an accredited lab, the data would be admissible.

> "Failure to follow precise regulatory or statutory requirements for laboratory tests generally does not render the test results inadmissible, provided the foundational requirements for establishing the reliability of the tests are met. The necessary foundational requirements are:
> (1) the testing apparatus is in proper working order;
> (2) the test was properly administered; and
> (3) the operator was competent and qualified. (*People v. Sangani*, p. 1276)"

People v. Adams: In what has been described as an explanation of the general rule of evidence in California, the court found:

> "Where a statute ...does not specifically provide that evidence shall be excluded for failure to comply with said statute...such evidence is not inadmissible. Statutory compliance or noncompliance goes to the weight of the evidence (*People v. Adams*, 567)."

THE APPLICATION OF RULES OF EVIDENCE

The legal cases which established rules of evidence were primarily created to deal with new scientific techniques, e.g., a crude predecessor to the lie detector, or to distinguish real science from "junk science." The examples of rules for admissibility of evidence given in the examples above should pose little problem for a validated technology which is operated correctly by a trained operator.

CONCLUSION

The rules on the legal defensibility of scientific data do not distinguish between measurements made in the field and measurements made in the laboratory. The rules used by the courts are very different than those established in regulation. In particular, courts have found that evidence may be reliable even if there were major deviations from methods specified in regulation, or if the analysis was done in a non-accredited laboratory, even if accreditation were required by regulation. As to the weight which is put to evidence, the validation of the method and the quality system documentation are certainly relevant.

REFERENCE LIST

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People v. Adams, 59 Cal.App. 3d at 567 (1976).

People v. Hale, 29 Cal.App. 4th 730 (1994).

People v. Kelley, 17Cal.3d 14 (1976).

People v. Sangani, 94 C.D.O.S. 1273 (1994).

U.S. EPA Office of Solid Waste, *Test Methods for Evaluating Solid Waste, Physical/Chemical Methods.*

EXTENDED ABSTRACT

GUIDE TO STANDARDS FOR EPA QUALITY MANAGERS

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Individuals responsible for managing the quality of environmental and related measurements traditionally must have a working knowledge of specific standards. Until recently, the types of standards encountered were limited to EPA and other Federal agency guidance/requirements and standard methodology for sampling and analysis. In 1996, the EPA adopted a standard developed through the American Society for Quality. This standard, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs* ANSI/ASQC E4-1994, was adopted under the statutory authority of the *National Technology Transfer and Advancement Act of 1995.*

In the particular case of E4, a "quality standard" was referenced which also is an "environmental standard." Other quality and environmental standards may be useful to quality managers working in enforcement, environmental investigations, and research. Also, many of the standards that address products or processes may be useful, but it is difficult to access the potential for their usefulness without a road map to the resources. Yes, *"the truth is out there."* This technical presentation presents a road map to standards which may be useful to the environmental quality manager.

The presentation considers the history of standards, the current standards under development, resources for new standards, and an overview of the various parties responsible for standards development and maintenance as well as Internet addresses for the resources.

ISO GUIDE 25 TO INTERNATIONAL STANDARD ISO 17025

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This paper addresses the move to change the existing International Standard Organization Guide 25, "General requirements for the competence of calibration and testing laboratories" to an ISO Standard 17025, "General requirements for the competence of testing and calibration laboratories." The reasons for the proposed changes and their implications for the US marketplace are discussed. Differences in content and coverage between the Guide and draft Standard are presented. The relationships of the ISO Guide and proposed Standard to other ISO Standards, and to NELAC, are explained. Potential benefits and costs of this proposed Standard are listed.

EPA

April 13 -16, 1999

Regal Cincinnati Hotel
Cincinnati, Ohio

U.S. Environmental Protection Agency

presents the

18th Annual National Conference on

Managing Quality Systems for Environmental Programs

with **Preconference Training Courses**
April 11-12, 1999

Agenda At A Glance

Sunday, April 11, 1999			
7:30 am - 8:30 am	Registration, *Grand Ballroom Foyer*		
8:30 am - 5:00 pm	Preconference Training Course: Integrating Quality Assurance into Project Development, *Bronze B*		
1:00 pm - 5:00 pm	Preconference Training Course: NELAP Accrediting Authority Assessor Training *(State and Federal employees only), Colonnade B*		
Monday, April 12, 1999			
7:30 am - 8:30 am	Registration, *Grand Ballroom Foyer*		
8:30 am - 5:00 pm	Preconference Training Course: Integrating Quality Assurance into Project Development *(Continued), Bronze B*		
8:30 am - 5:00 pm	Preconference Training Course: NELAP Accrediting Authority Assessor Training *(Continued), Colonnade B*		
8:30 am - 5:00 pm	Preconference Training Course: Introduction to EPA Quality System Requirements for Environmental Programs, *Colonnade A*		
8:30 am - 5:00 pm	Preconference Training Course: Introduction to Management Systems Review Process, *Pavilion*		
7:00 pm - 10:00 pm	Regional QA Managers Meeting *(EPA only), Pavilion*		
Tuesday, April 13, 1999			
7:30 am - 8:00 am	Registration, *Grand Ballroom Foyer*		
8:00 am - 11:30 am	Plenary Session: Keynote Address, Special Reports, *Grand A*		
11:30 am - 1:00 pm	Lunch Break		
1:00 pm - 2:00 pm	Technical Plenary Session: Report of the Inter-Governmental Task Force on Data Quality, *Grand A*		
2:00 pm - 3:00 pm	Technical Plenary Session: Implementing Performance Based Measurement Systems in a Regulatory Setting–Issues and Answers, *Grand A*		
3:30 pm - 5:00 pm	Discussion Breakout Sessions, *Grand A*		
Wednesday, April 14, 1999	*Grand A*	*Grand B*	*Colonnade*
8:00 am - 9:30 am Concurrent Sessions	Session W11: QA for Secondary Data Use–Lessons Learned	Session W12: Implementing NELAP Status Report	Session W13: The QA Professional as an Expert Witness in Court
10:00 am - 11:30 am Concurrent Sessions	Session W21: Environmental QA/QC Practices–Emerging Issues in Research	Session W22: Implementing QA in Environmental Labs	Session W23: A Sample is a Sample is a Sample
11:30 am - 1:00 pm	Lunch Break		
1:00 pm - 2:30 pm Concurrent Sessions	Session W31: Information Management for the QA Professional *(Mini-Workshop)*	Session W32: Environmental QA/QC Practices–Emerging Issues on	Session W33: Benchmarking–Processes and Lessons Learned Questionable Practices
3:00 pm - 4:30 pm Concurrent Sessions	Session W41: Information Management for the QA Professional *(Mini-Workshop continued)*	Session W42: Putting QA into Operation: Planning, Implementation, and Assessment	Session W43: Environmental QA/QC Practices–Oversight and Implementation
Thursday, April 15, 1999	*Grand A*	*Grand B*	*Colonnade*
8:00 am - 9:30 am Concurrent Sessions	Session T11: Cost of Quality–Real Dollars or Otherwise	Session T12: Practical Approaches to Quality Auditing *(Mini-Workshop)*	Session T13: Implementing QA in Health and Ecological Research
10:00 am - 11:30 am Concurrent Sessions	Session T21: Field Analytical Methods–Experiences and Lessons Learned	Session T22: Practical Approaches to Quality Auditing *(Mini-Workshop continued)*	Session T23: What's Happening in International Standards and Why You Should Care
11:30 pm - 1:00 pm	Lunch Break		
1:00 pm - 2:30 pm	Plenary Wrap-up Session, Reports from Breakout Sessions, *Grand B*		
Friday, April 16, 1999			
8:00 am - 12 noon	EPA QA Managers Meetings *(Closed to public), Bronze A, Grand A*		

A registration and information desk will be open during the entire conference.