12TH ANNUAL NATIONAL MEETING ON MANAGING ENVIRONMENTAL DATA QUALITY

P R O C E E D I N G S

Albuquerque, New Mexico February 10-14, 1992
Quality Assurance Management Staff
U.S. Environmental Protection Agency

EPA'S MANAGEMENT SYSTEM FOR ENVIRONMENTAL DATA QUALITY

TOTAL QUALITY MANAGEMENT (TQM) is the process whereby an organization, led by senior management, commits to focusing on quality as a first priority in every activity. TQM implementation creates a culture in which everyone in the organization shares the responsibility for improving the quality of products and services, and for "doing the right thing, the right way, the first time."

EPA's QUALITY ASSURANCE (QA) program for environmental data operations is based firmly on the principles of Total Quality Management. Quality assurance is the process of management review and oversight at the planning, implementation, and completion stages of an environmental data operation to assure that the data provided by a line operation to data users are of the quality needed and claimed. The TQM concepts which the Agency's QA program has put into practice include the following:

* Customer-supplier relationships, especially a clear statement of the customer's (data user's) needs;
* Establishment of measures of performance for supplier implementation and customer evaluation;
* Process analysis through techniques such as process flow diagramming; and
* Employee development, involvement, and recognition.

QA is not identical to QUALITY CONTROL (QC), which is an aspect of the implementation phase of an environmental data operation. QC includes those activities required during data collection to produce the data quality desired and to document the quality of the collected data (e.g., sample spikes and blanks).

At EPA, quality assurance is a management system based upon the proven management philosophy of Total Quality Management. The primary responsibility for implementing QA belongs to the line managers of EPA organizations which are involved in the collection or use of environmental data, whether in Headquarters, Regions, or Research and Development Laboratories. EPA managers at all levels benefit from a program which succeeds in bringing the Agency's environmental data operations into alignment with its decision-making needs: "the right thing, the right way, the first time."

CONTENTS

AGENDA

Monday, February 10

1:00 pm - Introduction
Nancy Wentworth, Director, Quality Assurance Management Staff

1:10 pm - Welcoming remarks
Louis E. Saavedra, Mayor of Albuquerque

1:20 pm - Keynote Address
Eugene Rouleau, Deputy Regional Director, U.S. Office of Personnel Management

3:00 pm - EPA's Environmental Monitoring Management Council (EMMC)
Fred Haeberer, Quality Assurance Management Staff

3:30 pm - The ANSI/ASQC E4 19xx: Quality Assurance Program Requirements for Environmental Programs
Gary Johnson, Quality Assurance Management Staff

3:40 pm - Agency-Wide Data Standards
Stephen Hufford, Information Management Branch, Office of Information Resources Management

4:10 pm - The News From QAMS
Nancy Wentworth, Director, Quality Assurance Management Staff

Tuesday, February 11

8:30 am - Merging Quality into Science and Research (panel discussion)
Gary Johnson, Quality Assurance Management Staff (CHAIR)
Lindsey Wood, Proctor & Gamble
Donald Summers, Los Alamos National Laboratory
Llewellyn Williams, Environmental Monitoring Systems Laboratory

10:30 am - Total Quality Management: What Does it Mean to the Analytical Laboratory?
Jackson Hicks, Waste Treatment and Environmental Services Department, Tennessee Eastman

11:15 am - Data Quality Assessment Overview
James Stemmle, Quality Assurance Management Staff

11:25 am - Data Quality Assessment: QAMS' Vision
Fred Haeberer, Quality Assurance Management Staff
Daniel Michael, Research Triangle Institute

1:00 pm - Assessment of Data Usability in Superfund

Larry Reed, Hazardous Site Evaluation Division, Office of Emergency and Remedial Response

1:30 pm - Assessing Data Quality for Agency Pesticide Decisions
Richard Schmitt, Health Effects Division, Office of Pesticide Programs

1:55 pm - Assessment of Error in Soil Data
Jeff van Ee, Environmental Monitoring Systems Laboratory, Las Vegas

2:45 pm - Using Power Analysis to Assess Office of Water Data Quality
Robert Graebner, TetraTech

3:10 pm - Facilitated Discussion Groups

4:15 pm - Discussion Group Summaries

4:30 pm - QAMS Wrap Up
James Stemmle, Quality Assurance Management Staff

4:40 pm - Adjourn

6:30 pm - Awards Banquet

- *Ralph Bauer, Deputy Regional Administrator, Region 5*
- Presentation of the Quality Assurance Manager of the Year Award

Wednesday, February 12

8:30 am - Training Sessions

1:30 pm - Training Sessions repeated

Thursday, February 13

8:30 am - Common Interest Group Sessions

Friday, February 14

8:30 am - Common Interest Group Reports, Closing

MEETING HIGHLIGHTS

Nancy Wentworth, Director, EPA Quality Assurance Management Staff, announced the theme of the meeting as "Customer Supplier Understanding: Measuring Environmental Quality Successes." She explained that speakers would be addressing the customer/supplier relationship: how it is defined and how it can be measured. Ms. Wentworth also gave a brief update on current activities and future plans for the Quality Assurance Management Staff.

Eugene Rouleau, Deputy Regional Director, U.S. Office of Personnel Management, discussed the importance of good customer/supplier relationships. He emphasized that every contact with the customer shapes their view of the supplier, and that customers look at their relationships with suppliers, not just what they provide.

Fred Haeberer, a Quality Assurance Management Staff member, gave a brief presentation on the Environmental Monitoring Management Council (EMMC): how it was formed, its purpose and organizational structure, and its progress to date. In a later presentation with Daniel Michael of Research Triangle Institute, Dr. Haeberer discussed the actions that QAMS is taking to address the issues and challenges of the data quality assessment process.

Gary Johnson, a Quality Assurance Management Staff member, reported on the current status of ANSI/ASQC E4 and discussed the purpose and implementation of the document.

Steve Hufford, Chief, Information Management Branch, Office of Information Resources Management, explained the six data-related standards, pointed out the challenges in the data standardization process, and discussed future directions in data standardization.

Jackson Hicks, Superintendent of Waste Treatment and Environmental Services, Eastman Kodak, Tennessee Division, described the basic principles and methodology for effectively implementing TQM in an organization.

Daniel Michael, Research Triangle Institute, defined data quality assessment, examined the three forms of input in the data quality assessment process, and discussed several issues and challenges currently facing the data quality assessment process.

Larry Reed, EPA Hazardous Site Evaluation Division (HSED), Office of Emergency and Remedial Response, explained HSED's role in the assessment of data usability of Superfund. He discussed two new guidances: "Data Usability in Risk Assessment," and "Data Usability in Site Assessment" and emphasized their importance to Superfund.

Richard Schmitt, EPA Health Effects Division, Office of Pesticide Programs, described the Office of Pesticide Program's role in reviewing data, the types of data that are reviewed, and the QA-related activities that are utilized to assure data of the right type and quality.

Jeff van Ee, EPA Environmental Monitoring Systems Laboratory in Las Vegas, discussed bias and variability in soil sampling: the types, ways of identifying, assessment, and methods of reducing.

Robert Graebner, Senior Scientist, Tetra Tech, discussed the use of statistical power analysis in assessing data quality, and its role in data quality management.

PANEL DISCUSSION:

Dr. Lindsey Wood, Total Quality Manager, Regulatory and Clinical Development, Proctor & Gamble; **Donald Summers,** Los Alamos National Laboratory; and **Dr. Llewelyn Williams,** Senior Science Advisor, EPA Environmental Monitoring Systems Laboratory, Las Vegas participated in a panel discussion on "Merging Quality into Science and Research." Each panelist gave his own perspective and experiences of the benefits of implementing a quality assurance program into fields of science and research.

SPEAKER BIOGRAPHIES

Ralph (Dick) Bauer is the Deputy Regional Administrator of Region 5 for the Environmental Protection Agency, where he assists the Regional Administrator in carrying out air, water, hazardous waste, and other pollution control programs in Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin. With a B.A. in Bacteriology, Mr. Bauer presently serves on EPA task forces on budget reform and multicultural diversity, and is chair of the EPA Quality Improvement Board.

Linne Bourget is the president of Positive Management Communications Systems, a company specializing in positive approaches to organizational change, such as vision-based planning, interpersonal communication, group dynamics, and leadership development. Dr. Bourget has a Ph.D. in Social Psychology/Organizational Change, and has 25 years of experience in management and organizational consulting and training.

Jeff van Ee is employed at the EPA Environmental Monitoring Systems Laboratory in Las Vegas, where he works on field sampling methods and quality assurance for soil studies. He has been with EPA for over 20 years, during which time he has developed quality assurance and monitoring systems for the Los Angeles Reactive Pollutant Program and the Regional Air Pollution Study; led EPA in the development of solar-powered monitoring equipment and satellite-based telemetry in remote areas; and developed monitoring approaches for locating abandoned oil and gas wells, geophysical and soil-gas techniques for hazardous waste site assessments, and monitored underground storage tanks.

Robert Graebner is a senior scientist for Tetra Tech. He is currently working on several database applications, including a dredged material tracking system (DMATS) for EPA Region 9, a data management system for the baseline ecological assessment of disposal activities for NOAA, an entry system for the EPA Ocean Data Evaluation System (ODES), and a project tracking system for the National Estuary Program (NEPTUNE). Mr. Graebner has an M.S. in Wildland Resource Science/Biometrics and is a member of the American Statistical Association and the Association of Environmental Professionals.

Fred Haeberer is a chemist with EPA's Quality Assurance Management Staff. He has 11 years of experience in analytical methods development at EPA and the U.S. Department of Agriculture, and is currently involved in the Environmental Monitoring Management Council (EMMC). Dr. Haeberer has an M.S. in Organic Chemistry and a Ph.D. in Physical Organic Chemistry.

Jackson Hicks is the Superintendent of the Waste Treatment and Environmental Services Department at Eastman Kodak, Tennessee Division. He has worked as an analytical chemist for the West Virginia Pulp and Paper Company and the Eastman Chemical Company, and has over 27 years of experience in analytical chemistry, waste treatment, and department management. Dr. Hicks has an M.S. in Physical Organic Chemistry and a Ph.D. in Analytical Chemistry.

Steve Hufford is the Chief of the Information Management Branch in EPA's Office of Information Resources Management (OIRM). He is responsible for agency-wide programs in form management, information security, data administration/standards, strategic IRM planning, IRM policy and reviews, Privacy Act compliance, and maintaining EPA's application systems inventory. Mr. Hufford has B.A. in Biology and an M.S. in Ecology from Duke University.

Gary Johnson is a member of the Quality Assurance Management Staff, where he develops and makes improvements on quality management policies and procedures. He co-authored ANSI/ASQC-E4-19xx, the ASQC Energy and Environmental Quality Division effort to develop a national consensus QA standard for environmental programs, and has presented numerous papers on QA and quality management in national and international symposia. Mr. Johnson is currently the Associate Regional Councilor and Chairman of the Environmental Restoration Committee for the ASQC Energy and Environmental Quality Division.

Joanne Jorz is the vice-president of Program Development at Conceptual Systems, Inc., a human resources consulting firm. Prior to joining CSI, Ms. Jorz was Director of Human Resources Development at JWK International Corporation, where she worked on decentralizing personnel functions, designing non-classroom training experiences and organizational analysis studies. She is a member of NSPI, FETA, and ASTD, and was a recipient of the ASTD TORCH award.

Daniel Michael manages Research Triangle Institute's Washington, D.C.-based Environmental Research Planning Department, where he facilitates the data quality objective (DQO) process for planning and designing soil, ground-water, and surface water surveys at Superfund sites. He has developed and co-presented seminars, papers, and workshops related to DQO concepts, the most recent of which was "Quantitative Decision-Making in Superfund, a Data Quality Objectives Case Study," published in Hazardous Materials Control. Mr. Michael is developing a generic set of procedures to assess the sufficiency of data for use in decision-making.

Robert O'Brien is a senior statistician at the Statistical Policy Branch of the Office of Policy, Planning, and Evaluation, where he is currently developing statistical computing methods and statistical hypothesis tests to evaluate chemical data at waste sites. Mr. O'Brien has an M.S. in Mathematics, and worked for the Bureau of Census for nine years in survey design and analysis before joining EPA in 1986.

Mary Ann Pierce is the project manager for environmental programs at JWK International Corporation, where she has provided training support to EPA's Quality Assurance program for the past six years. Ms. Pierce has 15 years of experience in instructional design and training, and developed various print, video, and classroom instructional materials, including the Train-the-Trainer workshops for EPA.

Larry Reed is the Director of the Hazardous Site Evaluation Division in the Office of Emergency and Remedial Response. He has been an EPA employee since 1974, when he worked for the Office of Planning and Evaluation, the Office Pesticide and Toxic Substances, and the Office of Water Permits and Enforcement. Mr. Reed has an M.P.A. from the JFK School of Government, Harvard University, and an A.B. from Youngstown State University.

Eugene Rouleau is the Deputy Regional Director for the Office of Personnel Management for the Dallas Region. Mr. Rouleau has an M.S. degree in Personnel from George Washington University, and has been a government employee for nearly 30 years. He worked for Senator Mac Mathias and Congressman Bill Steiger as a Fellow of the American Political Science Association in 1987, and was an employee of the U.S. Marketing Group of Xerox through the President's Executive Exchange Program.

Richard Schmitt is the Acting Deputy Division Director of the EPA Office of Pesticide Programs, Health Effects Division. He has worked in the Office of Pesticide Programs for 19 years, and has a Ph.D. in Chemistry from the University of California at Riverside.

James Stemmle is an environmental scientist with the Quality Assurance Management Staff, where he manages the annual national meeting on managing environmental data quality, reviews QA Program Plans, and promotes Data Quality Objectives. Dr. Stemmle has a Ph.D. in Physical Inorganic Chemistry from Catholic University, and has been with EPA since 1974.

Donald Summers is the leader of the Quality Operations Office at the Los Alamos National Laboratory, where he is currently establishing a lab-wide quality program. Mr. Summers has 29

years of experience in quality assurance and has developed and managed quality programs for nuclear and non-nuclear activities. He is the Secretary for the Subcommittee on Waste Management for ASME/NQA-1 and the Chairman of the Work Group for Low Level Waste.

John Warren is a senior statistician and Acting Chief of the Statistical Policy Branch of the Office of Policy, Planning, and Evaluation. With a Ph.D. in Statistics, Dr. Warren is currently developing efficient sampling schemes for the investigation of hazardous waste sites. His current efforts were presented at the agency's Eighth Conference on Statistics in March.

Nancy Wentworth is the Director of the Quality Assurance Management Staff at the Environmental Protection Agency. She has worked for EPA since 1978, and has received the EPA Bronze Medal for Commendable Service (1991). Ms. Wentworth has a B.S. degree in Civil Engineering from Tufts University and an M.S. in Engineering from Pennsylvania State University.

Llewellyn Williams is the Senior Science Advisor for EPA's Environmental Monitoring Systems Laboratory in Las Vegas, where he works on improving monitoring and measurement methods and data quality assurance. With a Ph.D. in Zoology, Dr. Williams taught at Rutgers and Fordham Universities before joining EPA in 1972 as a senior limnologist for the National Eutrophication Survey. He has authored and co-authored over 100 reports and scientific publications.

Lindsey Wood is the Total Quality Manager in Regulatory and Clinical Development at Proctor and Gamble. He has a Ph.D. in Microbiology, and was an assistant professor in infectious diseases at the University of Texas Medical School in Houston. Dr. Wood has published over 30 papers and abstracts on infectious diseases and is a member of the Infectious Diseases Society of America.

INTRODUCTION

INTRODUCTORY SPEAKERS

NANCY WENTWORTH, DIRECTOR OF THE QUALITY ASSURANCE MANAGEMENT STAFF, began the meeting at 1 p.m. on Monday afternoon. She announced the theme as "Customer Supplier Understanding: Measuring Environmental Quality Successes," and stated that speakers would be addressing how customer supplier relations can be defined, and how they can be measured. She further described the role of QAMS in the presentations as "trying to help you, our customer community, to better understand what we're doing, how the agency is operating these days, and the directions of the EPA Quality Assurance program."

Nancy then introduced **LOUIS SAAVEDRA, MAYOR OF ALBUQUERQUE.** Mr. Saavedra welcomed the attendees to the city of Albuquerque, and shared his concern on the topic of data quality and TQM. He showed his interest in preserving the environment, and emphasized that we must take a "dispassionate, rational, and scientific look at the issues." The speech ended with this thought: "When all is said and done, you have an incredible balancing act to undergo; and because the results of your work will perhaps not be revealed until you and I are long gone, our children and grandchildren are the ones for whom we are saving this land."

PRESENTATIONS

KEYNOTE ADDRESS

EUGENE ROULEAU
DEPUTY REGIONAL DIRECTOR
U.S. OFFICE OF PERSONNEL MANAGEMENT

"CUSTOMER-SUPPLIER RELATIONSHIPS"

First, I want to ask you a few questions: How many of you engage in some form of physical exercise each week? How many are into running? OK, how many run longer than an hour at a time as your longest run during the week? I run marathons. People who are into exercise, but aren't into distance running, wonder what we talk about when we're out there. This is what happened several weeks ago in Dallas with a friend of mine, Leo.

Leo is a roofing contractor. He works through a broker that has an agreement with a national chain of retail stores. Leo said to me, "Gene, I had such a tough week; I'm thinking about canning the business, uprooting the family, and moving to some other place." Now, Leo is usually a very upbeat, energetic, and optimistic person, so I asked him what was going on. He said, "I've got business management problems. I'm getting whipsawed. The broker's got my beeper number and he calls all day long. I've got three different levels at the retail store chain across the city where I get my business and I've got sales people, the managers on home improvement departments, and their total division manager calling me. They're asking all sorts of questions and constantly giving me negative feedback. I just don't feel good about these relationships. And on the other side, I talk to my workers on the job sites, and they're trying to get the work done, and what are they looking for? I haven't done this for them, I haven't done that for them...What can I do about this?"

We talked about the situation, and came up with some solutions:

1. Reduce the time he spends on his mobile telephone -- not be so accessible to so many people all of the time. Instead, buy mobile radios to talk to his crews, and only give his beeper number to a few people. He rented a voice mail box and opened up communications with retail customers. Now, customers can leave a message on Leo's voice mailbox, and he can pick up the messages every 15 to 20 minutes. Before he calls back, he contacts the job site to find out what's going on (has the customer said anything?). He asks the workers about the status of the work in progress, so that when he calls the customer back, he can tell them that either the problem has been solved, or that it is in the process of being solved. Leo also tells customers that they can talk to his crew leader at any time on job to ensure that their expectations are being met.
2. Empower and incent his worker to pay more attention to what the customer wants. If a worker hears from a retail

customer that there is a problem, and that worker takes actions to solve it, Leo will reward him with a bonus.

3. Meet with every retail customer before his crew begins to talk about what they have and have not bought according to the contract.

4. Listen to customers' special expectations for him and his crew. Leo gets rid of expectations that cannot be satisfied, gets everything out in the open from the beginning, and confirms when the job is to be finished.

5. Authorize the workers to spend up to $50 (in time and materials) beyond what the contract calls for to fix things that are unrelated, but that may be a problem for the customer.

After one month of following these guidelines, Leo reduced call-backs at customer sites by 80%. He now spends about 65% of his time with the customers, discussing their needs and expectations. In short, Leo is not behind a desk or driving around in his truck all day; he is negotiating and understanding customer expectations.

Several lessons can be picked up from Leo's experience. In the words of Ben Franklin: "We are what we repeatedly do. Excellence, then, is not an act; it's a habit." If you get into an excellent habit of relating yourself and your resources to what your customer needs, then suddenly, having a quality service or product is not difficult; it's a natural outgrowth of the way that we become. Vince Lombardi: "Practice doesn't make perfect, perfect practice makes perfect." If you begin to think about that customer (if you are the supplier), and if you think in terms of satisfying that customer's requirements, everything we do when we meet with the customer either leads toward the goal or away from the goal. You either get closer to the customer, or further away.

Dr. Michael Leboeuf, the author of <u>How to Win Customers and Keep Them for Life</u>: "Any organization, any industry's most valuable asset is its stock of satisfied customers." How satisfied are the customers of the data quality industry? Is the industry improving? Is your business improving based on customer satisfaction? Dr. Leboeuf says that the greatest business secret in the world is that rewarded customers buy, multiply, and come back. We reward customers every time we have contact with them in a way that's so human and yet so competent, that they look forward to doing business specifically with us.

One study from Texas A&M looked at 900 customers of diversified businesses and found out that what customers want from service delivery outfits is reliability, most of all. Customers expect us to be timely, responsive to their needs, accessible, available, credible, able to explain our stock and trade (from technical jargon to regular English), and willing to help them when they have problems. They expect quality; they expect it to be attractive to do business with us; and they expect to be treated as special individuals. Customers weigh how our people treat them in every part of the relationship.

Dr. Leboeuf observes that "Customer's perceptions are customer's realities." Their perceptions of how we serve them is the difference between what the customer gets from us versus what they expected to get from us. If customers perceive that the service we offer is reliable, on time, of high quality, and responsive, we're going to win them and keep them with us for a long business relationship.

When we look at the data quality industry in each of our business units within that industry, we need to see our industry in our own businesses through the eyes of the customers. Every contact that we have with customers shapes their views of us and it either increases their interest in doing business with us at the same volume and value, or decreases their business with us. Those are the consequences of every transaction between us and our customers.

The customers are valuable to us as people in the industry, because the customers have the insights and the understanding to tell us how we're doing and how we can get better. Customers aren't shy once you ask them what they think. If you don't have a well thought-out plan or process for collecting and analyzing customer satisfaction data, think about this: What is your method of assessing customer satisfaction? How about taking the information you collect from customers and translating it into the next phase (in the TQM sense) of customer requirements? Then, validate the requirements by asking the customers if these requirements are real for them. Begin the process by measuring how well your business is doing, and how well the industry is doing in meeting customer expectations and requirements.

What are some of the tools you can consider if you want to get customer satisfaction data? Develop short survey questionnaires for employees and customers that ask what their ideas are; and standardize short interview lists to be used during telephone conversations and in-person meetings with customers. The process of asking customers what they think about our services tells them that we value their views.

After listening to customers and improving our existing products and services, the next step is to work on identifying the customer's unmet needs. How do you get started in that direction? Ask customers and potential customers what services and products they would like to have, but either can't get, or can't get at a price they can afford. Based on what they tell us, we first try to stretch one of our existing products or services to meet their needs. We try to retool and repackage, change formats, etc. If that doesn't work, we brainstorm new products and services.

The relationship between customer and supplier is part of something bigger -- what is called "the service revolution." One of the proverbs in the Bible says it best: "Without a vision, people perish." The thinker with the most influence on the vision of the service revolution is Karl Albrecht, co-author of Service America and author of At America's Service. Each of us knows that seven out of ten Americans earn money in the service

sector of our economy. We also know that the data quality industry is part of the service sector of the American economy. But does the industry, and each organization within the industry, have a clear vision of managing the services that we provide to customers? Albrecht says that the quality of service increasingly makes the difference in which organizations are effective in the market place and in the public sector. He and Dr. Leboeuf agree that the customer's perceptions of the quality of service can be managed. It's not a random event; it's something that we can manage and participate in.

Our customers look at the relationships with our people, not just what we provide. We can manage myopically by thinking that if we have a quality product or service, it will sell itself. This is no longer true in the service sector of the economy. It's also tough to understand that controlling the quality of a service or product is not like controlling the quality of a physical product. Why? Because the person who provides that service is such an integral part of the service delivery, and it's the human element that is so difficult to control.

What do we do if we want to get with it in the service sector of the economy? What is the unifying idea behind what we do? Our strategy must be to focus our attention on the real priorities and needs of the customer, both current and unmet. Next, we need to have a customer-oriented front line of people who help customers get what they paid for, and create good will for our organizations. We must act on problems that come up in the systems that managers created; clean up systems so they decontrol people who are directly involved with customers; and make our work process system (that backs up service delivery people) more user-friendly. Any time a customer says they had trouble getting in to your people about an accounts receivable, a warranty, etc., it's not good.

One last observation from Albrecht: In the service business, we need to think in terms of employees having transactions with customers instead of simply operating in predefined roles and stereotypes that say "customer representative #1 will do the following things..." That isn't the way we want to create jobs for our people who face the customers. Our employees are engaged with customers in running transactions; they are not in predefined jobs where everything is cut and dried.

FRED HAEBERER
QUALITY ASSURANCE MANAGEMENT STAFF
U.S. ENVIRONMENTAL PROTECTION AGENCY

"THE ENVIRONMENTAL MONITORING MANAGEMENT COUNCIL"

Fred Haeberer reported on the Environmental Monitoring Management Council (EMMC): its formation, purpose, organizational structure, and progress to date.

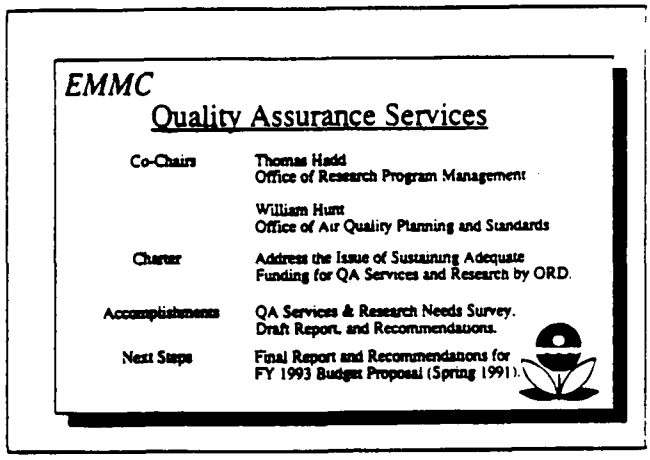
The EMMC was created in 1990 to "coordinate the agency's methods and research and development efforts to foster consistency and simplicity in the methods that were being developed and the methods that were already on board; to coordinate short and long term methods and development strategies to promote the adoption of new technology and new methodology; to coordinate QA and QC guidelines as they apply to specific methods; to evaluate the feasibility and advisability of a national laboratory accreditation program; and to coordinate other activities influencing the agency's environmental monitoring needs."

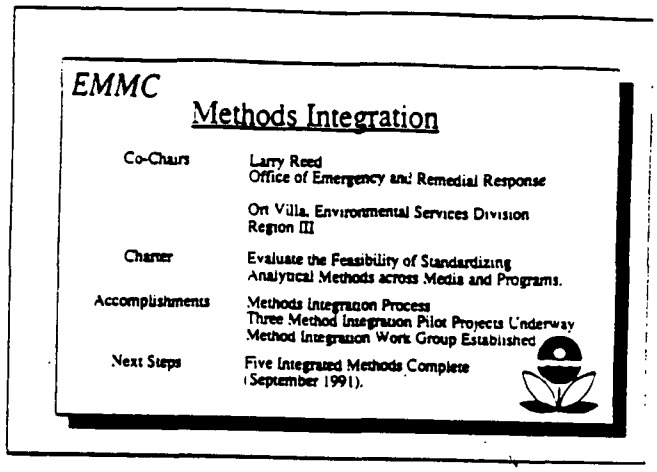
The Council reports directly to the Deputy Administrator, Hank Habicht. Below the DA is the Policy Council, the group responsible for identifying and addressing monitoring issues and needs, and formulating policies. It oversees the Steering Committee, which, in turn, oversees the activities of the five Ad Hoc panels.

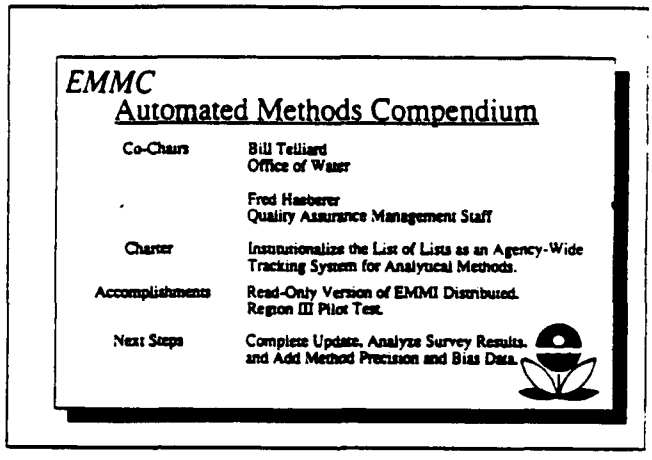
When the EMMC was created in 1990, the Steering Committee was asked to address five key issues. Ad Hoc panels were then appointed to focus on these issues:

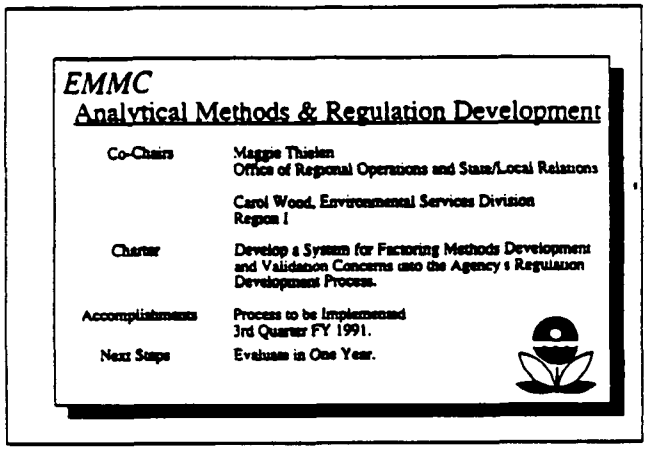
1. The agency's **QA Services** group -- How are these materials supplied and how are we going to fund them?
2. A **Methods Integration** group -- assigned to look at the methods that utilized very similar methodologies for analyzing the same analyte, but were slightly different for different programs or different matrices.
3. The **Methods Compendium** group -- responsible for identifying and developing software which would provide information on the agency's methods -- What methods are available, what methods are in progress, what analytes are affected, etc.
4. The **Quality Assurance in Regulation Development** group -- tasked with identifying and developing a process for ensuring that the agency's regulations, as they are developed and promulgated, will be backed by environmental monitoring methods that will support the regulatory requirements.
5. The **National Laboratory Accreditation** group -- responsible for examining the feasibility and advisability of a national environmental laboratory accreditation program.

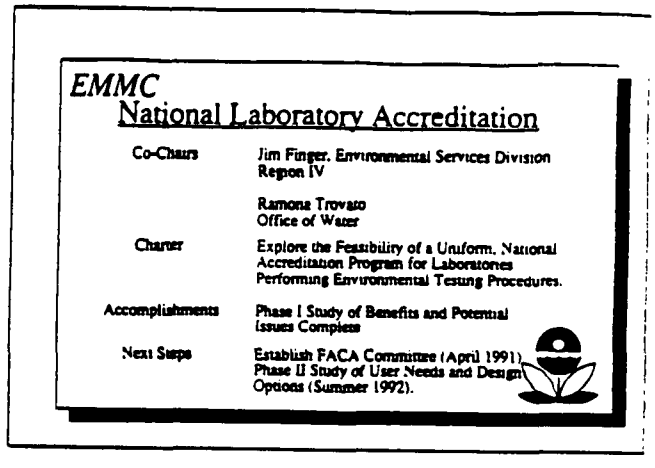
The five figures below present the co-chairs, the charter, and the accomplishments and future steps of each Ad Hoc panel.











The final five minutes of the presentation were devoted to the current status of the Environmental Monitoring Methods Index (EMMI), a cross-referencing tool that contains information on agency lists, analytes, and analytical methods. A pilot test was done with Region III in September to allow experts to review this software and suggest changes, additions, etc. Based on the feedback, Version 1 of EMMI was produced and selectively distributed in January.

EPA employees can obtain a copy of EMMI by contacting EPA's ALL-IN-1 electronic mail system at 1-800-334-2405. Employees from other Federal agencies should contact Bill Steltz at (202) 260-7120. EMMI is not yet available to the private sector, but privatizing efforts are being made so it can be distributed and sold to the general public.

GARY JOHNSON
QUALITY ASSURANCE MANAGEMENT STAFF
U.S. ENVIRONMENTAL PROTECTION AGENCY

"ANSI/ASQC E4, THE QUALITY ASSURANCE REQUIREMENTS FOR QA SYSTEMS"

In this presentation, Gary Johnson reported on the current status of proposed ANSI/ASQC E4, and discussed the stages of developing the document, from conception to implementation.

He began the discussion by stating that as a national standard for QA systems, ANSI/ASQC E4 strives to bring "harmony and consistency" to environmental decisions in the Federal Government, and to eliminate the dilemma of "...ten regions having ten different ways of looking at the same problem."

Gary explained that the absence of an existing set of criteria for government agencies induced the creation of a special group under the auspices of the American Society for Quality Control (ASQC). Their goal was to develop a national consensus standard for environmental programs, a process that could be used by all agencies within the Federal Government. During the search for a new approach, the group looked at "...a lot of good pieces of things that different groups had applied to environmental programs." They decided that in order to come up with the best QA standard possible, they would "...look at the best everyone had to offer, and steal shamelessly from all the good ideas that we could find."

Starting from scratch, the group took a TQM approach and began with the basic principles. They organized a scheme that focused on three parts: Planning, Implementation, and Assessment. Based on this design, "The standard will tell what needs to be done. It's not going to say how or by whom; that's your part. You have to develop a QA program to meet the needs of your organization."

Gary concluded with the current status of ANSI/ASQC E4. The first draft was released in March, 1991 at the International Waste Management Conference in Las Vegas. It was then distributed at the EPA QA meeting in Dallas. Senior level individuals from DOD, DOE, EPA, the contractor community, and the nuclear regulatory committee commented on the initial draft. By September, the draft was ready to undergo the wide review process through ASQC. More than six hundred specific organizations and individuals received a ballot, where they were asked to review the standard, make comments, and mark it acceptable or unacceptable. The closure date was January 31, but because of the enormous amount of review requests, a second ballot may occur in May or June. The standard is expected to be approved and published later this summer.

STEVE HUFFORD
CHIEF
INFORMATION MANAGEMENT BRANCH
OFFICE OF INFORMATION RESOURCES MANAGEMENT
U.S. ENVIRONMENTAL PROTECTION AGENCY

"AGENCY-WIDE DATA STANDARDS"

Steve Hufford began his presentation by briefly explaining the six basic data related standards. The first mentioned was the Chemical Abstract Service (CAS), used by EMMI as a registry numbers standard for identifying compounds. The second was a standard coding scheme to identify regulated facilities across the agency. The idea, according to Mr. Hufford, was "that establishing a common coding scheme for the regulated facilities could help EPA share data across the program boundaries." The third was "the locational data that deals with the use of latitude and longitude coordinates to identify where things are in the environment and also deals with noting down the method used to obtain the coordinate, the description of what the coordinates present, and an estimate of the accuracy of the coordinate." The fourth standard dealt with the essential data elements to take whenever a ground water sample is collected. Mr. Hufford added that "this minimum set of data elements is important to ensure good use of the parametric data..." The last two focused on standards for transmitting data rather than particular values of the data. The fifth dealt with transmitting measurement data from laboratories; and the sixth was a recently developed policy on electronic reporting. "This policy says, to the extent possible, use the ANSI X12 family of standards or transaction sets to automate the process, or if appropriate, use EDIFAC, a more internationally used set of standards."

Mr. Hufford then pointed out the challenges in the data standardization process. He emphasized that "what we're trying to do in the data standardization program is, very thoughtfully and with a lot of outreach and education, strike the appropriate balance between rigidity and flexibility..." He continued on to say that enforcing standards is an ongoing challenge, and the key to success is <u>education</u> and <u>awareness</u>. "I am particularly pleased about the formal amendment to the EPAAR, EPA's acquisitions regulations. The amendment requires compliance with IRM policies and standards, not only the data standards, but also other IRM-related guidance and policies, such as guidance for systems design and development." Mr. Hufford further noted one last challenge: that the process for creating standards is slow. "The process requiring absolute consensus tends to create standards that are either vague or generic or difficult to interpret. We're grappling with those and trying to make implementation and guidance as clear as we can."

The final portion of the presentation was devoted to future directions in data standardization. Mr. Hufford explained that the basic idea is to link data standards into a more broad

context of data administration. "A lot of parts of EPA deal with organisms, in one way or another, and a standardized way of communicating that information might be worthwhile." He further assured the audience that "a number of efforts are already underway."

In closing, Mr. Hufford mentioned that his branch, in the Office of Information Resources Management, currently maintains a computerized inventory of EPA's applications system. The inventory includes a summary and descriptive information on more than five hundred applications. While not highly detailed, the system "does serve as a useful pointer."

NANCY WENTWORTH
DIRECTOR
QUALITY ASSURANCE MANAGEMENT STAFF
U.S. ENVIRONMENTAL PROTECTION AGENCY

"THE NEWS FROM QAMS"

"The goal of this meeting is for you all to know what we in QAMS are doing -- what our current activities are, and what the plans are for the near and long-term future."

Ms. Wentworth began the presentation with her vision of quality assurance in the agency as "an excellent management program for environmental data collection through planning, implementation, and assessment activities which produce data of the appropriate type and quality for EPA decisions and for EPA decision-makers and research managers through efficient and cost-effective processes." She added that the main considerations of QA must focus on timing, politics, budgets, and perceptions of those outside the agency.

Ms. Wentworth continued on to describe the ways in which QAMS is approaching this vision. First, she explained that senior management knowledge and attention to quality issues across the agency are being improved. To this effect, she and the Deputy Assistant Administrator for the Office of Research and Development (ORD), John Skinner are meeting regularly to focus on these issues. Although John could not attend the meeting, he wanted Ms. Wentworth to relay several points to the audience:

1. "ORD recognizes and takes very seriously its responsibility for QA across the agency."
2. ORD has declared QA documentation to be a material weakness under the Federal Manager's Financial Integrity Act (FMFIA).
3. QA is an integral part of the internal management control process, a system that requires quarterly reports to the ORD Senior Management Council, which Skinner chairs.
4. QAMS should be given credit for "being in the vanguard of TQM implementation in the agency, and by showing that TQM can work in a technical decision-making process."
5. We must have decisions based on data and fact. "We can no longer make our decisions based on anything but strong, scientifically defensible, efficiently-generated scientific information.

Ms. Wentworth then gave a brief report on the panel that was organized one year ago to look at the role of science in the agency. Although the report from the panel was not yet available for release, several recommendations were cited that the administrator has accepted -- "recommendations dealing with how we do science, how we plan, how we manage, and how we coordinate internally." According to Ms. Wentworth, a particularly relevant proposal to the quality assurance community was "the specific recognition that the culture of the agency needed to change so

that it valued science." She further added that "...science is not a corollary to our job; it is primary to our job." Another recommendation was that there needs to be QA in peer reviews for all scientific and technical efforts across the Agency, including the regional offices. The report and an implementation plan to respond to these recommendations were released to Office Directors in March.

A brief discourse on the manager's role in attaining the QA vision was then given. Ms. Wentworth emphasized that managers provide an example of quality by knowing the QA program requirements; providing guidance/assistance on QA issues to co-workers and the public; identifying emerging issues/problems that may be Agency-wide; and assisting QAMS in developing new QA tools for application across the Agency.

Ms. Wentworth then gave a summary of specific QAMS activities. She added to Fred Haeberer's speech on the EMMC by saying "...through the methods integration panel's quality control sub-committee, we're trying to standardize terminology and definitions for things like detection limits, quantitation limits, reporting limits, and that strange and mystical term, validation of a method. I bet there are 175 different definitions for validation. We are trying to bring some standardization and common implementation of that understanding across the Agency." She added that Gary Johnson was currently working on revisions to the management systems review guidance and the management/program plan documentation, and that efforts were being made to write a new data quality objectives guidance document for Henry Longest, the Director in the Superfund office. "We are also doing case studies in regions across the country to be able to append real examples of data quality objectives for soil cleanup, sediment, groundwater, etc. to this guidance document." Ms. Wentworth went on to describe several projects with the Department of Energy: data quality objectives, case studies, a compendium of radiological and mixed waste methods, and alternate designs for quality control programs for attaining different levels of defined data quality. She then mentioned a cooperative agreement with the National Academy of Science, Mathematical Sciences Division. "NAS is doing a program review of our quality assurance program and looking at whether the approaches we are taking in statistical design are successful in the context of teaching them an experimental design." Going back to the QA documentation issue, Ms. Wentworth commented that the first step in the development and oversight of the QA corrective action process is to make sure that the documentation is in place across the agency; the second step is to assess the quality of the programs.

Ms. Wentworth ended her presentation by reiterating the need to work together, and the importance of senior management involvement. She also emphasized the significance of success stories: "...this is one way to get positive attention, and improve your perception and standing in the Agency."

JACKSON HICKS
SUPERINTENDENT
WASTE TREATMENT AND ENVIRONMENTAL SERVICES
EASTMAN KODAK - TENNESSEE DIVISION

"TOTAL QUALITY MANAGEMENT: WHAT DOES IT MEAN TO THE ANALYTICAL LABORATORY?"

"Let's assume that you want to institute Total Quality Management (TQM) in your organization. My first question to you is why?"

Jackson Hicks explained that there is only one reason to embrace TQM: to improve your business. If you implement TQM for other reasons, such as to win the Deming or Malcolm Baldrige awards, to impress customers with the "avant garde" position of your business, or to use in advertisements, stated Dr. Hicks, "you are destined for disappointment. It will not sustain the process and will lead to unsatisfactory results."

How, then, do you begin? "I can't tell you exactly what to do; there is no secret step-by-step formula. If you follow some general guidelines, you can implement TQM effectively in your organization." Dr. Hicks continued on to give four basic principles for implementing TQM:

1. Never lose sight of the fact (and your focus) that you are improving your business and satisfying your customers.
2. Keep it simple and involve the total workforce.
3. Use all of the quality management tools that are appropriate to help accomplish what you want.
4. Be evolutionary rather than revolutionary.

He explained that the implementation process must begin at the top and filter down throughout the organization. Successful TQM cannot happen without involving all of the employees; and all employees can't be involved without total commitment from the top manager all the way down. "If the parts are to join and build a true framework, then the entire organization must embrace the concept."

Figure 1 on the following page represents a system of interlocking teams, the process that Dr. Hicks attributes as the reason for the success of the Waste Treatment and Environmental Services Department.

Figure 1
Interlocking Teams

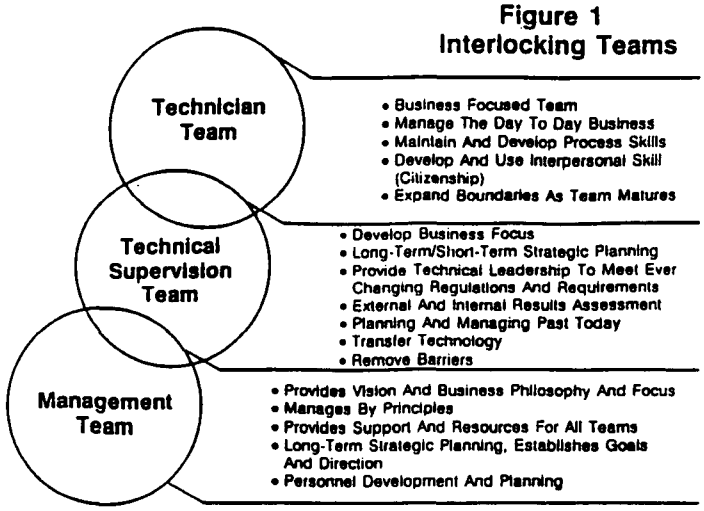
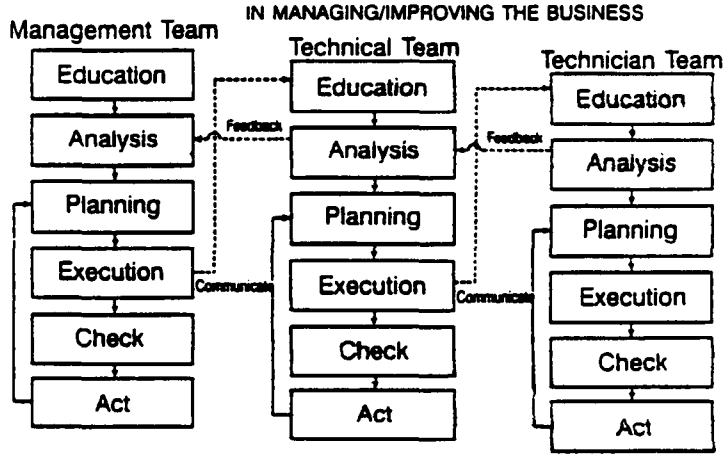


Figure 2 shows the method of implementing TQM, and outlines the major steps in the process for each team.

FIGURE 2
STRATEGY FOR INVOLVING EMPLOYEES
IN MANAGING/IMPROVING THE BUSINESS



The first step, EDUCATION, involves reading materials on successful TQM processes (Deming, Juran, etc.), watching videos that relay success stories of businesses, and visiting other companies that are using TQM. "Such visits help you see what others are doing, aid in developing support networks, and establish benchmarking. You will want to learn from the best, and shouldn't be afraid to steal shamelessly."

The second step is ANALYSIS. This stage involves conducting a business focus evaluation where the management team reviews the entire business of the organization. Management then determines what modifications are needed and focuses on what teams are needed and what boundaries should be established for these teams.

PLANNING is the third step. In this stage, the management team develops a list of business improvement plans and promotes a communication plan to share the concept at all levels. The plan contains provisions to providing training, education, and any additional resources that may be required.

The management team begins the Plan-Do-Check-Act cycle, and the plan is rolled down to the next level team until every employee has been involved. "This is not a quick process and may require several years to evolve. The entire process is evolutionary and is always changing as continual improvements are made."

While Dr. Hicks admitted that he could talk about the implementation process for "quite a while," he changed the topic back to what TQM means to the laboratory. In his own words, the TQM system represents:

- o Commitment v. Compliance
- o Make It Work v. Did My Part
- o Best Ever v. Standard
- o Continual Improvement v. Status Quo
- o Team Work v. Individual
- o Cooperation v. Competition
- o Celebration v. Chewing Out
- o A Way Of Life v. A Program
- o Every Employee As A Manager v. Management Control

"In TQM organizations, employees have input into decisions that affect them. They are given responsibilities and they accept accountability for their actions. They are not part of the organization; they <u>are</u> the organization."

Dr. Hicks stated that the <u>real</u> rewards and incentives to the employee was being a part of the process. "Ham biscuits, baseball caps, pins...they serve a purpose. But the real reward comes when a team feels real satisfaction and realizes, 'Hey, we've improved our process; we're part of the system!'"

Dr. Hicks continued to describe some accomplishments that have occurred since using the TQM system. "The result of team efforts is that during our last inspection involving our incinerator, our wastewater treatment operations, our analytical laboratory's support, the federal and state inspectors could not find a single item that was not in compliance. This had never happened before. Our analytical laboratory is responsible for collecting and analyzing all of the samples required to show environmental compliance. This amounts to over 11,000 points each year. During 1988, we lost 143 pieces of data; in 1989, we lost 148. These data points had to be reported to state and federal regulatory agencies as exceptions and were subject to regulatory fines. A team of our analysts and samplers then began a project to eliminate exceptions. They met their goal of 0 exceptions in 1990. Since the project began in January 1990, there has only been one exception, which occurred in March of 1991. To date, we have lost one piece of data in twenty-five months -- one piece out of 22,900."

An additional accomplishment, Dr. Hicks added, was the facility and investigation plan that Tennessee Eastman Division was required to develop in early 1990. "The services analytical lab initiated a plan to develop and implement a quality assurance project plan. As a unit team, consisting of laboratory supervisors, chemists, analysts, and sample collectors, they were asked to study the requirements and guidelines for establishing a project plan, and determine how the plan could most effectively be implemented. The team developed and documented a complete plan that would meet the requirements of written procedures, QA/QC checks, chain of custody procedures and forms, identification of personnel, etc. The plan was completed in less than six months and has been successfully integrated into the total laboratory program."

Dr. Hicks' last words emphasized the importance of Total Quality Management: "I believe that TQM will be sustainable because it is not a fixed system, but rather a system of continual improvement. It involves the best of many systems and it develops an atmosphere where individuals can take pride in their work and gain personal satisfaction from performing their jobs. It's a team approach where the organization's and the employee's needs can all be addressed. It involves the best of quality control and the integration of technology and sociology."

"Do I think TQM is for everybody? The answer is yes."

PANEL DISCUSSION

"Merging Quality into Science and Research"

MODERATOR:

GARY JOHNSON
QUALITY ASSURANCE MANAGEMENT STAFF
U.S. ENVIRONMENTAL PROTECTION AGENCY

PANELISTS:

DR. LINDSEY WOOD
TOTAL QUALITY MANAGER
REGULATORY AND CLINICAL DEVELOPMENT
PROCTOR & GAMBLE

DONALD SUMMERS
LOS ALAMOS NATIONAL LABORATORY

DR. LLEWELYN WILLIAMS
SENIOR SCIENCE ADVISOR
ENVIRONMENTAL MONITORING SYSTEMS LABORATORY
U.S. ENVIRONMENTAL PROTECTION AGENCY

OPENING REMARKS

GARY JOHNSON:

"Each of these gentlemen I will introduce will share their perspectives on the activity of merging quality into science and research. Our first speaker will be Dr. Lindsey Wood from Proctor & Gamble in Cincinnati. Lindsey will share his perspective on integrating quality and total quality management into the aspects of the health care division of Proctor & Gamble's research and development work. Following Lindsey will be Don Summers from the Los Alamos Laboratory, a 29-year veteran of quality assurance. Dr. Llew Williams, the senior science advisor at EPA's Environmental Monitoring Systems Laboratory in Las Vegas, will be our last panelist. Llew will present a perspective on merging quality in science from EPA's viewpoint.

Each panelist will give a 10-minute presentation. Following that, I will pose a series of questions for them to address. And lastly, we will open the floor for questions from the audience."

DR. LINDSEY WOOD:

Dr. Wood targeted the five key activities that must be in place to have a successful total quality program:

1. Strategy/Results Focus. "You have to combine the ideas of quality initiatives or research projects with improving systems or improving capabilities; and focus improvement efforts on the capabilities most critical to business results. For example, our management team made a list of processes that needed to be improved, and we geared our training around those suggestions."
2. Leadership. "The Director must be a leading advocate and a role model. He has to practice total quality, or the whole thing falls apart. Also, process improvements need to be part of the project reviews, and it is critical to get mid-level managers on board. And finally, you've got to get out there with concrete successes and actively market those to your organization."
3. Training. "Training, of course, is critical. We've used the Plan Do Check Act (PDCA) cycle, which is actually the scientific method restated. We use trained facilitators, because it's not good having amateurs teaching amateurs. And finally, you have to document progress and learnings that each group comes up with. Their current best approach must be circulated to the other groups, so different divisions aren't reinventing the wheel."
4. Innovation Teams. "The innovation teams must have the right people involved and the right team size. We recommend teams of six to ten people, so it's small enough to keep working, but not too big to get confusing. These teams must be empowered to make changes; management has to be prepared to let them run the experiment. And finally, successes have to be celebrated and rewarded. For instance, we have a project team of the year, and a process improvement team of the year. These are things where a team may get a dinner certificate for $100."

5. Measurement. "The teams have to be charged with clear objectives and result measures. We tally these up with monthly and quarterly progress reviews. In fact, participation in these teams and the results they get have become part of our written 'what counts' factors."

Dr. Wood summarized his presentation with some clear-cut results of using the success model. "What we've seen in health and personal care is a much sharper focus on the customer; better technology transfer; reduced cycle time; reduced costs; and improved employee satisfaction."

DON SUMMERS:

Mr. Summers used several personal experiences to relay the benefits of a quality assurance program. The first occurred in a facility at Los Alamos, where he studied a metal pressure vessel. "I didn't know what it was, but as a certified welder, I knew that there should be a weld on the neck of the vessel. I couldn't see it, but I knew it was there." He learned that the welder had not been certified and thus, the procedure was not qualified. "It defied QA principles. You have to have traceability to the materials, and you have to have a procedure qualification record. But there it was, and it was working." A quality assurance program in that particular situation, Summers told the audience, would have provided the necessary documentation for others to come along and repeat the process. It would, in essence, have allowed "the information to be passed on, other than by word of mouth, to the people who were going to come behind them."

Another more recent incident took place while Mr. Summers was meeting with individuals who performed criticality experiments. One of the group leaders asked him why they needed quality. In response to Summer's request, the leader explained that they built devices that detected radiation, each of which cost millions of dollars. She further added that "they had no design control, but they knew what they were doing." After delving a little deeper, Summers learned that they did, indeed, have design control -- in the form of peer review meetings.

Summers concluded his presentation by emphasizing that scientists and the community have to look at what they're doing and recognize the merits of a formal quality program. He added that you can't push a quality program, but if you start working with people and leading the process, it <u>will</u> work.

LLEWELYN WILLIAMS:

Llew Williams opened his presentation by citing several misconceptions about quality assurance:

1. That it assures quality. "...quality assurance procedures don't assure quality; people assure quality."
2. That quality can be legislated.
3. That elevating quality is all positive. "If you elevate

quality assurance to a great independent operation, you take the responsibility away from the individual at the bench. He is the person responsible for quality."

4. That quality is more a millstone than a milestone. "They don't feel that the imposition of quality assurance procedures on their research will improve what they are doing. They only feel that it will be decreative and slow them down."

The topic of discussion then turned to the barriers to quality and science. The first barrier, according to Williams, is the lack of management commitment. "This may be a very personal lack of commitment, even in the face of an organizational statement." Lack of vision and visualization was also cited as a problem. "Vince Lombardi once said that if you can't visualize the result of a play, of exactly how it should look if it's successful, you will never be able to coach it successfully." A third barrier mentioned was a poor understanding of what quality is. "Documentation is great to show what we've done, but if we can stress the fact that by bringing quality to our scientists, we can bring them an enhanced level of satisfaction in their work, we may be able to hook them." Finally, the disintegration of personal value systems such as pride in workmanship, job satisfaction, and client satisfaction, was named. "If there are low quality expectations, then people are willing to accept less. A problem in maintaining high personal values in light of some of the institutional values (those that stress profit at the expense of quality, and an obsession with liability), is that they have a quality assurance program for all the wrong reasons."

Llew also included several recommendations for changing these values: quality-oriented training and education; inspirational leadership; creating a low-risk environment to bring out creativity; rewarding quality ethics; and synchronizing personal institutional visions.

The presentation ended with a poem:

The operative word is quality,
And oh, what a mess we are in,
'Cause everyone want in, they all look at us,
And we don't quite know where to begin.
You see, quality's not just the seal on the lid,
Or the slop in the pocket of slacks;
And there's no guarantee that you'll get what you want
At a K-Mart, a Sears, or a Saks.
But ask them, "Exactly what is it you want
In a product, a service, or such?"
Any they'll likely respond with the strangest of looks
And insist that "You're asking too much!"
"Just dial in the settings and turn the thing on,
Then there won't be a human to err."
So we dial in the settings, and we get the garbage out,
Cause there wasn't a human to care.

QUESTIONS

Quality is frequently seen by scientists and researchers as not being applicable to them. What ways or approaches have you found to be successful in raising the awareness and appreciation of quality among these groups?

LINDSEY:

"At the start of training, we have everyone do a time log for a week to determine how much time they spend doing the right thing right. It turned out that many of the groups came out at 60 to 70%. Then we turn that around and say, 'wouldn't you like to have 40% more time to do research and not do these things that aren't of value'? Scientists turn on to quality when they realize that it's going to give them more time to do creative science. We focus on that and sell it as a benefit."

DON:

"We use the same approach that Lindsey mentioned. We emphasize that a good quality program will allow them more time to do their science and research, but it will also help them reproduce what they've done."

LLEW:

"Many researchers have a difficult time dealing with data quality objectives and their application to a tree-like structure where there are a lot of decisions in research and no fluid operation. I ask them to partition their work, look at each critical decision point and what kind of information they need, and decide what level of quality they are going to demand. Once they've divided it into pieces, suddenly the data quality objective concept works."

What do you see as some of the specific obstacles or barriers that hinder the acceptance of quality among scientists and researchers? Do you think these barriers are real or are they merely perceived?

LINDSEY:

"One obstacle is the familiar 'I already do good work.' Another is that some scientists feel that quality implies a loss of control. To answer the second part of the question, I would say that because barriers are perceived, they are real."

DON:

"The biggest obstacle in promoting quality is that we have a quality control inspector with two years of experience telling the superintendent with thirty years of experience how to place concrete or structural steel. We drove up the cost tremendously. Quality costs too much money -- at least that's the perception. We have to promote quality as making money, or at least saving money. And it can be done."

LLEW:

"The major barrier is getting scientists to understand what quality can do for them. One area to explore is the concept of quality assurance teams, where the objective is to leave the scientist improved in the way that he doesn't do things just to satisfy your bookkeeping as a quality assurance professional."

Much of what we see and hear with respect to total quality management places great emphasis on measuring success. Is it practical to emphasize performance measurement in R&D, given the inherent uncertainties involved. If so, how can research performance be measured in a meaningful way?

LINDSEY:

"What we need to do in R&D is break things down into bite-sized pieces. Look at what you can measure to determine if your processes are getting more successful: turn-around time, milestones to meet, percentages, etc. It's not good enough to say that it's impossible to measure research. It is, but it's not easy."

DON:

"In an R&D environment, total quality management and quality assurance will provide the ability to reproduce what has been done. So many times in an experiment, the final result pops out, but we're not sure how it happened. So we have to go back and duplicate it. But once again, R&D is very difficult to measure."

LLEW:

"I think that if we're going to measure and monitor, we've got to take a giant step back and ask why we're measuring and monitoring. We have to find a way to feed back those measurement monitoring processes in a way that is clear to the scientist that this is done on behalf of and in support of his science."

Traditional R&D depends greatly on peer review as the means of determining the quality or acceptability of a research product. In what ways can quality be more effectively integrated with the peer review process?

LINDSEY:

"We don't have any real problem with peer review fitting into total quality; they're integrated. As part of the plan cycle, it's automatic."

DON:

"If you get quality established when you start determining the design phases, and start the review process at the same time, the project will be successful."

LLEW:

"Peer review should start at the conception and design of an experiment or study. Bring in someone from the outside to determine if you're doing things right. But, bring him in early."

DATA QUALITY ASSESSMENT

"DATA QUALITY ASSESSMENT"

Tuesday afternoon's presentations were devoted to the topic of Data Quality Assessment (DQA). The chair, James Stemmle from the Quality Assurance Management Staff, explained that QAMS is heavily involved in DQA, and is currently developing guidance for agency-wide use. Having recognized that assessment of data quality is "going on everywhere," several important areas were targeted for discussion. The first area was presented by Dan Michael of Research Triangle Institute (RTI) and Fred Haeberer of QAMS. Mr. Michael focused on RTI's support to QAMS' current activities and ongoing research, while Dr. Haeberer discussed QAMS' vision. Following that was "Assessment of Data Usability in Superfund" from Larry Reed, Office of Emergency & Remedial Response; "Assessing Data Quality for Agency Pesticide Decisions" from Richard Schmitt, Office of Pesticide Programs; "Assessment of Error in Soil Data" from Jeff van Ee, Environmental Monitoring Systems Laboratory, Las Vegas; and "Using Power Analysis to Assess Office of Water Data Quality" from Robert Graebner of TetraTech.

Later in the afternoon, following the presentations, six facilitated discussion groups convened to discuss and formulate answers to five questions. Each group then designated a speaker to address their response to the question.

DANIEL MICHAEL
RESEARCH TRIANGLE INSTITUTE

Dan Michael began his presentation by asking, "Why worry about data quality?" He answered this question by giving several reasons: 1. To preserve the integrity needed in the product we're delivering; 2. To ensure customer satisfaction (spend time developing measures of performance that reflect the customer's needs); 3. To maintain credibility (failure to generate data which allows us to take action decreases our believability); and 4. To make acceptably accurate decisions.

Expanding upon these reasons, Mr. Michael stated that "data of inadequate quality will lead to higher probabilities that we fail to take action when we should or we take actions inappropriately when our budgets and our taxpayer's precious dollars could be better spent somewhere else. If we fail to take action when we should, we are exposing the public to unacceptable risks. So, the consequences of making incorrect decisions cause us to focus on data quality."

Mr. Michael then defined data quality assessment (DQA) as "a process for evaluating a data set to determine whether the data are appropriate for supporting a specific decision." He emphasized that "supporting a specific decision" provides the relative criteria to establish what quality means. "The key is the strength of the decision and our ability to compare data or a data set to some performance standards so we can determine if those data are appropriate." DQAs that include the level of uncertainty that is acceptable to the data user, he added, are important to the whole process of data quality assessment.

The audience learned that the data quality assessment process contains three forms of input: Data Quality Objectives (DQOs), Data, and Statistics. As planning inputs, all three represent the "DO" or "EXECUTE" phase of the PLAN-DO-CHECK-ACT cycle. Mr. Michael examined each input to determine its composition:

1. **Data Quality Objectives:** "The outputs of the DQO process include a statement of a problem or decision to be addressed, the input variables, the characteristics we need to measure, and the criteria against which we are going to compare them to the boundaries of where and when we are going to sample. The decision rule addresses how we are going to use data." The answer to this question, Mr. Michael says, is in how we are going to use the data to make a decision and in determining how much uncertainty can be tolerated in that decision. "Did we collect data that would describe/define the correct variables? Do we have the variable that we need? Were they collected in the right location to represent the scale from which we want to make the decision? According to Mr. Michael, these are all important criteria against which the final data set should be measured.
2. **Data:** "We have to think about how data are generated and about the error that can creep into the data set throughout the

data collection process. The questions are: What amount of error exists in one of those numbers? How does that affect the overall total study error which is going to affect the degree of certainty that we have in making a decision?" Mr. Michael emphasized that if total error is too great because not enough samples were taken or there was too much error in the subsampling or analytical process, then the next question must be: Where is the major source of error in this particular study and what do we do about it?

3. **Statistics:** "We need to think about the assumption that the data corrected for bias can serve as a zero bias data set, which can then be used in a statistical test. Perfection in environmental studies is finding out how the substance that we're looking at actually varies in nature." Mr. Michael conceded that studies will never be completely error-free, even when using extensive sampling and the best technology for analyzing data. He added that "what we need to know is just how variable the data are and what effect that variance has on making the right decision."

Mr. Michael then discussed key issues and challenges for achieving QAMS' vision of data quality assessment. "We look at it in two domains: the technical side and the management side. From the technical side, we know what information and data are required to perform the data quality assessment. It's not a very straight-forward answer, because it depends on how you define the goals of that data quality assessment, and if you can diagnose any problems that may be contributing to the problem or insufficiencies. On the management side, we need to develop management procedures and communication tools to ensure success. Obviously, getting to the bottom line can be a somewhat threatening process. If you had never known that there was more uncertainty in data than you would have been satisfied with, then why should you want to know it now? It's through the process of analysis and education that we hope to overcome these potential snags."

Another key issue involves statistics. According to Mr. Michael, QAMS' statistical vision can be achieved by formulating the right hypothesis (making sure the decision is based on the answer to the right question -- is it stated succinctly enough to determine whether there are adequate data to prove or disprove the hypothesis?); determining acceptable error rates; establishing the best statistic to be used (ones that will be appropriate, given valid assumptions); and evaluating whether the statistical design assumptions are valid.

A third issue/challenge is total study error. Several recommendations include estimating total study error directly by looking at the generated data set and noting its distribution and variance; identifying the components of total study error (what must be in place in the QC program to ensure enough data to estimate the major sources of error?); determining when estimates of the error components are needed and building that into the design of the programs so the QC data will be readily available;

and evaluating which components contributed the most to total study error.

The last issue discussed came under the heading of management:

1. Communicating with the statistician (when and how do we ask for this type of assessment?)
2. Interpreting and using the results (how are we going to ensure that they give us the answers to the questions that most affect us?)
3. Defining the roles and responsibilities among participants
4. Recognizing and overcoming the threats and obstacles to DQA.

FRED HAEBERER
QUALITY ASSURANCE MANAGEMENT STAFF
U.S. ENVIRONMENTAL PROTECTION AGENCY

Following Dan Michael's discussion on the issues and challenges impacting data quality assessment, Fred Haeberer presented the actions that QAMS is taking to address those issues and challenges. He emphasized four main areas of action: Retrospective DQA, Total Study Error Analysis, Improving QC Design, and Future Work.

Under the first area, Retrospective DQA, Dr. Haeberer defined the development of statistical procedures and the cultivation of a user-friendly guide for project managers as the near term actions. A report on statistical procedures has been drafted by the Research Triangle Institute (RTI), and plans are being pursued for an updated version, with input and comments from various reviewers. The user-friendly DQA guide has not yet gotten off the ground, but it is on the current agenda. Long-term plans include performing retrospective analyses based on case studies using existing data sets. "Our idea is to demonstrate the methodologies that we propose in the guides in the statistical procedures and to assure ourselves and you that they do, indeed, work."

Beneath the heading of Total Study Error Analysis, Dr. Haeberer explained that RTI completed a working diagram of error partitioning last year. "We've got the estimation procedure and equations documented at this point, and our long-term goals are to go into existing data sets to perform case studies, and to assure ourselves that these partitioning procedures actually work."

Under Improving QC Design, Dr. Haeberer stated that QAMS is "...trying to link the QC of sampling and laboratory analyses to what is actually required by the data user. The intent is to design the QC operations so that the resulting data will support the decisions by achieving the required error levels. Our long-term goal is to develop QC design procedures that can be used with the DQO process to directly address management's concerns and to come up with designs that address, and are responsive to, the data quality criteria and data quality constraints that management requires."

Dr. Haeberer stated that Future Work would include documenting the lessons learned from analyzing case studies. He then encouraged individuals with relevant case studies or data sets to join in a collaborative effort of QAMS working with its customers.

LARRY REED
HAZARDOUS SITE EVALUATION DIVISION
OFFICE OF EMERGENCY AND REMEDIAL RESPONSE
U.S. ENVIRONMENTAL PROTECTION AGENCY

"ASSESSMENT OF DATA USABILITY IN SUPERFUND"

Larry Reed works as the director of one of the four divisions at the Superfund Headquarters office. His division, the Hazardous Site Evaluation Division (HSED), runs the front end of Superfund, "providing policies, guidances, and services to the regions, which implement Superfund clean-ups." In a brief description of Superfund, Mr. Reed stated that "Superfund is not a delegated program. Unlike many of the other environmental programs that have a delegation requirement or process built into the statute, we don't have such a thing. We're trying to build a state partnership within the limits of the statute, but much of what we do in Superfund, we either have to do with the regions or contractor staff."

The Superfund process begins with Preliminary Assessment/Site Investigation (PA/SI), where the site is ranked using the Hazardous Ranking System (HRS) to determine if the site should be on the National Priority List (NPL). Relative questions of this phase of the process are: Is there a release? What is it? What are the pathways of exposure? After the site is placed on the NPL, the Remedial Investigation/Feasibility Study (RI/FS) process begins under the direction of the Hazardous Site Control Division (HSCD), which ultimately leads to a Record of Decision (ROD) regarding the disposition of the site. HSED provides analytical services by the Analytical Operations Branch (AOB) through the Contract Laboratory Program (CLP), while risk assessment guidance and services are supplied by the Toxics Integration Branch. Relevant questions include: What are the contaminants of concern? What are their concentrations? What are their boundaries? Is there danger to the public health or the environment? Where should we place monitoring wells? Additional questions for the baseline risk assessment during the RI/FS are: What are the exposure pathways? What is the exposed population? What is the estimate of magnitude, duration, and frequency of exposure for each receptor group? Are there contaminants with toxic effects? Are they at levels that are a problem? Record of Decisions are based on answers to: On what analytes should we focus remediation? What level is our clean-up goal? What interferes with our proposed remedies? The third phase, the Remedial Design/Remedial Action, begins when a ROD has been developed. During this construction and clean-up period, analytical services are provided by HSED. Questions of concern are: Is it clean? Is it still clean?

"In addition to providing contractor services for analyses of samples, and methods development to keep up with Superfund needs and state-of-the-art technology, HSED is also responsible for providing guidance for data assessment."

HSED first provides Contract Compliance Screening for all CLP data. This process uses a computer to check contract deliverables against the requirements, and determines appropriate payment for services. HSED also develops, maintains, and updates "Functional Guidelines for Review of CLP Data," a document that establishes a standard way to evaluate and review data and qualify it for use.

Another guidance, RI/FS DQO, was produced in 1986 to take advantage of the data quality objective (DQO) process by: 1. determining what to do with data that had not been collected using DQOs, since there was no predetermined level of uncertainty for sampling or analysis; and 2. identifying data quality needs for major Superfund uses.

In 1988, HSED initiated the Data Usability Workgroup, which produced the draft guidance for "Data Usability in Risk Assessment." Designed to "provide data users with a nationally consistent basis for making decisions about the minimum quality and quantity of environmental analytical data that are sufficient to support Superfund decisions," this guidance helps identify performance measures and sets acceptable limits for confidence level, power, and minimum detectable relative difference. It also provides strategies for designing sampling plans and describes how to select an appropriate sample design strategy for these questions: What is present and how much? Is it different from the background? Are all pathways identified and examined? Are all pathways fully characterized? "Data Usability in Risk Assessment" has completed peer review and is currently being finalized.

An additional guidance, "Data Usability in Site Assessment," was sent out for review in October of 1991. It covers planning and assessment issues related to the generation and use of analytical data, and provides "generic data use categories with specification of analytical data quality parameters required for that use category." Relevant questions in this guidance are related to ground water releases to aquifers, surface water releases to surface waterbodies, soil exposure contamination of surface materials, and air releases as gases or particulates to air.

Mr. Reed stated that "Our message to you is that HSED is dedicated to identifying appropriate data needs for Superfund and providing analytical services to meet these needs, including analyses, planning guidances, and assistance/guidance in assessment of the data."

Mr. Reed concluded his presentation by emphasizing that the Hazardous Site Evaluation Division would like to know the audience's perception of the Data Usability Guidance: What would they like to see in the guidance? How can the HSED help identify and get the right data for their uses?

RICHARD SCHMITT
HEALTH EFFECTS DIVISION
OFFICE OF PESTICIDE PROGRAMS
U.S. ENVIRONMENTAL PROTECTION AGENCY

"ASSESSING DATA QUALITY FOR AGENCY PESTICIDE DECISIONS"

Mr. Schmitt started his presentation by explaining the function of the EPA's Pesticide Programs. He stated that although these programs do not generate much data, they do review large volumes of data. The reason for this, he added, was that the Office of Pesticide Programs registers pesticides (registration is basically a license to sell a pesticide in the United States). "Before a pesticide can be sold or distributed in this country, it must be registered by EPA. And before this can happen, we require that chemical companies such as Dupont develop enough data to allow us to decide if the pesticide is safe."

The discussion then turned to the types of data that the Office of Pesticide Programs (OPP) reviews: Product Chemistry - reviews data on the composition of pesticides, including concentrations of impurities such as dioxin; Residue Chemistry - reviews data on the chemistry of the pesticide related to residues in food such as beef; Product Performance - evaluates information that is required to make sure that a product works (e.g. kills the weed as it should); and Plant Performance - data to show that the pesticide will not harm the crop it is trying to protect.

In terms of data volume, Mr. Schmitt explained that OPP receives roughly 12,000 studies a year, ranging from a few pages on the physical properties of a pesticide to a four-foot stack of data on a long-term chronic feeding study for toxicology purposes. "There are about 650 pesticide chemicals currently registered, thousands of inert ingredients [chemicals that are added to pesticide formulations, but are not active by themselves], and about 24,000 pesticide products registered by the EPA."

The final section of the presentation was devoted to the question, "How do we assure that the data we get are of the right type and quality?" Mr. Schmitt explained that they utilize nine QA-related activities:

1. Regulations/Guidelines. "Title 40 of the Code of Federal Regulations (CFR), Part 158, contains a list of studies that the Office of Pesticide Programs requires for registering a pesticide. It lists the types of studies, and gives information on when the studies are required. Different types of data are required for different types of usage. For instance, a pesticide that's used to protect the seed while it's in the ground has different data requirements than a pesticide that is supplied by an airplane to a growing crop. The location or use of the pesticide is also an important factor in determining what data

requirements are necessary. An indoor pesticide, such as a cockroach spray, for example, has entirely different data requirements than a pesticide applied to soy beans, where contamination of the environment is more likely. We require an even larger data set for food pesticides, including large residue data and toxicology data requirements."

2. Data Reporting Guidelines. "The data reporting guidelines are an addendum to each set of guidelines, and are used as instructions to the data generators on how to format their studies. The purpose of these guidelines is to make sure that all the data are included in the study, and are easy for the scientists to find."

3. Standard Evaluation Procedures. "The standard evaluation procedures are a set of guidelines that instruct our OPP scientists how to review the studies. We developed these procedures so that two scientists reviewing the same study would come up with the same conclusion."

4. Phase III Guidance Package. "The Phase III Guidance package is a recent set of criteria designed to instruct the people who develop data on how to decide if EPA will reject the study. These were developed for what we call re-registration."

5. Re-Registration Conferences. "Since data requirements were less stringent 20 or 30 years ago, Congress has mandated that EPA bring the databases for these chemicals up to standard. Chemical companies cannot sell their pesticides and make a profit until EPA registers the pesticide. That, in itself, is a strong incentive to develop good data. For products already registered and currently being sold, there is little incentive to develop good data to keep them on the market, because EPA is not very good at taking pesticides off the market. So, we developed what is called acceptance criteria. Registrants must use these criteria to decide if their data are acceptable. If they submit a study they think is acceptable, and we decide it's not, then we can take their product off the market."

6. Screening Procedures. "...a series of screening tests that registrants must pass before we accept their data. These consist of administrative screens and science screens. Administrative screens ensure that the submissions are complete, legible, and contain all the confidential business information and good laboratory practice forms that we require. Surprisingly, about 80% of submissions for new chemicals fail this administrative screen. Science screens make sure that all the required studies are there, and data are suitable for review."

7. Good Laboratory Practices (GLP). "We require GLP certification for each study. We cooperate with our Office of Compliance Monitoring in carrying out laboratory and study audits. If one of our scientists sees a study that looks suspicious, we will recommend to the Office of Compliance Monitoring that the study be audited to check for legitimacy."

8. Study Rejection. "If the study is not up to our standards, we will not register the pesticide. In some cases, information is left out on how the study is conducted; in other cases, they may have to go back to the laboratory and generate additional data or analyze more samples. Or, in extreme cases, a whole study may have to be repeated."

JEFF VAN EE
ENVIRONMENTAL MONITORING SYSTEMS LABORATORY, LAS VEGAS
U.S. ENVIRONMENTAL PROTECTION AGENCY

"ASSESSMENT OF ERROR IN SOIL DATA"

Jeff van Ee focused his presentation on the subject of bias and variability in soil sampling: types of, ways of identifying, assessment of (using QA/QC), and methods of reducing.

He began with measurement quality objectives, a relatively new term similar to data quality objectives (DQOs). The chief difference between the two, however, is that DQOs "apply to the bigger part of the problem," (i.e. to the total acceptable error -- design, sampling, and measurement) while measurement quality objectives focus on a smaller sampling site. "A data quality objective might be posed to you that someone wants to know the average concentration at a particular site with a certain degree of confidence and accuracy. But, depending upon where you go at that site and how you sample, you could get any number you want." With measurement quality objectives, new terminology has been introduced to narrow the sampling field. One term, exposure unit, refers to pinpointing a certain area of concern. "Depending upon how the contaminant is distributed across the site, you can get any number. So, during the process, we bring in statisticians, soil scientists, and the people making the measurements in the lab, and try to narrow the process down to: what area of the site do you want to know the average concentration and to what degree of confidence?" Another term is called remediation unit. "The concept is if there is contamination, how small of an area does it have to be in before you will do something about it? With the heterogenous nature of soil, you can have contamination in a very small volume, contamination that may be missed by your sampling grid design, or because of the particular tool you're using to collect samples. We try to pin people down and say, 'OK, if we were to miss a hot spot in our sampling design, what size would it have to be before it's a cause for concern?'"

Mr. van Ee then mentioned a document that the Environmental Monitoring Systems Laboratory (EMSL)-Las Vegas has recently completed. As the lead author, he describes the purpose of the document: "It defines the numerous sources of bias that can occur in a soil sampling study. Since assessing bias in a soil sampling study can change over time, from contractor to contractor, and laboratory to laboratory, we're hoping to assess the total measurement bias in sampling and analysis." He emphasized that variability and systematic error (i.e. bias) can be the result of specific choice of tools ("...contaminants are typically spread across particle size distributions, and depending upon the type of sieve you use, you could be rejecting all of the contaminants"); handling, transportation, and preparation of the sample; and the analytical laboratory.

"By pairing samples--taking a routine sample and taking a sample right next to it, which we call a field duplicate--and analyzing those samples separately, we can begin to get a handle on some of these sources of variability." According to Mr. van Ee, these sources can be identified by using blank samples and field evaluation samples. He added that the only way to control variability is to determine the cause of that variability. This can be partially achieved by a new computer program called ASSESS. Modeled after a spreadsheet, ASSESS enables the user to assess errors in the sampling of soils, and thereby identify possible locations of bias and variability in the sampling system.

To wrap up, Mr. van Ee mentioned several tools that can be used to solve the bias and variability problem in soil sampling:

1. "Guide to Site and Soil Description for Hazardous Waste Sites Characterization"--a document that contains over 900 definitions related to soils;
2. "Characterized Site Specific QA/QC Materials"--a new type of QA/QC samples that consists of contaminated soil that very closely represents the site being investigated; and
3. "From Risk Assessment to Remediation," a CD ROM that holds all current guidance.

ROBERT GRAEBNER
SENIOR SCIENTIST
TETRA TECH

"USING POWER ANALYSIS TO ASSESS OFFICE OF WATER DATA QUALITY"

Robert Graebner focused his presentation on the use of statistical power analysis, the desired evaluation of environmental monitoring programs, and the role of power analysis in data quality management.

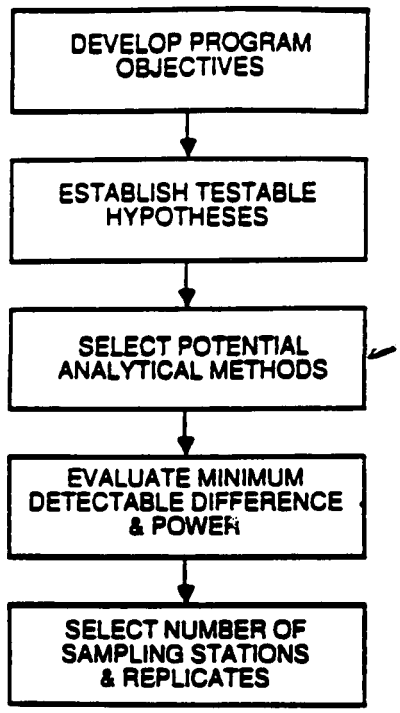
Mr. Graebner introduced the topic by stating that "sound management decisions require data that are not only accurate but sufficient." In other words, having data that are accurate is of little use unless there is enough to produce a statistically sound decision. He further expressed a strong belief in getting managers and statisticians involved early in the planning process so they can easily understand the system itself, the components of the system, and how the components interact. This allows managers to provide full knowledge on the type of decision to be made - a decision vital to designing an effective environmental monitoring system.

Mr. Graebner then described the five basic steps to designing an environmental monitoring program as:

1. **Developing program objectives.** This also includes defining objectives and making decisions that concur with these objectives.
2. **Establishing testable hypotheses.** This involves determining the questions that must be answered to support sound management decisions, and then restructuring the questions into testable hypotheses.
3. **Selecting analytical methods.** This includes selecting analytical methods with the interaction of engineers, scientists, and statisticians so that valid assumptions can be made prior to sample design and collection.
4. **Evaluating minimum detectable difference and power.** This step involves setting the criteria for data quality in terms of an acceptable level of significance and power, and an acceptable minimum detectable difference.
5. **Selecting the number of sampling stations and replicates.**

The remainder of the presentation focused on describing basic statistical concepts to demonstrate the value and importance of statistical power analysis in assessing and managing environmental monitoring data. The following six pages show how Mr. Graebner demonstrated the application of statistical power analysis in assessing data quality.

ENVIRONMENTAL MONITORING PROGRAM DESIGN



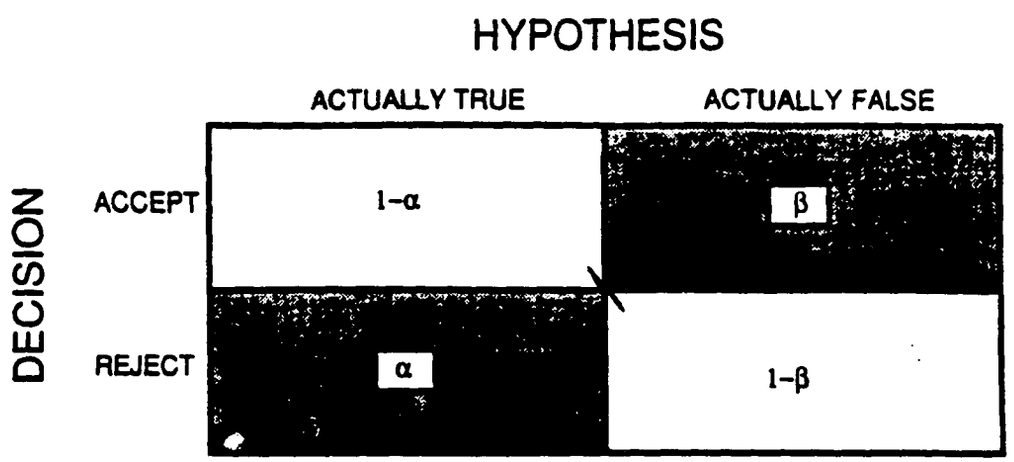
ANOVA STATISTICAL MODEL

$$Y_{ij} = \mu + \gamma_i + \epsilon_{ij}$$

Where:

- Y_{ij} = Observations at Station i & Replicate j of, for example, the concentration of a selected chemical
- μ = Mean of all Y_{ij} observations
- γ_i = Effect of the i^{th} level of an environmental factor (e.g., station location)
- ϵij = Random errors not accounted for by either μ or γ_i

HYPOTHESIS TESTING: POSSIBLE CIRCUMSTANCES AND TEST OUTCOMES



STATISTICAL POWER ANALYSIS

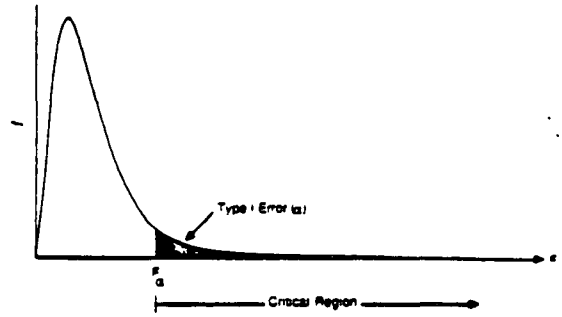
ENVIRONMENTAL PROTECTION PERSPECTIVE

- **TYPE II ERROR (β) Real differences exist but are <u>not detected.</u>**

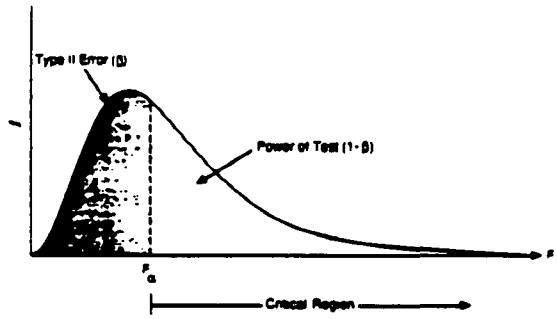
  e.g. - A bioaccumulation monitoring program may fail to detect elevated concentrations of contaminants in fish tissue.

- **STATISTICAL POWER (1-β) Probability of correctly detecting differences.**

PROBABILITY DENSITY OF THE F STATISTIC

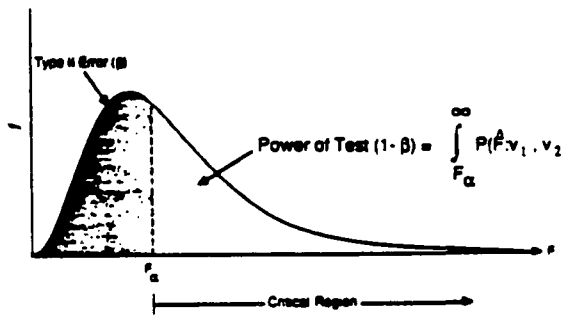


(a) Probability Density of F When Null Hypothesis is True



(b) Probability Density of F When Null Hypothesis is False

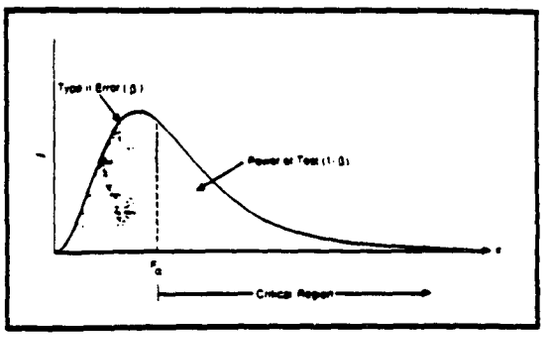
POWER CALCULATIONS



where:

- ν_1 = **numerator degrees of freedom**
- ν_2 = **denominator degrees of freedom**
- λ = **noncentrality parameter**

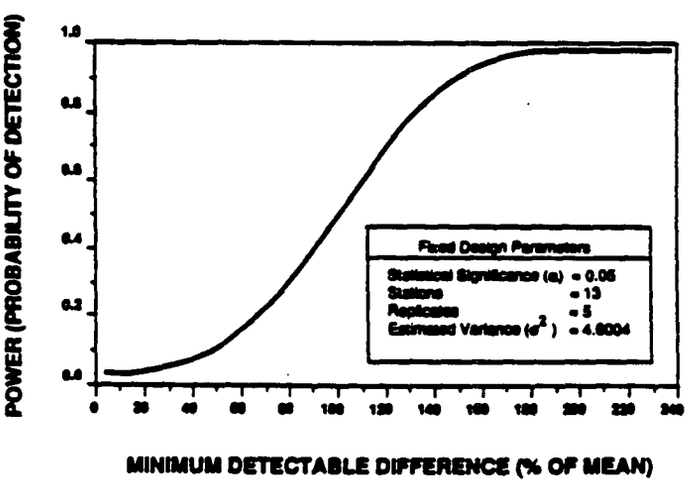
ODES STATISTICAL POWER ANALYSIS



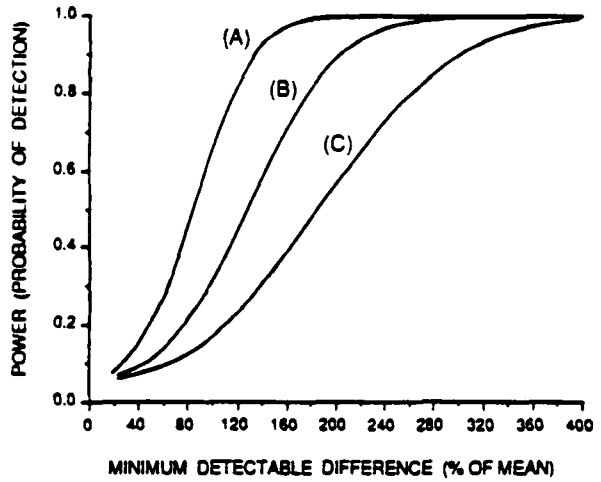
MARCH 1986
PREPARED FOR:
MARINE OPERATIONS DIVISION
OFFICE OF MARINE AND ESTUARINE PROTECTION
U.S. ENVIRONMENTAL PROTECTION AGENCY
WH-556M
WASHINGTON, DC 20460

PROBABILITY OF DETECTION vs. SPECIFIED LEVEL OF DIFFERENCE

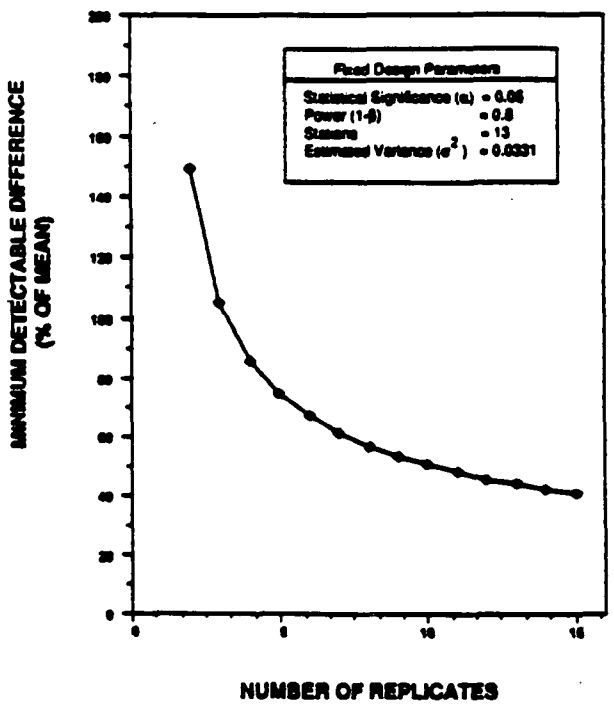
Pectinaria californiensis



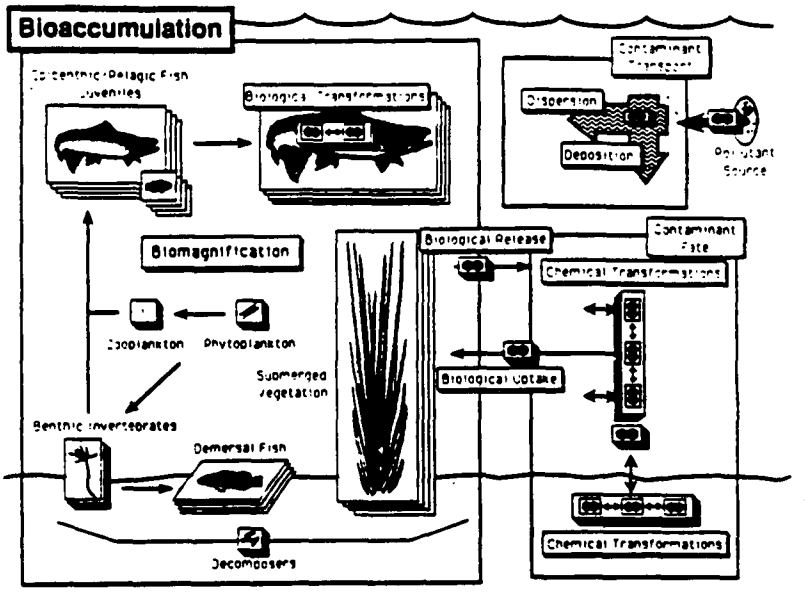
EFFECTS OF INCREASED SAMPLING EFFORT ON THE POWER OF THE ONE-WAY ANOVA. NUMBER OF REPLICATE SAMPLES AT EACH STATION: A=10, B=5, C=3



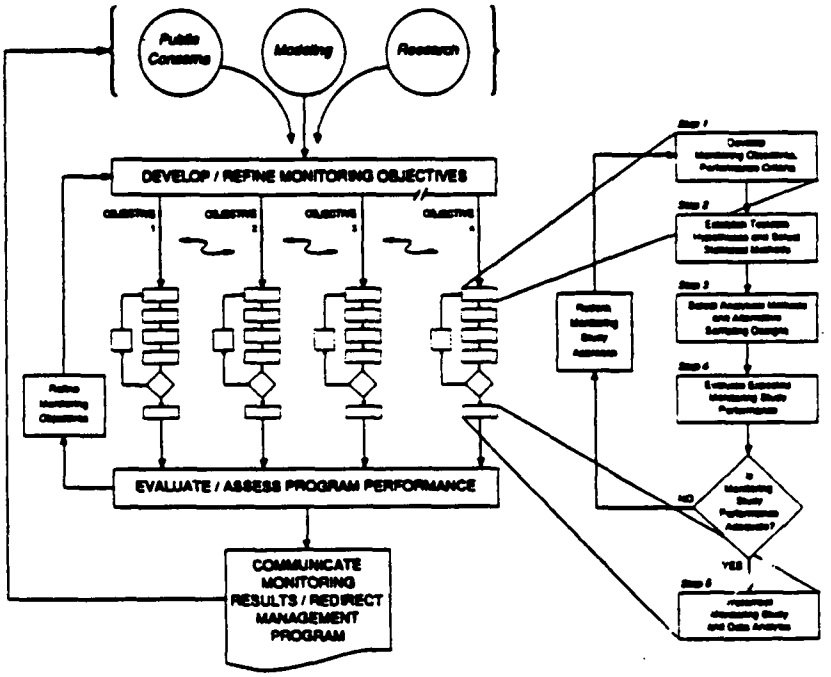
MINIMUM DETECTABLE DIFFERENCE IN THE ABUNDANCE OF *Pectinaria californiensis* vs. NUMBER OF REPLICATES



Conceptualization Tools



Monitoring Guidance for the National Estuary Program



AWARD BANQUET

RALPH R. BAUER
DEPUTY REGIONAL ADMINISTRATOR
REGION 5
U.S. ENVIRONMENTAL PROTECTION AGENCY

"When Nancy asked whether I would come this evening and address you, the answer had to be yes. I think the best way to demonstrate my commitment to quality in the agency is the way I spend my time.

I would like to address the question of who the customer is for the Federal Government, but I'd also like to speak to some broader issues: managing environmental data quality and its relationship to customers and suppliers and measuring environmental success. I have devoted a fair amount of effort over the years to get the agency to focus on environmental results rather than activities. If you will indulge me, I'd like to talk a bit about that.

The whole context of my remarks will be couched in terms of TQM. Since I am presently the Chairman of the agency's Quality Improvement Board, I'm on a mission to talk about TQM and its implementation in EPA. In that context, I will try to weave in who the customer is.

Most of you know that EPA is the first agency in the Federal Government that is committed to implementing TQM from top to bottom in all of its organizations. Now, why is that? Why should we do that? At a meeting held about a year ago with the Regional Administrators and Assistant Administrators, they invited David Nadler to speak. Mr. Nadler is one of the principals of Delta Corporation, an outfit in New York that specializes in leading companies through big changes. When Mr. Nadler was asked, what does it take to make TQM go in your organization? he responded that the 'only place he had seen TQM successfully implemented was in organizations that felt they had no choice; that were going under if they didn't.'

That's certainly true of the private sector. What are the hallmarks of quality in the private sector? Being a successful company? The Fortune 500? One of the measures we use is whether the companies are successfully competing in this country. If you look at the list of companies that were in Fortune 500 from 1978 to 1988, 40% of those that were in Fortune 500 in 1978 were not there in 1988. That's how rapidly things change. Another indication of quality in the United States comes from Peters and Waterman, the authors of <u>In Search of Excellence</u>. They profiled 44 companies that were considered to be the essence of quality. Of those 44 companies, only 14 still meet the test of excellence, according to the criteria of Peters and Waterman. Why is this happening? Why are all these companies going out of business? I think the answer is in a single word: CHANGE.

What are some of the things that cause us to want to get behind this quality move? The first is the fiscal crisis that this country faces. Our industry is certainly hard pressed to compete in an international market. So, what are the implications of that to us? Rosabeth Kanter, the Editor of the Harvard Business Review, uses the analogy of the croquet tournament in Alice in Wonderland to describe the situation: the mallets turn into flamingos, the wickets grow, the Queen is yelling 'off with her head,' and they're constantly changing the rules on people.

I think that's a reality of the business climate. If we want to have a strong economy in this country, we at EPA are going to have to be more responsive to our customers. Another one of the fiscal crises is with our state agencies. Many of them are in financial duress, and I think the problem will get worse. I'm told that we may receive back some of the programs that have been delegated to our states, because they simply can't shoulder the load anymore. The states are another one of our principle customers, if not the principle customer. And what do they need from us? They need for us to eliminate a lot of the inspections we do. If I were with the state, I think I would get very tired of EPA continually inspecting everything we do.

We've got to look at these customer/supplier relationships between us and the states and decide what can be eliminated. Significant changes can be made. For one, we're going to have to address the impending change in the workforce. There's going to be a large increase in the entering workforce of women and minorities. Statistics say that by the year 2000, white males will represent only 15% of the new entrants in the workforce. Also, young people today are not driven by the same workaholic attitude about work that my generation suffered under. They're looking for more balance in their lives, more of a say in how they do work.

Another is the changing nature of pollution. When I first got into this business, the pollution problems in this country were a relatively small number of very large sources. In some instances, you could smell the rivers before you got to them. Well, thanks to the work of a lot of people in this room, we have largely corrected those problems. We've made tremendous progress in the last 20 or 30 years, and the remaining environmental problems in this country are now a very large number of small sources.

We're going to have to use different approaches to pollution prevention and environmental education. There will always be a place for command and control, but if we want to move the ball to the next yard mark on the field, we're going to have to use a different set of tools than we've been using. To me, that implies a different approach. We're not going to get what we want by commanding people to do it; we have to give them a good reason to do it. As Kendall was attempting to do, we have to create a vision, and get people to buy into that vision.

Another change is the loss of confidence in the Government as an institution. Just recently, we brought together all the Assistant Administrators (AAs) and Regional Administrators (RAs) to look at the question of how we were going to provide leadership to the whole endeavor. We brought in a couple of inspirational speakers, one of whom was Mark Roberts, an economist from Harvard University. Dr. Roberts said that the government has lost credibility. The public no longer feels that the government is fair, and questions their effectiveness to solve society's problems.

Dr. Roberts wrote a book stating that EPA asks all the wrong questions. For instance, one of the wrong questions is, 'Is it safe or is it not safe'? Although we tend to look at things as either being safe or unsafe, the reality indicates that it's on a continuum. You can't ever promise people things that are absolutely safe. We can't give that kind of guarantee. You can reduce the risk to a tolerable level, but you can't eliminate it entirely.

On the question of fairness, Roberts uses the Johnson Space Center in Houston. Does it really make any sense to the public to have a space center in Houston? Is it only coincidental that it was put there during the LBJ administration? I think most people realize that there are politics that go into the decisions that we make. And as a consequence, there is concern about the fairness of our decisions. An environmental example is that people are concerned that a disproportionate amount of risk in this country is borne by the poor and disadvantaged. Black people, for instance, have two to three times the amount of lead in their blood levels than the non-black population. So, environmental risks are clearly not fair across the population.

Effectiveness. Roberts says that this country isn't going to come out of its economic doldrums in the near future. And in the meantime, he added, real harm is being done to individuals. The middle man is being stripped away, causing a significant loss of standard of living for the middle income people. So, since there is an increasing percentage of our population that experiences this loss, is it any wonder that they are demanding that their tax dollars be used for good purposes? I think that we at EPA have to make sure that we are sensitive to this issue when dealing with the regulated public, and responsive to their concerns.

There are a lot of agencies out there competing for tax dollars. And the polls show that the environment is definitely not at the top of the list. Jobs, health care, education, safety, etc. all rank above the environment; and as the economic condition worsens, the environment continues to drop in importance. Roberts says that the way out of the predicament is to be credible, fair, and effective. I think TQM is the vehicle to help us do that. We need to get in touch with our internal and external customers to find out what they expect from us; and we need to measure our successes in terms other than beans or administrative actions.

Another of my visions of success is that people will find better and faster ways of doing business. We're going to have to teach people new tricks: education, outreach, public/private partnerships using economic incentives...I think these kinds of things have great promise.

Lastly, I think success will occur when all our internal and external processes involve fewer pointless hassles...when companies can get permits from EPA in a timely way and with enough information upfront so they're not guessing what is necessary...when we have a helpful attitude about answering questions...and when we can eliminate rework.

I'd like to finish my presentation with a true story that has changed my thinking about the importance of data. About a year ago, I went to an international conference on environmental indicators in Florida. As a moderator for one of the sessions, I decided to kill some time and sit in on a presentation by a university professor. I can't remember his name, but he was talking about a mathematical model of climate change in North America. He had created and built the model, but decided that he needed to establish its credibility and veracity. He did this by running the model backward to determine if it would predict the weather pattern in the past. He ran the model all the way back to the last ice age, some 20,000 years ago, and found that vegetation was extant during those years. The way he got the data was through cores in boggy areas. The areas were sectioned, and carbon was dated to assess when the sediment was laid down. They also got botanists to determine what pollen was present, and thus the types of vegetation that existed. So, they ran the model and used these indicators to predict the weather, and hence the vegetation.

The professor then told the audience what the model said about the future: that the world would experience more weather change in the next 100 years than it has in the last 20,000 years; that there will be an order of magnitude increase of violent weather activity, which means ten times the number of lightning strikes, ten times the number of hurricanes and tornadoes, etc.; that the Great Lakes and other areas will become dust bowls; that the change in weather will cause a redistribution in rain, so more moisture is going to be taken out of the soil than is replaced; that trees are going to be increasingly set on fire by lightening; and that most of the deciduous forests in the mid-west will burn to the ground.

I hasten to add that there are competent scientists who think this is all nonsense...that there will be some mitigating factor that will cause this not to occur. But, should we sit around and wait to find out which rocket scientist is right?

We have to move post-haste to implement the kind of monitoring systems on a global scale that will give us an early warning and tell us who is right on this issue. It's not something that we can sit around and guess about. We have to find data that's credible, quality assured, and has been put through models of verification.

So, I think the type of activities that you and we at EPA are engaged in are extremely important, not only to this country, but to the globe at large. We need to implement quality throughout our organization, and we need to take whatever effort is needed to make EPA a quality organization."

QA MANAGER OF THE YEAR AWARD

The QA Manager of the Year award is given to the individual who demonstrates outstanding contributions in the field of quality assurance. Sponsored by the Office of Research and Development (ORD), the award consists of a plaque and a $2,000 cash award. Nominations are accepted by the Assistant Administrator for ORD, and reviewed by a panel of senior managers.

The nominees for this year were Bill Laxton from the Office of Air Quality Planning and Standards, who is noted for his efforts in transferring the precision and accuracy data for the ambient air monitoring networks from ORD databases to the ambient monitoring network; Vicky Lloyd from the Office of Radiation Programs, who has been instrumental in the EMMC activities on methods integration and work on SW 846 waste methods, and acted as liaison with the Department of Energy and interagency agreement dealing with radioactive and mixed waste analytical test methods; Lee Salmon and Phil Jalbert, also from the Office of Radiation Programs, recognized for using TQM to develop a successful national radiation measurement proficiency evaluation; Kendall Young, recently retired from Region 6, known for his contributions to the Drinking Water and other programs, and for developing and presenting training programs for regional and state employees; the Pretreatment Unit in the Water Division of Region 6, noted for developing and implementing a pre-treatment program audit process to ensure that the municipalities pre-treatment program was functioning properly; and Bill Mitchell from the Atmospheric Research and Exposure Assessment Laboratory in Research Triangle Park, recognized for his involvement in developing high quality control materials for QA training, and for saving $2.8 million by redesigning an air monitoring study and making sure that enough data was collected for an adequate decision. Guy Simes and Barry Towns were nominated again this year for continuing to help QAMS better understand the status of programs across the agency, but Nancy Wentworth announced that "until we reward all of the stellar performers, nobody gets it twice."

Calling for a drum roll, Nancy Wentworth announced Kendall Young as the 1991 QA Manager of the Year.

KENDALL YOUNG
1991 QA MANAGER OF THE YEAR

"To be honored by your peers is one of the greatest honors you could give and I consider this one of the highest honors that I've ever had. EPA has been a great life, and I certainly appreciate all of the associations that I have had with so many of you people here tonight. It has been well worth my life's efforts and I hope that what I contributed was worth this honor.

I had a dream the other night about receiving a meshed bag of gold dust, where the dust was gradually falling out. Maybe there's some symbolism there which says that the environment is in a meshed bag and is slowly falling out. That bag could possibly be made more impervious by using all of our efforts to protect the environment.

I'd like to share a vision with you, a vision of EPA: that it will be called the Environmental Quality Protection Agency, a multi-media organization with a water program, an air program, a waste program, a toxic program, and all the other legislative parameters that come along. I'd also like to see EPA make ethics a cornerstone in the agency, and have the quality assurance director report to the administrator. I'd like to envision that there's a total commitment at EPA to the environment and quality assurance, and that quality assurance and total quality management not be a dichotomy. And lastly, I'd like to see the fluff taken out of the agency's vernacular. For instance, quality. What is quality? How much quality? That is too generic a term. We need to talk in terms of standards and parameters that define what quality is. I think that these ambiguities can be removed. And for the nation, I'd like to envision the President having a quality assurance person report directly to him. I think that would be very useful to our nation.

I thank you all and wish you well. I hope that the road will rise up to meet you and the wind be always at your back."

TRAINING SESSIONS

Four training sessions were offered on Wednesday, February 12 to help the conference participants enhance their technical and management skills as QA professionals.

The Training Doctor Is In
Mary Ann Pierce, JWK International, Inc.

The purpose of this session was to give participants an overview of the QA training system and to provide answers to specific QA training problems.

The session began with a detailed examination of all available Quality Assurance training courses and materials that have been developed by QAMS during the past several years. The discussion featured mini-lectures, video clips, and computer-based training demonstrations. The second half of the workshop consisted of participants creating their own individual training agendas, tailored to the needs of their organizations and programs.

Career Skills and Strategy for Marketing QA
Joanne Jorz, Conceptual Systems, Inc.

This training session was designed to encourage attendees to focus on their own strengths and development areas in the field of quality assurance.

The session began with a brief presentation on the Meyers-Briggs Type Inventory test and its relationship to the role of the Quality Assurance officer. The concept of marketing was discussed briefly, and participants were asked to assess their own ability to perform specific QA marketing tasks. Based on their assessments, each participant wrote an individualized career development plan to address weaknesses and reinforce strengths.

The last portion of the session required participants to tailor particular marketing strategies to a personal marketing plan for a QA product or service.

Essential Skills for Change Agents: Change, TQM, and Communications
Linne Bourget, Ph.D., Positive Management Communications Systems

The purpose of this session was to provide insights and practical skills for managing change with positive results. The workshop focused on initiating changes involving QA and TQM within the EPA organizational structure. Special emphasis was placed on understanding customer needs, building relationships with customers, communicating effectively, and understanding change styles.

Environmental Statistics for the QA Practitioner

This training session consisted of three sequential presentations related to environmental statistics.

How Many Samples Do You Want Me To Take?
John Warren, Office of Policy Planning and Evaluation

This session was designed to familiarize even non-statisticians with the different ways this question could be answered, and the merits of various approaches such as: the historical variability of the data (the variance or the standard deviation); using trial samples to estimate variance; and using tolerance intervals.

Statistical Sampling Design
Robert O'Brien, Office of Policy, Planning and Evaluation

This presentation was targeted to participants whose statistical background ranged from elementary to intermediate. A review was given on frequently used approaches in developing sampling designs, with an emphasis on designs tailored to support real world decisions based on data collected. The primary components of the sampling design were listed as: constructing the sampling frame, sample selection procedures, estimation procedures, and procedures for calculating sampling errors.

A Chemist Looks at Statistical Methods
Charles Ramsey, National Enforcement Investigation Center

This session addressed problems encountered when applying statistical techniques to environmental samples, methods for subsampling, and quality control methods for sampling. Key information included materials on sample design, quality control, number of samples, and approaches to sampling design.

OFFICE OF RESEARCH AND DEVELOPMENT (ORD)

Topics of discussion:

"Scientific Integrity:
Data Authenticity and Data Integrity"

"EPA and Contractors: Practical Considerations
for Implementing QA Programs"

"Revision of QAMS QA Documentation"

"Scientific Integrity - Data Authenticity and Data Integrity"

The purpose of this session was to discuss and recommend solutions for incorporating data authenticity into QAMS policy. Jeffrey Worthington, Corporate Director of Quality Assurance, TechLaw, Inc. gave a brief presentation on ensuring data authenticity in environmental laboratories. He stressed the need for laboratories and other generators of environmental data to develop policies and procedures to ensure data authenticity as a normal part of conducting business. While Worthington acknowledged that there is no absolute method to guarantee data authenticity, he noted several activities that environmental professionals can perform to increase data authenticity:

1. Education and Training. A training program should be developed that includes training schedules and goals for current staff. The program should also be used for the orientation and training of new staff.

2. Ethics and Data Integrity Agreement. Individuals who sign this agreement will better understand the responsibilities of reporting data to the public and private sector. This document would focus responsibility on all staff members, not just the final data reviewers. See Figure 1 on the next page.

3. Internal Audits. Internal audits should be conducted on a routine basis. The quality assurance officer and field or laboratory personnel should develop a plan for implementing corrective action. After the plan is included in the internal audit report, the quality assurance officer should review the findings and ensure that corrections have been made.

4. Participation in Accreditation Program. Accreditation officials would serve as third party auditors. There are two advantages of using third party auditors. First, a third party auditor may notice something an internal auditor does not. Secondly, a third party auditor is more credible when showing clients that the laboratory is reporting authentic data.

5. Quality Assurance Officer Observation Log. The quality assurance officer should maintain a record of problems and corrective actions taken as evidence of implementation.

6. Written Standard Operating Procedures (SOPs). SOPs should be developed that describe the process for conducting internal audits and outline a corrective action plan. These procedures should be provided to the client.

7. Documentation Procedures. Environmental professionals should develop and enforce procedures that ensure that information is not recorded on temporary records for later transfer to a "neat" field record or laboratory benchsheet.

8. Automated Laboratory Practices. Many laboratories use the laboratory management system (LIMS) for recording data. Guidance on the procedures for entering information into these systems is available in draft guidance by the EPA Office of Information Resources Management (OIRM). Areas included in the guidance are: quality assurance of software, ensuring the accuracy of data entry, lifecycle documentation of software development, definition of computer raw data, traceability of data edits, and physical security and tiered access considerations.

9. Data Certification by the Laboratory. Formal data validation, which is similar to a certification process, should verify that data meets contractual requirements and is authentic.

10. Usability Determination. Environmental data users should verify data authenticity as an informal part of the usability determination process. This process can be facilitated by providing good evidence of data accuracy in data packages.

Figure 1: Ethics and Data Integrity Agreement

_____
(Laboratory)

ETHICS AND DATA INTEGRITY AGREEMENT

I. I, _____ *(Name)*, state that I understand the high standards of integrity required of me with regard to the duties I perform and the data I report in connection with my employment at _____ *(Laboratory)*.

II. I agree that in the performance of my duties at _____ *(Laboratory)*:

a. I shall not intentionally report data values that are not the actual values obtained;

b. I shall not intentionally report the dates and times of data analyses that are not the actual dates and times of data analyses; and

c. I shall not intentionally represent another individual's work as my own.

III. I agree to inform _____ *(Laboratory)* of any accidental reporting of non-authentic data by myself in a timely manner.

IV. I agree to inform _____ *(Laboratory)* of any accidental or intentional reporting of non-authentic data by other employees.

_____
(Signature)

_____
(Date)

"EPA and Contractors: Practical Considerations for Implementing QA Programs"

The goal of this session was to examine the ORPM Transmittal 92-13, entitled "Quality Assurance Activities in ORD's Contract Research," and discuss concerns about contractor personnel performing QA oversight activities that may involve their own companies or their competitors. The outcome was a list of potential problems and recommendations compiled by ORD QA Managers regarding ORPM Transmittal 92-13. The five key points discussed were:

1. The Project Officer is the final authority on accepting the quality of a product, but must consult the QA program when environmental measurement data are involved (i.e standards for the data quality objective process (DQO) and requirements of the quality assurance project plan (QAPjP).
2. A contractor cannot evaluate the work of another contractor who is a competitor or potential competitor without proper controls. Controls in a contractor/contractor evaluation should include the opportunity for the reviewed contractor to check the evaluation for accuracy, and enable an EPA employee to examine and approve the report for accuracy and bias.
3. Any contract under $50,000 that has QA support services within its statement of work should require justification for on-site evaluations.
4. Self-evaluation by the contractor should not be the only criteria for judging product adequacy. Controls for contractor self-evaluation should include the use of predefined criteria; a requirement that QA personnel report to a different organizational unit than technical personnel; and a requirement that QA personnel certify that they will perform evaluations in an impartial and ethical manner. All controls must be overseen by an EPA employee.
5. The group was asked to complete a survey on the types of activities performed by QA contractors with and without EPA oversight. Figure 2 shows the results of the survey.

"Revision of QAMS QA Documentation"

The goal of this session was to analyze current guidance documents for appropriate revisions and new guidance. Members of the group reviewed existing documents and discussed future ORD QA guidance needs. Three key questions were identified: Which current documents are being used? What improvements are needed in current documents? What additional guidance is needed for ORD? Among the needs addressed were:

1. More guidance on data review/data validation
2. A quick, computerized system for QAPP development
3. Development of training and education programs
4. To make clear who needs it, and why and how it "serves the science"
5. Reassess Standard Operating Procedures

Figure 2: Survey Results on Activities Performed by QA Contractors With and Without EPA Oversight

	Activity	EPA Staff	Contractors w/ Oversight	Contractors w/o Oversight
1.	Review of QA planning documents.	7	5	0
2.	Review of final reports.	5	5	0
3.	Conduct of audits, including assessing the quality of field studies or laboratory studies or modeling research.	6	7	0
4.	Assistance in preparing QA planning documents.	7	5	0
5.	Preparation of QA/QC materials for meetings/symposiums.	7	6	1
6.	Presentation of QA/QC materials at meetings and symposiums.	6	6	2
7.	Literature search relative to QA/QC issues	5	4	2
8.	Preparation and presentation of relevant QA training courses and material.	6	7	0
9.	QA tracking and reporting.	5	4	0
10.	Experimental design development.	4	3	0
11.	Experimental design review.	6	6	0
12.	Project management of subtasks.	6	3	0

NATIONAL PROGRAM OFFICES

Topics of discussion:

"The Scope of Quality Assurance at EPA HQ:
Current Challenges/Future Extensions"

"HQ QA Group Expectations of QAMS/QAMS Expectations
of the HQ QA Group"

"The Scope of Quality Assurance at EPA HQ: Current Challenges/Future Extensions"

The purpose of this session was to discuss current and future challenges of the EPA Order and identify possible improvements. The group focused on several key questions: What are the primary current challenges for viable QA in the current scope of the EPA Order? What are the overall Agency needs in QA and how are they being met? Should the Agency expand the QA function beyond "environmental data?" Who should be responsible for any identified expansions of QA beyond "environmental data?"

By the end of the session, the group had compiled a list of current challenges. These included:

1. Increase QA visibility and assure suitable priority for QA
   a. Better educate management on QA Manager's role
   b. Better coordinate and define Quality Assurance roles
   c. Better involvement in engineering processes
   d. Better involvement in regulation development

2. Improve communication and linkages
   a. Hold more meetings between Headquarters and QA Managers
   b. Formalize the status of HQQAG meetings
   c. Better define jurisdiction of QA activities
   d. Identify overlapping areas
   e. Define linkages of Headquarters QA Managers to cross-cutting program offices and groups like OIRM, OPPE, CES, etc.

3. Expand QA scope beyond current narrow definition
   a. Include non-environmental data (i.e Administrative data)

4. Close the QA assessment loop so feedback on data quality gets to the Headquarters QA Manager for evaluation

5. Improve the QA for compilation of data
   a. Better interagency data
   b. Better indicators and indices

6. Improve interaction on Information Management QA needs

7. Identify impacts on HQ QA activities from ANSI/ASQC-E4 and potential update of the EPA Order 5360.1

"HQ QA Group Expectations of QAMS - QAMS Expectations of the HQ QA Group"

This session was designed to familiarize participants with the HQ QA group and how it interacts with QAMS. Group members discussed and compiled a list of HQQAG's expectations of QAMS. Some of the expectations included:

1. Leadership
   a. Ensure that QA officers are at proper level, visible, have access to senior managers
   b. Ensure that QA officers have sufficient time to perform QA activities
   c. Work with OIRM and OPPE to get QA into Agency-wide strategic planning, data integration, and environmental indicators
   d. Develop an effective strategy for the next 3-5 years

2. Customer-oriented support
   a. Develop effective Headquarters QA Team/Network for frequent communication on substantive issues and effective peer assistance across program lines
   b. Promote linkage between different offices and cross-program solutions as often as possible

3. Guidance
   a. Include Headquarters and Regional QA managers earlier and more frequently in developing and reviewing policies and guidance
   b. Expect QAMS to reflect program needs and capabilities in its guidance
   c. Develop a process/mechanism to ensure coordination between QA and those developing policy, regulations, and Agency guidance

4. Increase Technical Assistance

5. Training
   a. Develop a QA curriculum
   b. Establish a training fund

REGIONAL PROGRAM OFFICES

Topics of discussion:

"QA in Regulatory Development"

"QA Management Plans and FMFIA Issues"

"Development of a Model Management Systems Audit (MSA) Format for the Removal and Emergency Preparedness Programs"

"Drinking Water Monitoring Quality Issues"

"Documentation Requirements for Data Produced by Non-CLP Laboratories"

"QA in Regulatory Development"

This session focused on the regional role in the regulatory development process. Group members discussed current activities and objectives for maximizing regional participation in Regulatory Development Quality Teams. Several suggestions for improving region involvement included: 1. generating better documentation for QA within the Agency and 2. having documents that are accurate and implemented, rather than documents that are in-hand.

The Start Action Notice form and the effects of a regulatory moratorium were briefly discussed. The process was described as "in place," with relevant forms currently available.

The outcome of the session was a greater awareness of regional opportunities to participate in the regulatory development process and a greater awareness of regional issues important to the Quality Action Team.

"QA Management Plans and FMFIA Issues"

This session was designed to update the group on current political and management views of QA documentation. A short presentation was given on FMFIA designation of QA documentation as an Agency-wide weakness and the role that QA plays in response to the designation. Key questions addressed were: Why use FMFIA now? Is this a bureaucratic response to the beancounters? Will this make any difference?

"Development of a Model Management Systems Audit (MSA) Format for the Removal and Emergency Preparedness Programs"

The purpose of this session was to examine Region II's case study in developing a Management Systems Audit format as a pilot for use by other regions and adopt a format for conducting MSAs on the Removal and Emergency Response components of the Superfund program. The first half of the discussion focused on the process and materials used to develop the format for an MSA; and the second half focused on the effectiveness of the MSA's content, format, and applicability in other regions. Key questions included: Does the audit content adequately address all issues of concern? Can the audit format be improved? Is the model format easily implemented?

"Drinking Water Monitoring Quality Issues"

This session began with a short presentation on the structure, participants, and accomplishments of the Drinking Water Quality Monitoring Work Group (DWQMWG). The discussion centered on quality-related issues being addressed by the DWQMWG,

and the draft Federal Register notice on the quantification of drinking water analyses. The outcome of the discussion was a list of comments and suggestions on the effectiveness of DWQMWG's proposals.

"Documentation Requirements for Data Produced by Non-CLP Laboratories"

The group examined the requirements specified for Superfund CLP laboratories under CERCLA to determine their applicability to Non-CLP laboratories. A brief presentation on the history of the Superfund Contract Laboratory Program was given, along with a 30-minute talk on "Documentation Requirements for Analytical Data" by Region 10. The goal of the discussion was to produce a National Guidance document that could be referenced in Quality Assurance Project Plans and given to any laboratory producing environmental monitoring data under such plans.

JOINT SESSION (ORD, RPO, NPO)

Topics of discussion:

"Quality Assurance in Model Development,
Computer Software, and Electronic Data Transfer"

"Quality Assurance in Model Development, Computer Software, and Electronic Data Transfer"

The session began with a presentation by Rick Johnson on a recent review conducted on the capacity of EPA's information resources. He addressed the historical perspective and the findings and recommendations from the review. The group then separated into three sub-groups to identify the problems and issues regarding inadequate QA/QC in the areas of model development, software development, electronic data transfer, and electronic recordkeeping. The list included the following:

Model Development
- o Applications limits not given
- o Assumptions not documented
- o Sensitivity analysis not performed
- o Required time and spatial scales not clearly specified
- o Generated output precision often missing
- o Hardware requirements for running model not clear

Software Development
- o Documentation often missing or incomplete
- o Failure to debug before release
- o Failure to assess or consult user's capabilities
- o Failure to adequately specify performance criteria
- o Failure to use case tools
- o Re-invent software testing procedures

Electronic Data Transfer
- o Lack of specification for transferred data
- o Incompatibility with other systems
- o Transferred data not checked for completeness or defects

Electronic Recordkeeping
- o Undocumented changes, loss of traceability
- o Data quality screens
- o Legally defensible? Authentic?
- o Access and security?
- o Failure to backup
- o Need to reformat to keep up with current technology

The group then recommended ten action items for resolving the issues and problems identified:

1. Gather literature on model QA/QC
2. Develop standard for format and transmission
3. Establish standards and requirements for model evaluation
4. Develop/review/archive appropriate documentation
5. Conduct performance evaluations using valid data sets
6. Develop agency policy to address:

a. Model/software QA/QC
b. Inherent error in models
c. Validating assumptions
d. Minimum data entry requirements

7. Give results of this session to QAMS for follow-up with OIRM committees and work-groups
8. Require progress report from QAMS/OIRM at 13th annual meeting
9. Make related guidance, standards, procedures available as part of proceedings
10. Supply list of participants as potential contacts for work-groups or committees