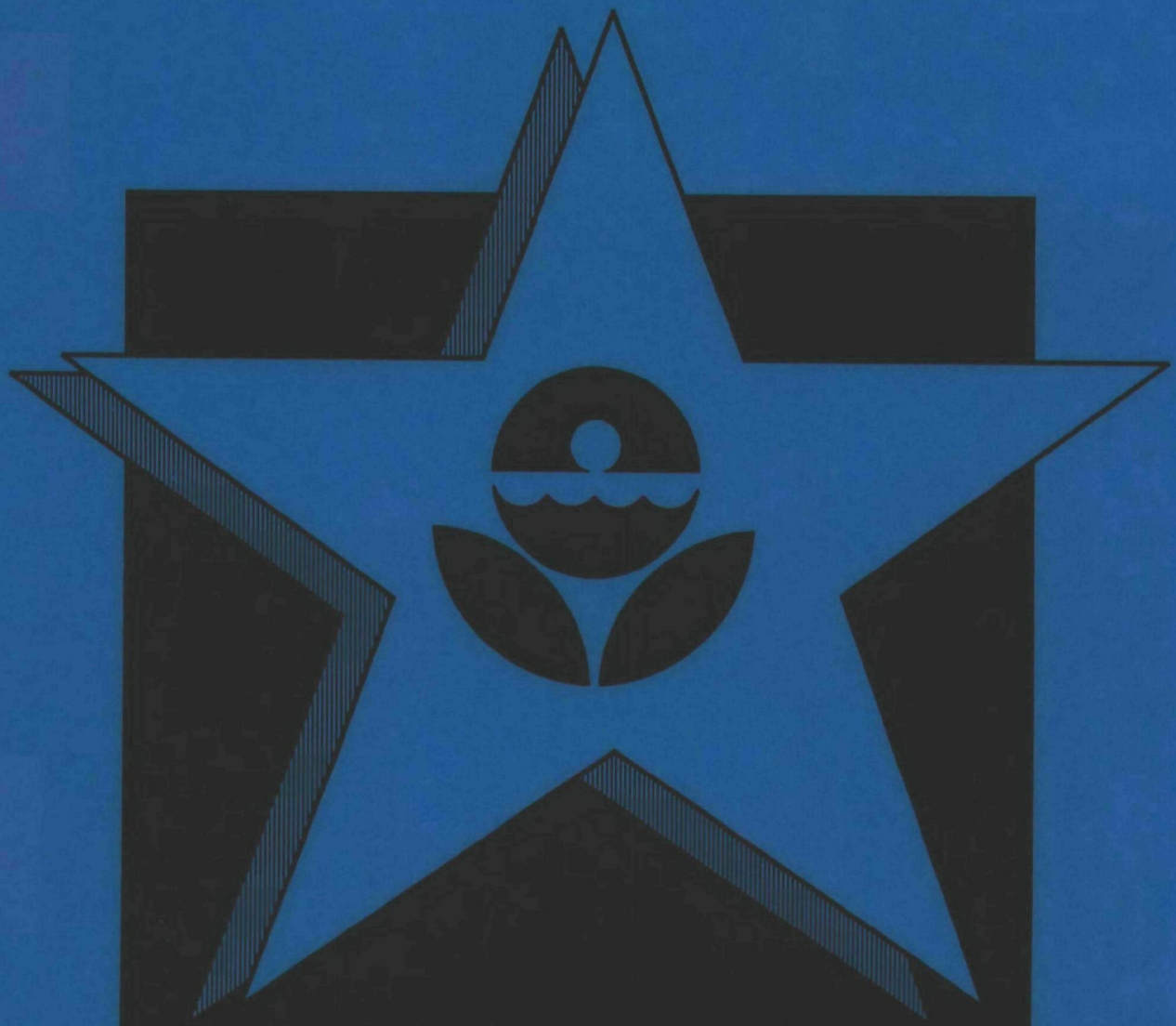

11TH ANNUAL NATIONAL MEETING ON MANAGING ENVIRONMENTAL DATA QUALITY

P R O C E E D I N G S

Dallas, Texas April 22-26, 1991
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."

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AGENDA

Monday, April 22

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

1:10 pm - Welcome
Robert E. Layton, Regional Administrator, Region 6

1:30 pm - Keynote Address
Joe Winkle, Deputy Regional Administrator, Region 6

2:15 pm - Good Automated Laboratory Practices (panel discussion)
Kaye Mathews, National Enforcement Investigation Center (MODERATOR)
Joan Fisk, Office of Emergency and Remedial Response
Jeff Worthington, TechLaw, Inc.
Rick Johnson, Office of Information Resources Management

3:15 pm - EPA's Environmental Monitoring Management Council (EMMC)
Ramona Trovato, Executive Secretary of the EMMC Policy Council, Analysis and Evaluation Division

4:00 pm - Common Interest Group Discussions,
Introduction and Planning by Nancy Wentworth

Tuesday, April 23

8:30 am - Harmonization of QA Requirements Across the Government
Introduction by Nancy Wentworth

9:00 am - Hazardous Waste Site Remediation (panel discussion)
Gary Johnson, Quality Assurance Management Staff (CHAIR)
Marcia Davies, U.S. Army Corps of Engineers
John Edkins, Naval Energy and Environmental Support Activity
Duane Geuder, Office of Emergency and Remedial Response
Tom Morris, Martin Marietta Energy Systems, Oak Ridge National Lab

11:00 am - Ecological Monitoring (panel discussion)
Robert Graves, Environment Monitory Systems Laboratory (CHAIR)
Adriana y Cantillo, National Oceanic and Atmospheric Administration
James Andreasen, U.S. Fish and Wildlife Service
Thomas Cuffney, U.S. Geological Survey

2:00 pm - Discussion Groups - Harmonizing QA Across Government

3:30 pm - Summary of Discussion Groups

4:00 pm - Integrity in Research
Adil Shamoo, Editor in Chief, Accountability in Research

5:00 pm - Adjourn

6:30 pm - Banquet

- Journey Toward Quality: The Federal Express Story
  Gilbert Mook, Vice President for Properties and Facilities, Federal Express, Inc.
  1990 Malcolm Baldrige National Quality Award Winner

- Presentation of the Quality Assurance Management of the Year Award

Wednesday, April 24

Training Sessions:

QUALITY AUDITS FOR IMPROVED PERFORMANCE
Dennis Arter, Columbia Quality, Inc.
- A one-day condensed version of the ASQC course

COMMUNICATION SKILLS
Dr. Linne Bourget, Positive Management Communications Systems
- A half-day seminar on communication skills for positive power and influence, relationships, and organizational change

TRAIN-THE-TRAINER SEMINAR
Mary Ann Pierce, JWK International Corp.
- A half-day seminar on how to use QA training tools effectively

QUALITY CIRCLES
RADM Frank Collins, Frank Collins Associates
- A half-day seminar on how to organize, train, implement, and nurture Quality Circles in your organization

QA CAREER MANAGEMENT SEMINAR
Joanne Jorz, Conceptual Systems, Inc.
- A half-day seminar designed to help QA professionals develop and manage their careers

Thursday, April 25

Common Interest Group Sessions

Friday, April 26

8:30 am - Common Interest Group Sessions Wrap-up

10:00 am - Summary Reports from Common Interest Groups

11:30 am - Closing

12:00 noon - Adjourn

MEETING HIGHLIGHTS

Nancy Wentworth, Director of the EPA Quality Assurance Management Staff, welcomed attendees to the meeting, touched upon the theme "Data Quality Across the Government," and stressed the need to work together with a common goal to meet environmental challenges that lay ahead.

Robert Layton, Regional Administrator of Region 6, described the concept of Total Quality Management (TQM) and emphasized the importance of providing a uniform approach to assuring data quality.

Joe Winkle, Deputy Regional Administrator, Region 6, discussed the benefits of standardizing quality assurance requirements in Federal, state and private sectors.

Ramona Trovato, Executive Secretary for the Environmental Monitoring Management Council's policy council, described the Environmental Monitoring Management Council: how it was formed, its structure, and its functions.

Adil Shamoo, Editor of Accountability in Research: Policies and Quality Assurance, discussed integrity of research: problems and their causes, the role of quality control and quality assurance, and ideas for improving data integrity.

Gilbert Mook, Vice President for Properties and Facilities, Federal Express, Inc., talked about the Malcolm Baldrige National Quality Award: the goals and philosophies of Federal Express, their commitment to the customer, and their quality of service.

PANEL DISCUSSION SUMMARIES:

Kaye Mathews, QA Manager, National Enforcement Investigation Center; **Jeff Worthington**, Quality Assurance Director for TechLaw; **Joan Fisk**, Deputy Chief, Analytical Operations Branch, Office of Emergency and Remedial Response; and **Rick Johnson**, a member of EPA's Scientific Staff in the Office of Information Resources Management, participated in a panel on "Good Automated Laboratory Practices: Recommendations for Ensuring Data Integrity in Automated Laboratory Guidance." The discussion focused on the trend toward computer automation in the laboratory.

Gary Johnson, a Quality Assurance Management Staff member; **Thomas Morris**, QA Manager for the Hazardous Waste Remedial Actions Program; **Duane Geuder**, QA Manager/Program Analyst in the Office of Emergency and Remedial Response; **Marcia Davies**, HTW Branch Chief of the Missouri River Division of the Army Corps of Engineers; and **John Edkins**, QA Manager for the Navy Installation Restoration Program, participated in a panel discussion on the National

Consensus Standard that is being developed through the American Society for Quality Control (ASQC). Panelists focused on the structure of the proposed standard and ways to effectively implement the standard process.

Robert Graves, Acting Coordinator for the Environmental Monitoring and Assessment Program; **James Andreasen**, from the U.S. Fish and Wildlife Service in the Division of Environmental Contaminants; **Adriana y Cantillo**, Manager of the National Oceanographic and Atmospheric Administration (NOAA) National Status and Trends Program/Quality Assurance Management Program/Quality Assurance Program; and **Thomas Cuffney**, an Ecologist in the Water Resources Division of the U.S. Geological Survey, participated in a panel that focused on harmonization of ecological monitoring. Panelists discussed the monitoring process in their respective agencies.

BIOGRAPHIES OF SPEAKERS

Nancy Wentworth is the Director of EPA's Quality Assurance Management Staff. Prior to working for QAMS, she was a manager in the Office of Drinking Water for seven years. In 1988, she was awarded the USEPA Bronze Medal for Commendable Service; in 1989 and 1990, she was the recipient of the USEPA Special Service Award. Ms. Wentworth has a B.A. in Civil Engineering and a Master's degree in Sanitary Engineering.

Robert Layton has served as the Regional Administrator of EPA's Region 6 since February 1987. He initiated a Value Engineering Program in the Hazardous Waste Management Division, and negotiated the first EPA Superfund program agreements with the Navajo Tribe. Mr. Layton is the Vice Chairman of the Policy Committee for the Galveston Bay Estuary Program and Co-Chairman of the Policy Committee for the Gulf of Mexico Program. He is a member of the National Council of Engineering Examiners, and was selected Engineer of the Year for 1976-1977.

Joe Winkle has been the Deputy Regional Administrator of EPA Region 6 since April 1988. From October 1982 to 1988, he served as the Director of the Disaster Assistance Programs for the Federal Emergency Management Agency (FEMA). Prior to joining the national office of FEMA, Mr. Winkle was the Acting Regional Director and Deputy Regional Director for FEMA Region 6 in Denton, Texas. He served as Regional Director of the Federal Disaster Assistance Administration (FDAA) from 1973 to 1979 and has been the Federal Coordinating Officer for more than 50 Presidentially-declared major disasters.

Ramona Trovato is the Executive Secretary for the Environmental Monitoring Management Council's policy council and a division director in the Office of Water. She is a chemist who has worked for EPA for many years: in the Region 3 Central Lab in Annapolis, on the Quality Assurance Management Staff, and as a liaison between Headquarters and the regional offices.

Adil Shamoo has been a professor of Biological Chemistry at the Maryland School of Medicine since 1979. He is the editor of the journal, Accountability in Research, and the textbook, Principles of Research Data Audit. In 1988, Dr. Shamoo organized the First International Conference on Scientific Data Audit, Policies and Quality Assurance.

Gilbert Mook is the Vice President of Properties and Facilities for Federal Express Corporation. He joined the company in 1983 as Director of Space Operations and Advanced Programs, was named Vice President of Satellite & Video Systems in 1985, and assumed his

current position in 1988. Federal Express is the first winner of the Malcom Baldrige National Quality Award in the service category.

Kaye Mathews serves as EPA's Quality Assurance Manager for the National Enforcement Investigation Center in Denver, Colorado. She provides evidentiary consultation to EPA's Contract Laboratory Program and oversees the Contract Evidence Audit Team's involvement in the CLP.

Joan Fisk, Deputy Chief, Analytical Operations Branch, Office of Emergency and Remedial Response, has been involved with the Superfund Contract Laboratory Program since July 1983. With a B.S. in Chemistry from the University of Bridgeport, Ms. Fisk has worked as an Analytical Chemist throughout her entire career. She is presently a member of EPA's Environmental Monitoring Management Council's panel on Method Standardization and chairs the "Interagency Work Group on Data Authority."

Jeff Worthington is the Quality Assurance Director for TechLaw, Inc. in Denver, Colorado. He also serves as the Technical Programs Coordinator for TechLaw's Contract Evidence Audit Team (CEAT) contract to EPA's National Enforcement Investigations Center.

Rick Johnson is on EPA's Scientific System Staff in the Office of Information Resources Management. He is currently directing the development of EPA's Good Automated Laboratory Practices, of which he is the original author, and the integration of ORD's Data Quality Objectives with the agency's System Design and Development Guidance to establish a methodology for sharing environmental data of documented quality.

Gary Johnson serves on EPA's Quality Assurance Management Staff. With a B.S. in Nuclear Engineering, he was a nuclear engineer for Duke Power Company and an environmental engineer for EPA's Office of Research & Development. In his eleven years in Quality Assurance, Mr. Johnson has received two EPA Bronze Medals for outstanding contributions. He is a member of the American Society for Quality Control (ASQC), and presently serves as an Associate Regional Councilor for the ASQC.

Marcia Davies, the HTW Chemistry Branch Chief of the Missouri River Division of the Army Corps of Engineers, has a Ph.D. in Analytical/Inorganic Chemistry. Her branch of the Army Corps of Engineers is responsible for the continuing development of the ESACE Chemistry Data Quality Management Program and national oversight of its implementation.

John Edkins is currently employed by the U.S. Navy at Port Hueneme, California as a hydrologist, and is the Quality Assurance Manager for the Navy Installation Restoration Program. He has an M.A. in Geology and is registered as a professional geologist. As a Section Vice-Chairman in the American Society for Testing and Materials subcommittee D-1821 for Ground Water and Vadose Zone Investigations, Mr. Edkins is also a member of the Interagency Ad Hoc Committee for Quality Assurance in Environmental Measurements.

Duane Geuder has an M.S. in Radiation Biology/Biophysics. He has worked as a chemist in the Marine Corps, as an oceanographer for the U.S. Navy Oceanographic Office, and most recently as a Quality Assurance Manager for EPA's Superfund. He has more than 25 years of experience in environmental sampling and analysis and related QC and QA activity. Mr. Geuder is a member of the Ad Hoc Panel on QA/QC services under the Environmental Monitoring Management Council, and belongs to the Association of Official Analytical Chemists.

Thomas Morris is currently employed by Martin Marietta Energy Systems, Inc as the Quality Assurance Manager for the Hazardous Waste Remedial Actions Program. A member of both the Working Group and the Policy/Steering Committee for QA Harmonization, Mr. Morris has eight years of experience in Total Quality Management concepts.

Robert Graves has worked for EPA's Environmental Monitoring Systems Laboratory in Cincinnati since October 1978. Prior to that, he was employed by the U.S. Treasury's Bureau of Alcohol, Tobacco, and Firearms to examine and analyze evidence from various law enforcement agencies. Mr. Graves has an M.S. in Chemistry and an M.B.A. in Finance.

Adriana y Cantillo currently works for the NOAA/National Ocean Service (NOS)/Office of Oceanography and Marine Assessment/Coastal and Estuarine Assessments Branch. She is the Manager of the NOAA National Status and Trends Program/Quality Assurance Management Program/Quality Assurance Program, and the Coordinator of NOAA activities of the multiagency Ocean Dumping Ban Act Research and Monitoring Program. With a Ph.D. in Chemistry, Dr. Cantillo is a member of EPA's Methods Integration Work Group, the NOS representative to the National Ocean Pollution Policy Board, and the NOS representative to the Working Group developing the Federal Plan for Ocean Pollution Research. Development and Monitoring: Fiscal Years 1991-1995.

James Andreasen has 18 years of experience, in both research and operations, evaluating the effects of environmental contaminants on fish and wildlife populations and water quality. He has a Ph.D. in

Zoology/Natural History and is employed by the U.S. Fish and Wildlife Service in the Division of Environmental Contaminants. As the technical advisor for the Service on the Department of Interior Irrigation Water Quality Program, Dr. Andreasen is responsible for pulling together various elements that contribute to harmonization of field methods and in formulating standard operating procedures for the operational contaminant program.

Thomas Cuffney is an Ecologist in the Water Resources Division of the U.S. Geological Survey. He serves on the Technical Issues Committee of the North American Benthological Society and the 1992 Program Committee of the Society of Environmental Toxicology and Chemistry. He has a Ph.D. in Biology and seven years experience in aquatic ecology and environmental toxicology.

INTRODUCTION

Nancy Wentworth
Director
EPA Quality Assurance Management Staff

I'd like to welcome you to the 11th Annual National Meeting on managing environmental data quality. The theme of this meeting is "Data Quality Across the Government."

Today is Earth Day. There are probably a fair number of people here in the audience who participated in the first Earth Day 21 years ago. It was something that made a mark on my life and created a commitment to protecting and preserving the environment. I think that's what we're here to consider this week. There are people from a wide diversity of agencies and their supporting contractor communities, and we need to work together. We need to work efficiently, because we have many things that we must do and we do not have unlimited resources. So efficiency is our only hope in the long term of being able to meet the challenges that are before us in the environment.

One of the things that I have most enjoyed in my six years with the Quality Assurance Management Staff (QAMS) is the opportunity to learn and to grow, and to try to build continuous improvement into EPA's Quality Assurance Program. I look at this meeting as a significant opportunity for all of us to come to a much greater understanding of our mutual concerns, our mutual problems, and our mutual goals. Your gift to QAMS this week is your knowledge. The QAMS staff who are here are going to be listening and probing and trying to gain as much as they can. Please share your experiences with us. This is what we need to hear so that we can do our jobs better.

We value the diversity of the audience that's here. We have people from all backgrounds, from all geographical areas of the country, and from all of the programs that EPA is concerned with, either directly or indirectly. That is very important to us. How we are going to succeed in the long term is to bring all of these views and visions together and move forward as a group. We can't afford to go in separate directions; we must work together. I think we have a tremendous goal ahead of us this week and I look forward to achieving it.

WELCOME

Robert E. Layton
Regional Administrator
EPA Region 6

Welcome to Region 6 of EPA and to Dallas, Texas. You know that Texas is the largest state in the Union. Now don't tell me Alaska is. I know it covers more area, but when all the ice melts, Texas is still the largest.

Texans are proud of their quality as well as their quantity, and we always like to think of Texas as being the biggest and the best. I sound, perhaps, like a couple of fellas in this story about a Texan and a man from a Arkansas who got on a train in Texarkana to go to El Paso. The Texan began bragging about the size of the state and he said, "You know, we could ride all day on this train and still be in Texas." And the man from Arkansas quietly replied, "Well, don't feel bad sir, we've got slow trains in Arkansas, too."

Of course, they weren't speaking from a uniform standard of data. The man from Arkansas wasn't looking at the train from the same standpoint as the Texan. And that is likely to occur sometimes in quality assurance (QA) management--we may not all be looking at it from the same perspective.

The theme for this year's meeting is "Management of Environmental Data Quality Across the Government." All of you who are EPA QA Managers should take great pride in your contribution to providing quality data for this Agency. For all of you who are here representing other agencies, we welcome your interest and your participation, and we know you are as dedicated to helping provide quality data as we at EPA are. We look forward to continuing a dialogue that will result in strengthening all of our programs.

Perhaps this week could be the beginning of a process that could change the way government does business in the field of data quality management. I challenge you to begin a communication with one another which transcends agency lines. You have a unique opportunity to lay a foundation for a uniform approach to data quality throughout the government.

If you can begin to devise methods for providing a uniform approach to assuring data quality, you will provide an invaluable service to not only your particular agency, but to the entire structure of government as well--Federal, state, and local. Your ability to communicate, compromise, and come to a consensus on QA and data gathering would certainly be within the framework of what Administrator Reilly calls Total Quality Management (TQM).

Implementing the ideal of TQM is both realistic and beneficial, and it is mandated in EPA. And so I charge you this week to seek out each other. Discuss common values and standards as they relate to data quality. Become involved in creating new and excellent approaches for improving data quality across the lines of Federal agencies. Find similarities and build on them. Look closely at differences among existing QA programs and see if they can be reconciled. Good luck in this worthy endeavor.

KEYNOTE ADDRESS

Joe D. Winkle
Deputy Regional Administrator
EPA Region 6

It's a pleasure to be here today and to address such a distinguished group of people that has such an important mission as it pertains to the job of environmental protection and science in general. F. Henry Habicht, our Deputy Administrator of EPA, in an article back in November 1989 in *The Quality Manager*, said that "few things are more important to our success as an Agency than credible, usable data. Indeed, virtually every regulatory decision, research activity, and budgetary action taken by this Agency is based, in significant part, on environmental data. Our Agency is in the business of making decisions--often difficult decisions. In order to achieve our shared mission, our actions must be supported by reliable environmental data."

Habicht went on to say that Administrator Reilly intended to pursue top priority initiatives to ensure that the Agency had access to the best data from all significant sources. To that end, our Administrator and his Deputy have established an internal task force to explore the merits of creating a National Center for Environmental Statistics. However, the National Center will only be as good as the data it receives from the various agencies.

Quality of interagency programs and projects across the government is always a critical issue, particularly in Region 6 where we work with many Federal, state, and local agencies. All are involved in environmental data operations. We have numerous facilities under our jurisdiction; sometimes we feel there are more than we can comfortably work with. Standardization of QA requirements will lessen the number of documents that must be written and reviewed, resulting in savings of time and money. Each Agency has different requirements for the generation and documentation of environmental data; therefore, it would be prudent and feasible to have a uniform approach for producing such information. Each time we standardize and streamline we save ourselves untold work.

It is imperative that we address cost-saving issues in these days of budget crunch. Oversight of interagency programs and projects becomes simplified with harmonized data quality assurance standards. The framework for QA in data operations would be common across agencies, thus eliminating confusion. There could be no question about which set of standards would apply, as all would be the same. Newer, more efficient techniques would allow us to spend our time working toward constructive solutions to our problems, instead of discussing the style and scope of QA efforts which may have resulted from a variety of approaches to assuring data quality, none of which may be suitable for decision making. This

additional time saved in having a uniform approach to data quality would allow us to launch into new and even more challenging areas.

However, providing a single set of standards applicable across the board for programs and assuring the quality of environmental data will be a formidable task. Standard definitions are a must. You must more clearly define what is being sought. At times those whom you interface with do not clearly understand what is being stated. Since environmental data is at the core of so much of what we do, decisions are only as good as the data on which they are based. Our effectiveness as regulators and enforcers depends on our credibility. Without credibility, the regulated community and the public will be reluctant to accept the decisions and actions of any governing or regulating agency. We must, therefore, ensure the quality of our data and thus the quality of the foundations on which our decisions are based.

Perhaps you can build communication this week which will become a cornerstone in building the data and enable us to make sound and defensible environmental decisions. An important example of this team communication concept took place in a recent meeting in Washington between the Office of Water and the Office of Enforcement. In this meeting the participants sought to identify areas in which there were differences. The intent was to achieve a smoother operation. The participants included members from the Office of Regional Council, Office Directors from the Office of Water, and the Office of Enforcement, as well as Water Management Division Directors. The consensus was that with good communication and smoother relationships, a rapid solution of problems would result and get the job done in a timely and efficient manner.

We are hoping that you QA Managers can begin to fashion a national standard for environmental data quality programs. You could format QA principles and policies which would enhance cooperation and improve the quality of environmental data in the Federal, state and private sectors. As you begin discussions this week, there could evolve a common goal--to provide a framework that would accomplish our variant but important missions in addressing the complicated task of a harmonized approach to data quality. You can make an effort to implement Mr. Reilly's mandate to become involved in TQM, for you have the unique opportunity of applying that TQM principle to a vital task. As each of you provides your own special expertise, and as you discuss and compromise for the common good, you will exercise the very principles of TQM.

The key task you will face this week is to communicate on what the Federal environmental mission really is and how you, as QA Managers, can best support it. Through joint efforts you can lay the foundation for harmonization of QA requirements: planning, implementing and reviewing data collection programs. A closer look at data raises some important questions. When a manager is making a decision based on environmental data, that manager must ask: "Do

these data meet the needs? Does it help me to make the decision I'm facing? Can I live with this level of uncertainty? Are these data legally defensible?" Much of our data must survive the close scrutiny of court cases.

These are only a few of the many questions which arise when assessing data as they relate to an environmental decision. One very important question is often raised when resampling is required: Was the resampling required as a result of too wide a variance in the data? Or, was it required as a result of unclear objectives to begin with? Exact standards, clearly defined objectives, uniform procedures and precise testing--in short, a good job of upfront planning--will eliminate a great deal of resampling.

We at EPA use the term data quality objectives (DQO's). As you know, this term refers to a planning process which determines upfront how good the data need to be to support Agency decisions. So many times, we shoot first, then aim. We have to reload, aim, and then shoot--a procedure we should have used to begin with.

All data have a level of uncertainty. We need to know that the level of uncertainty is acceptable. During the planning stage we must ensure that the technical insight of the laboratory analyst who is testing the sample is compatible with the needs of the decision-makers who will use the data. This communication is essential between two cultures: management and technical. DQO's are a cross-cultural communication that provide decision-makers with the ability to manage the level of quality in data that is needed to make the important regulatory decisions they face. The astronomical costs involved in cleaning up the environment dictate that trustworthy data be assured.

All these problems could be resolved with a standard, universally-accepted approach to data quality assurance. Our tools are acquiring data--and the data itself must be above reproach, for we are the regulators. Just as the police force should be uniform in the manner in which they enforce the laws, we should be uniform in the manner in which we make regulatory decisions. To gain confidence from the public and from those being regulated, the data used in making those decisions must be appropriate.

One of the challenges of the DQO process is that you must strike a balance. Too much quality is as poor an idea as not enough. There should be a balance, and the emphasis must be placed upon arriving at that balance.
So we set before you the task to begin communications which will ensure uniform Federal standards for environmental data quality. Provide us this week with a foundation for meeting this goal; give us the building blocks for getting and creating a standard uniform management system for environmental data quality which would begin with how to plan it; then go on to say who will do it, what methods

will be used, and most importantly, what standard will be applied in evaluating. This is the heart of data generation.

Recent budget constraints make it mandatory for us to seek better methods for doing our job. You QA Managers are at the forefront in providing assistance in doing just that--better, more productive QA management methods, derived from universally-acceptable standards. Your challenge is to begin creating that harmony. I am confident that you will excel at this task; your challenge is great, but it can be achieved. We look forward to the results of your deliberations during this conference.

EPA'S ENVIRONMENTAL MONITORING MANAGEMENT COUNCIL

Ramona Trovato
EPA Analysis and Evaluation Division

The Environmental Monitoring Management Council (EMMC) was formed by Deputy Administrator F. Henry Habicht in FY 1990. The EMMC was formed because of three events. One was that a white paper was developed on long term development of analytical methods and short term analytical method development that recommended a need for a senior management group to address monitoring methods issues. Then there was a report called the Section 518 Report that looked at the availability, adequacy and comparability of the Agency's analytical test methods under section 304-H. They were then directed to look further than just the water methods and to look at the other Agency methods and to make recommendations. One of the recommendations they made was to set up an environmental monitoring management council.

That happened in 1988. Then in 1989 Region 3 got a new Regional Administrator, Ted Erickson, and he sent a letter to the Administrator that said he thought it would be a good idea if a group was set up like this; the Agency does have some issues in lacking comparability across programs and in methods and in QA and QC.

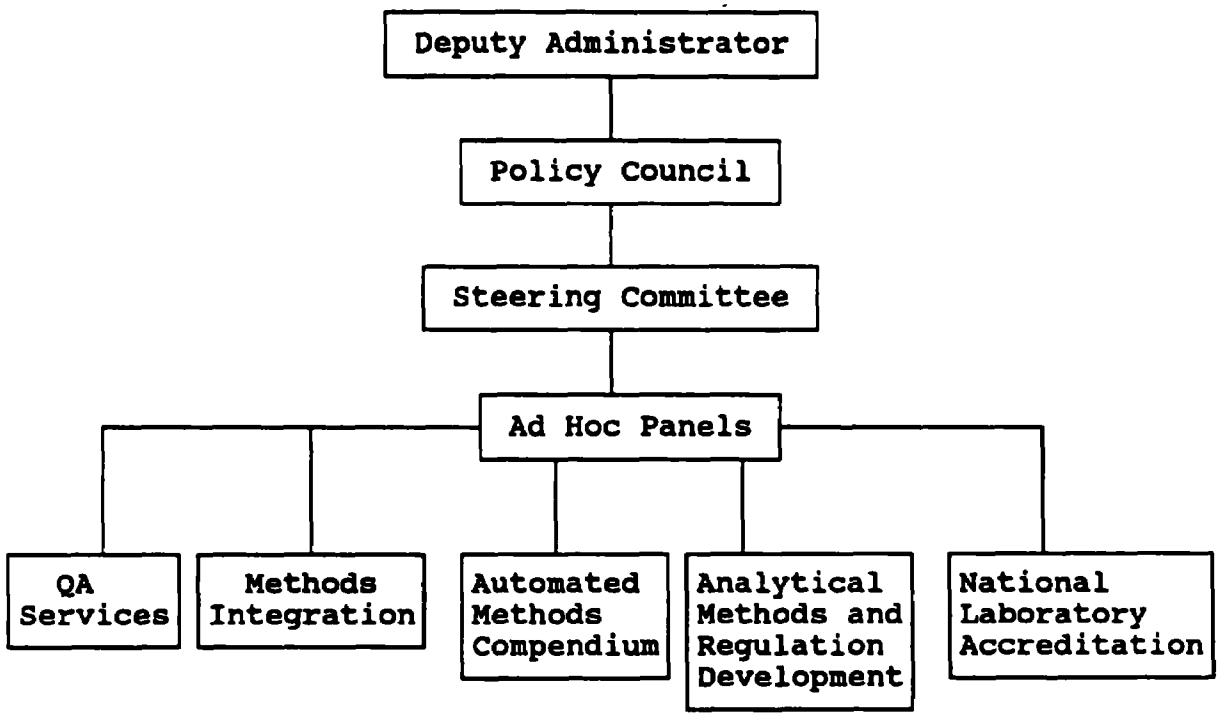
As a result, the Deputy Administrator established the EMMC in FY '90. The EMMC's purpose is to recommend coordinated Agency-wide policies concerning environmental issues. Our charter covers seven areas that EMMC is supposed to look at: 1) coordinate the Agency-wide environmental methods research and development needs; 2) foster consistency and simplicity on methods across media and programs; 3) coordinate short and long term strategic planning and implementation of methods development needs and promote adoption of new technology and instrumentation; 4) coordinate development of QA/QC guidelines as they apply to specific methods; 5) evaluate the feasibility and advisability of a national environmental laboratory accreditation program; and then, other activities that influence environmental monitoring.

The EMMC can focus on any issues that affect environmental monitoring which they feel are important. The bottom line is that they're supposed to recommend coordinated Agency-wide policies concerning environmental monitoring issues. All of us have recognized for a long time that we need somebody who's looking across the programs. And I think this is the first time we've had a coordinated effort where we got some senior managers involved in looking at the issues associated with environmental methods development and the QA/QC in environmental laboratory accreditation.

I should mention that we're not just inside folks. On the ad hoc panels we have folks from states and from other Federal agencies. In one instance we're going to set up a Federal Advisory Committee so we can have folks from industries come in and talk to us and provide us with advice.

Figure 1 shows how the EMMC is structured. The Deputy Administrator is a tie breaker if the Policy Council has issues they can't decide on their own. The Annual Reports also go to the Deputy Administrator. We're in the process of finalizing the first year's Annual Report which we'll be talking about at the next Policy Council Meeting later this week.

Figure 1
Structure of Environmental Monitoring Management Council



The Policy Council identifies the big issues of concern that need to be coordinated across programs. It meets at least twice a year; in this first year I think it met four times. The Steering Committee oversees the investigation of specific monitoring issues. It meets at least four times a year; it met more this year.

The ad hoc panels are the people who really get out and do the leg work. They're the ones who identify the issues, come up with the

options, and make recommendations to the Steering Committee which are then elevated up the chain and implemented. They meet as often as they need to meet.

The folks who are on the Policy Council are: Erich Bretthauer, who is the Assistant Administrator for the Office of Research and Development, is one co-chair; Edwin (Ted) Erickson, who helped get this ball rolling, is one of the other co-chairs. I'm the executive secretary. Then we have members--one member from each office. Members include the Deputy Assistant Administrators and the Deputy Regional Administrator from the lead region for research and development. The first year it was John Wise; recently it's been Jack McGraw. This representative changes as the lead region changes--every two years.

The Steering Committee reports to the Policy Council and they're the ones who make sure that things on the ad hoc panel are moving along in the direction they ought to be moving. The Director of the Office of Modeling, Monitoring Systems, and Quality Assurance is the chair of the Steering Committee. That was Rick Lindhurst until he recently moved upstairs to work directly for Erich on some other projects. Now Jack Puzack's acting in the meantime. David Friedman, whom many of you may know from his days in the Office of Solid Waste, is the executive secretary for the Steering Committee. The members are comprised of Division Directors from headquarters and the Office of Research and Development (ORD), the Environmental Systems Division (ESD) Directors from the lead region for ESD, and the ESD Director from the lead region for research and development.

So we have on both of these committees good representation from ORD, the regions, and the headquarters program offices, which is what we were trying to achieve. The regional folks know where the problems are because they're trying to implement the regulations. The program offices write the regulations and need feedback from the regions. ORD folks have to go out and come up with whatever the program offices think they need. We were trying to get everybody represented on these committees so we could move ahead and no one would feel left out.

There were five ad hoc panels established about a year ago which started meeting maybe nine months ago. There was one on QA Services which was supposed to look at what the Agency's needs were in terms of QA services, what it cost, and how we could fund it.

There was a Methods Integration panel which was supposed to look across the Agency and see where there were opportunities for consolidating methods. I think this panel's an exciting one because, having been in a lab for 13 years where I had to do one method for drinking water and one method for the National Pollutant Discharge Elimination System (NPDES) and another method for the Resource Conservation and Recovery Act (RCRA), I was excited about the idea of doing one method for the same analyte in the same

matrix. So I have high hopes for this group. But they also have a tough problem, because they have to make sure that they're going to get the detection limits they need, the precision and accuracy that they need, and still be able to meet the regulatory requirements of that program.

The Automated Methods Compendium panel was set up so that we could have a single database that would list all of the Agency's methods.

The Analytical Methods and Regulation Development panel was supposed to figure out a way to get analytical methods and QA more visible in the regulation development process. You have to have a good idea of how our regulation development process works and where you can plug things in in order to make a change. And I think this group found out how to do that.

The last panel was set up to look at National Laboratory Accreditation. First, is it feasible--can we do it--and second, is it advisable--should we do it?

The QA Services panel is co-chaired by Tom Hadd from the Office of Research Program Management and William Hunt from the Office of Air Quality Planning and Standards. We tried to have two folks co-chairing each ad hoc panel. The people had to come from a different organization, and there were three main organizations: ORD, the regions, and headquarter's program offices. We would pick any of the two to try to get this covered and get people who were interested in the area so that we could get good representation on the chair so things didn't go too much one way or the other.

The charter of the QA Services group states that they will address the issue of sustaining adequate funding for QA services and research provided by ORD. The QA Services panel did a QA Service and Research Needs Survey to identify needs; they're in the process of trying to quantify those needs and decide how much money we're spending now so they can get a good idea of how much more we need. They're also trying to find a way, or make recommendations on a way, to fund those needs in the future. QA services includes such things as training and QA research methods. Everybody has a slightly different idea of what we need and what they're willing to pay for. So this one's turning out to be very difficult.

The next step will be to develop a Final Report and Recommendations for the FY 1993 Budget Proposal. We are trying to get this budget initiative together and are working hard to figure out how we can pay for it and how we can have a stable base.

I think the most important thing that's come out of this panel so far is the recognition that when it comes to funding QA services and methods development activities, they always take a back seat to everything else. It's the first time I think that has been recognized by folks up the chain as a problem. So at least we've

made headway that far, even if we're not able to get a budget initiative going this year. We hope we'll be ready to have a budget initiative next year for that one, so that we have money actually set aside and earmarked for QA activities and QA research and development.

The Methods Integration panel is chaired by Larry Reed from the Office of Emergency and Remedial Response and Ort Villa from Region 3, Environmental Services Division. This is the group that is trying to figure out how to consolidate methods. Their charter is to evaluate the feasibility of standardizing analytical methods across media and programs. They have two basic activities that they need to address. One is how to consolidate existing methods or integrate existing methods; the other is how to get a handle on all the new methods that are getting developed in such a way that you don't keep proliferating lots of methods that are slightly different but do the same thing.

They've begun by addressing existing methods and they're trying to find opportunities where they can consolidate those methods with a minimum amount of difficulty. There are three method integration pilot projects underway. They began with volatile organics, metals digestions, ICAP--those are in process and they feel that they will be done by the end of this fiscal year in September. The other two that they have just decided to start looking at are semi-volatiles and microwave digestion. They feel that microwave digestion will fit in nicely with metals digestion and they're hoping to have those two done by September '91. This group is trying to figure out what the best way is for it to be organized to address these issues, because this is a big area and there's a lot of work to begin.

On this panel, we have a lot of other Federal agencies represented because many other groups use EPA's methods. So we have the National Oceanic and Atmospheric Administration, the Department of Energy, the Department of Defense, and a number of others because our methods are not just for our use but for other agency's uses too.

There are some other issues: How do we format the method? Should we come up with a whole new methods manual in addition to all the already existing methods manuals that we have? How do we go about making them legal, that is, including them in the Federal Register? And when we figure out how to do that, do we make them supplement or supplant existing methods? There are lots of different strongly held opinions on how we should go about doing this. So those meetings are very interesting. And if anybody has two cents they'd like to throw in, I would encourage you to talk to David Friedman, who is heading up the work group that's dealing with this issue.

The Automated Methods Compendium panel is co-chaired by Fred Haeberer from the Quality Assurance Management Staff and Bill

Telliard from the Office of Water. This is, I feel, one of the success stories for EMMC in the first year. What the EMMC decided to do was to adopt the existing List of Lists system that the Office of Water had been putting together over the years as the Agency-wide tracking system, and to include methods from Superfund and RCRA and Air and other programs that they didn't already include in their database.

Each of the other programs was going to kick in some money to help fund this and keep it going. It has gone out in a read-only pilot form to Region 3 and its states. I think about 36 copies of this went out to Region 3. Another 22 got distributed to folks around the Agency that Bill and Fred knew were interested. They're expecting feedback by the end of this month on how things went and then, based on that, they'll modify the existing system and make it available for distribution. We thought it would be a good idea to have this in EPA's library in headquarters so that the reg writer folks could have access to it, and then also have it in the regional lab libraries, the regional libraries, NEIC, and the three Environmental Monitoring Systems Laboratory (EMSL) libraries.

We'll look at the results from the pilot study and make any changes. So far the feedback I've heard from people who are using it is that it does address which program the methods support, what the detection limits are, and what type of method it is, and that it's been very useful to those folks so far.

The Analytical Methods and Regulation Development panel started out as the Quality Assurance and Regulation Development Project at one of these national QA meetings. Anyway, the Regional QA Managers decided that they didn't feel QA was getting enough attention in the regulation development process, so they started an initiative with Carol Wood of Region 1 as their leader, figuring out how they could get QA better highlighted in the regulation development process. When EMMC got started, and they were talking about analytical methods in the regulation development process, we volunteered Carol and said, "She's already leading this effort; why don't we just let her continue on as one of the ad hoc panel co-chairs." The other co-chair is Maggie Thielen from the Office of Regional Operations and State/Local Relations. Their charter is to develop a system for factoring methods development and validation concerns into the Agency's regulation development process.

The panel was recently successful in getting the regulation development steering committee to adopt their recommendations, which is in the Start Action Request, the document that begins all regulation writing at EPA. They would have a question that says, "Does this method require environmental measurement?" And if the answer is yes, then the work group chair must go out and find somebody who knows something about environmental measurements and include them on the work group to make sure that whatever they come up with is implementable.

In addition, Jim Weaver, who's from the Office of Regional Operations and State/Local Relations, and is the steering committee representative from that office, will contact the programs in the region and the ESD in the lead region to make sure that we get representation from the regions on the group.

Finally, once it comes to workgroup closure, the chair of the Regulatory Steering Committee, who is, I think, Tom Kelly from the Office of Policy Planning and Evaluation (OPPE), will ask the question, "Is this rule implementable from the perspective of environmental measurements?" If the answer is no, it doesn't go to red border; it stops until they can work it out. If it's yes, it can go on to red border, which is the final step within EPA in getting something ready to go into the Federal Register.

This was a big step, because it's very difficult to get something included in the guidance to reg writers. So we feel that this one's quite a success story, too. They're going to try it out for a year, and when the year's over, evaluate and see how well it worked, how should they change it, and if they should leave it alone.

We felt strongly that the national program office QA Officers needed to play a strong role in this, because they're the folks who are going to know what regs are coming forward and are already being worked on. We wanted them to be our first line of defense to notify others in case they feel that's not being addressed.

I think one of the driving forces was not whether there were court challenges or not, but how well the regional folks felt they were getting methods in time and appropriate QA and proper quality control (QC) requirements in time to carry out the regulations as they came down the pike. In the spirit of TQM, this will be one incremental step forward in improving our whole process.

The last panel is the National Environmental Laboratory Accreditation panel, which I co-chair with Jim Finger, the ESD Director in Region 4. We were charged with two things: first, to decide if a uniform National Environmental Laboratory Accreditation program for labs performing environmental testing procedures was feasible, and second, if it was advisable. After a number of meetings and a lot of disagreements, we agreed that National Environmental Laboratory Accreditation is probably a good idea and that it would benefit the programs. We thought that if we decided we wanted to do it, we could do it.

What we didn't decide is should we do it. And we didn't decide that because we felt what we needed was a Federal Advisory Committee because the reason this all started was that EPA's Deputy Administrator F. Henry Habicht got a call from the private lab industry and said we really need national environmental lab accreditation. We felt very strongly that we ought to hear from

all the users of environmental lab data and not just from EPA. So our ad hoc panel did include one state representative.

Initially, we had some folks from the lab community and were told by general counsel that we were not allowed to do that. If we wanted to talk to the lab community or any of the users of laboratory data such as API, we had to set up a Federal Advisory Committee. So I'd say for about the last five or six months we've been in the process of trying to figure out how to set up a Federal Advisory Committee and get it going. That committee will consist of representatives from the states, from EPA and other Federal agencies, from the laboratory industry, laboratory associations, and trade associations to make recommendations to the Deputy Administrator on what they think would be valuable to them in terms of a National Environmental Lab Accreditation Program.

We felt that one of the keys to having a National Environmental Lab Accreditation Program was getting the states on board. Without the states, it seems to me we'll just be layering another bureaucratic program on top of a lot of already existing programs. That's why we felt very strongly that we had to have a lot of state representation on this Federal Advisory Committee. If we can't get reciprocity, which seems to be one of the big problems, then I'm not sure we're ever going to be successful with National Environmental Lab Accreditation. We did invite the National Institute for Standards and Technology (NIST) to come and talk to us about their lab accreditation programs. They felt very strongly that if they were going to set up a program it would have to be centralized; they would have to have complete control of the program from NIST in Maryland, and based on the existing programs that we already have--almost every state has some kind of a lab accreditation program--we felt that wouldn't work at all. So the NIST model doesn't look good for what we want to do.

We're hoping to have our first Federal Advisory Committee meeting in June. Our goals within the next year are to identify the critical elements and design of a national environmental lab accreditation program, identify the benefits to all the users of laboratory data, and provide options on how it could be funded and how it should be managed. So that's what we hope to do in the next year on National Environmental Lab Accreditation.

We have talked to the Health Care Financing Administration, which has recently set up a program where they have to certify medical laboratories, and we invited them to come and tell us what they were doing and how well it was working. They declined and said it was too soon to tell and that they would have something to talk to us about later; so we're going to try them again, since it's now later.

The Clinical Lab Improvement Act was passed by Congress in 1988, and they have to set up a clinical lab accreditation program. They

proposed the requirements for that about a year ago in the Federal Register, and that's something in excess of 20,000 comments. Under court order they have, just recently I think, re-proposed because of the extent of the comments they got. But they do have some very good and interesting techniques in there for monitoring performance of the lab.

Some of the states have said they want a Federal regulation that says you have to participate in this. And some of the folks we've talked to have said they want a voluntary program. So one of the things we need to recommend is whether it's going to be Federally mandated or not. What the private lab community is telling us is that if we set up a national program, they will participate because they'd rather be part of a national program than subject to each of the individual states' programs.

Jeanne Hankins of the Office of Solid Waste has agreed to serve as our executive director of the Federal Advisory Committee and to handle these lab accreditation issues for us. I'm looking forward to having her join us, because this is a big issue and I haven't been able to give it as much of my time as I would have liked. We welcome her to this project.

Just to sum things up: the two big achievements, I think, are the Environmental Monitoring Methods Index (EMMI), which is the automated database that Bill Telliard and Fred Haeberer were working on and the QA Services group, which is still struggling to convince program offices and others how much is really being spent, how much needs to be spent, and how we should go about funding QA needs and methods development needs in the long term. That's all I have to say about it.

HARMONIZATION OF QA REQUIREMENTS ACROSS THE GOVERNMENT: INTRODUCTION

Nancy Wentworth
EPA Quality Assurance Management Staff

We're going to be talking about the differences and similarities between QA programs across the government. We have representatives from the Army, the Navy, the Department of Energy (DOE), EPA, U.S. Geological Survey (USGS), and the National Oceanic and Atmospheric Administration (NOAA)--a wide range of people dealing with many different programs and many different concerns.

One of the things I've enjoyed most in QAMS is the ability to meet people from across the Agency and across the government. All of us in QAMS enjoy the opportunity we have to learn from other people. Harmonization of QA requirements is one of the areas that we have learned a tremendous amount about over the last few years. We've talked to many people across the Agency and, as part of our responsibility for oversight and review, we've looked in detail at a number of programs and found that there are many common concerns manifested across the country. We have found that the exchange of information has provided us with a tremendous resource.

One of the major things we have recognized is that the guidance that we have available to the QA community within EPA is outdated. It's in need of revision to better reflect the QA program that we are now operating. Many of you are aware that the QAMS-005/80 guidance is approaching 11 years old. The QA program in the Agency when that was written was not the program that it is today. There have been many strides forward and we need to have our guidance accurately reflect the current program. One of the things that is a priority to me as the Director of QAMS is to bring our guidance up to date to the program that we're operating now, and the program that we see is needed across EPA and all of the environmental programs.

We've learned a lot from you. And one of the things we've learned is that we need your help if we're going to be able to revise the guidance and improve it and make it usable across the Agency. We realize that the guidance has to be readable; it has to be easy for people to translate into their day-to-day environmental monitoring operations. It can't be written in hard tech engineering dialect if it's going to be used in laboratories where people are used to the chemistry dialect. It has to be in a common dialect that we all understand.

We're trying to look at the issue from a Total Quality Management (TQM) perspective--not from a narrow EPA-only issue, but from the wide spectrum of environmental monitoring operations that go on across the government. It seems appropriate, if we are going to

improve our guidance, that we consider all of the needs of the other monitoring programs we run that affect other agencies in the government. As long as revisions are needed, it seems appropriate to incorporate the concerns and requirements of other agencies and to harmonize the requirements. I think that's an important thing to recognize. We're trying not to have EPA stand alone, but to have EPA stand with the other government agencies--to have a logical, reasonable, usable program across the board. I think that will help significantly to eliminate a lot of the problems and concerns that you share.

A few years ago when we saw TQM rising as an important way of doing business, we made a point of talking to the QA managers of other environmental programs across the government. What we found was very similar to what was in our own Agency--that the same guidance was being interpreted differently across the country and in different applications. It became clear that there needed to be an effort to take some of the differences out of the program so that we could operate more efficiently.

The vehicle that presented itself to us as a way of doing this was the American Society for Quality Control (ASQC) Energy Division, which has an Environmental Waste Management Committee with representatives from EPA, DOE, Department of Defense (DOD), and contractor communities. This committee provided an opportunity for a small number of people to sit down and begin to work through the issues and concerns that their agencies had. Through this vehicle we were able to begin discussions on harmonizing a standard.

The EQA-1, Quality Assurance Program Requirements for Environmental Programs, is a draft that has been prepared through this ASQC committee to begin the discussion and the widespread comment within the community to try to develop this consensus standard. We have spoken about this document at a number of meetings outside of EPA--ASQC meetings and other technical meetings--and the document has been widely distributed.

We are seeking your comments. For this effort to succeed we must have your input on how QA programs can be made more common across the government. We'd like to get a wide range of comments from the QA community, both from within EPA and across the DOE and DOD organizations and the contractor community. We're interested in hearing from all of you.

We have assembled two panels to talk about the differences and similarities in QA programs across government agencies. I think this is a valuable opportunity for us to exchange ideas. It's important for us to talk about our differences or similarities in programs, the differences in our needs, and the differences in our management and operating circumstances.

For those of you who are not EPA employees, we need to know what

your views are on the benefits of harmonizing QA requirements, the savings that you can see in that kind of a shift, and the types of concerns you have that are not, as you read it, addressed in the EQA-1. This is an interagency activity that is unprecedented. We are committed to improving EPA's QA program, EPA's guidance across the country, and EPA's clarity in explaining what people are expected to do to meet the EPA requirements. We are hoping that this effort will respond to a lot of those points.

We're also looking at this as an important team effort within EPA. I do not want any of you to think that what's presented to you is a done deal. We are in need of supporting and improving our QA program. We have made a proposal that we think responds to the concerns that have been voiced to us over the years. We need to hear back from you whether your concerns have truly been addressed and dealt with. With that information, we can revise, modify, make more user friendly, and make clearer the document that you have so that it can work for EPA.

After the panel discussions, we will be breaking into discussion groups to talk about the issue of Harmonizing QA Across the Government. The purpose of that discussion is to talk about the process of changing our approach to QA and making it more consistent across government and the processes that you, as individuals with QA responsibilities in different organizations, will have to go through to change your program. We'd like to know what support you need from us, and what support you need from within your own organization to help implement change.

I know from experience that change at EPA is often difficult, because people don't want to do things a new way or a different way. What we're trying to do now is begin both the continued refinement of EQA-1 or a new QA guidance system for EPA, but also the process of people looking at it and beginning to assimilate it into their operations. So I think we'll have some interesting discussions from a process perspective, not from a technical standards perspective.

I'm particularly looking forward to hearing how other agencies are handling QA issues, what they view as their major differences and major similarities with EPA's program, and the results of the discussions on what kinds of process things we need to consider as we look at implementing changes in our QA program.

INTEGRITY IN SCIENCE

Adil E. Shamoo
Editor in Chief,
Accountability in Research: Policies and Quality Assurance

I want to thank the organizers for giving me this opportunity to share my views with you. Some of what I am about to say has been said, but it's going to be from different perspective. I came into this area 10 years ago, when there were a lot of people suffering on both sides as the investigator and the field in general on issues involved in integrity of research.

There are two key areas that we are trying to change in order to ensure the integrity of research: policy and individual investigators. Both areas are important; however, policy changes, I believe, can have quicker and farther-reaching consequences. Therefore, we need to address policy makers and emphasize to them that these policies can foster integrity in research or breed fraud, misconduct, and sloppy work. And that's basically what we are dealing with here; that's quality assurance: to prevent and reduce sloppy work.

To influence individual investigators without changes in policies is nearly impossible. However, even if policies are appropriate, changes in individual investigators will be slow. Are the current concerns regarding the integrity of research data an indication of: (a) the decline in the ethical values and conduct of research by investigators; (b) a new awareness of an old problem that is produced by a small and negligible number of sociopaths and deviants of our society; or (c) an old problem, but increasingly larger enterprise makes them appear bigger? What are we talking about? Are we talking about fraud, misconduct, careless practices or error, or all of them?

In order to answer these questions, an historical perspective of the problem is needed. Researchers at the turn of the 20th century were no longer monks on top of a mountain. After the industrial revolution and specifically after the first and second World Wars, the research enterprise grew rapidly. In the United States alone there are now one million research scientists, two and a half million participants, and a budget exceeding 160 billion dollars annually. So it is a big business.

Just a few examples to illustrate some of the irregularities in the research area in the 20th century; first, the famous story of the Piltdown Man. Piltdown is a city near London, where in 1908 fake skull bones were found. The bones were made to appear thousands of years old and made to look as if the skull was a mixture of a monkey and a man, thus proving that man came directly from apes. Charles Blinderman--and this is the last paragraph in his book The

Piltdown Inquest (1986)--said something which is true at all times. He said that anyone conversant with Piltdown and history will readily, if not eagerly, agree that many of the researchers shaped reality to their heart's desire. Protecting their theories, their careers, their reputations, all of which they lugged into the pit with them, because that's where it was found, in the pit, in the Piltdown. This story lasted for 40 years. There were over one thousand research papers and Ph.D. theses written in support of the fake skull bones.

An example now of an error that affects national policy: A 1985 report on Social Security statistics, presented by Martin Feldstein, who was a chief economic adviser for the President, said that an attempt to replicate Feldstein's construction of Social Security wealth revealed that his series was incorrect. Feldstein has acknowledged that a computer programming error was made in incorporating with those benefits provisions of the 1956 amendments to the Social Security Act. As a result of this error, his Social Security wealth series grew rapidly after 1957. By 1974 the series was 37 percent larger than the correct value. Our national policy was based on those error numbers.

There are numerous other cases of alleged and proven cases of errors, misconduct, and fraud. We have been deluged recently with investigations, reports, and Congressional hearings regarding misconduct in science. What are the issues of data integrity? They are: 1) falsification of data; 2) plagiarism, which is the hardest one; 3) suppression and selection of data; 4) misuse of privileged information; and 5) what you are concerned with--poor data quality.

What are the causes of these problems? In my view the causes are numerous, but they can be categorized into two broad areas: institutional in nature and generic in nature. The initial institutional response to the problems of data integrity is like a sick patient being told for the first time he has cancer--his denial, defensiveness, combativeness, then, of course, followed by reluctance. However, due to public pressures, research now has new regulations--the National Science Foundation (NSF) has, the National Institutes of Health (NIH) has, EPA has, and the Food and Drug Administration has. But none of the regulations or their basic foundation acknowledges the very generic nature of the problem. Thus, there is no development and formulation of policies and procedures to prevent, deter, deal with, and remedy the problem on a continuing basis.

In his book, The Strategy of Social Regulation: Decision Frameworks for Policy in 1981, Lave summarized our society's dilemma with regulations. Americans can live with social regulation despite its cost and disruption and can't live without it because of the strong public desire to curb the worst abuses of an industrial economy. That's what you're dealing with; if all

industry were perfect, EPA would not exist. Neither of the extreme choices--putting more resources into the regulatory agencies and increasing promulgation of rules versus eliminating the laws and agencies--is viable. Americans have no choice but to learn to accomplish these social goals with less controversy and greater efficiency.

Sociologists such as Emil Durkheim, of the late 19th and 20th century, and those who applied his theories to the sociology of science in the past 50 years, such as Merton and Zuckerman, tell us that deviant behavior is due to "breakdown in values," whether in the community at large or a sub group, such as the scientific community. Furthermore, sociologists deduced that "social control" was the guardian of norms and values in science.

In 1977 Zuckerman stated:

> Social control and science depends partly on scientists internalizing moral and cognitive norms in the course of their professional socialization and partly on social mechanism for the detection of deviant behavior and the exercise of sanctions when it is detected....They must also provide for the detection of deviant behavior and for the exercise of sanctions when it occurs. In science the institutionized requirement, that new contributions be reproducible is the cornerstone of the system of social control. It has two functions, deterrence and detection.

Zuckerman then realizes the potential in her argument when she states:

> Critics of the social organization of science contend that in all fields insufficient incentives are provided for regulation, and, of course, as long as reproducability of scientific results remains an ideal not often realized in practice, it cannot serve as a deterrent to the cooking of data.

This is exactly one of the reasons why dependence on social control does not work. More importantly the cost of reproducing large and complex research is financially, in current day economics, prohibitive. It is also undesirable for society to wait for a very long time such as 5 to 10 years to repeat the study when the research results address an important public health or the security of our society. As a matter of fact, the majority of research, by its very nature, is not contestable, and so won't be reproduced. Not too many research findings fall in the category of cold fusion where everyone wants to repeat those experiments.

Social controls also fall apart where research scientists promote a product, or a drug in which they themselves have large financial

interests. We all are under certain kind of pressures to cut corners. Be aware of them. You in the environmental field acknowledged these problems years ago. In the past 20 years you have developed a framework for how to deal with the issue of the integrity of data. Furthermore, your policies continue to keep up with the changes in the field and the profession.

We in the research field, especially in the sciences, have a long way to go since we barely admit there is a problem. This audience is easy to convince that these generic problems exist in the research field; moreover, that these type of problems exist in any complex and large enterprise. Remember, research and development is a $160 billion business per year.

The generic problems are really three. One is conflict of interest. To me, that's the most important one. It exists in every aspect of what you do and what research and development does. Second is complexity and third is remoteness. Research is no longer conducted by a certain individual in a small laboratory, but rather in a large and complex group with a differing expertise. Therefore, laboratory directors rely on numerous portions of research data from different areas. Furthermore, the project leader may physically be at a remote location from the research laboratory, just like the people in Washington, as well as disconnected from the daily bench research.

I want to go back to the conflict of interest issue, which I think is even more important and critical in research than in any other system. For example, in the financial world one can compartmentalize and isolate several functions that have inherent conflicts of interest. However, in research those who collect, analyze, and manipulate the data are one and the same. Furthermore, in research it's not only undesirable to compartmentalize, but rather nearly impossible. In a fertile research environment you want all those involved in research to know and have access to the data on a daily basis. Accessible research data is as crucial for each subsequent step in research.

Justice Learned Hand describes conflict of interest in 1939, in the Yale Law Journal:

> Our convictions, our outlook, the whole makeup of our thinking, which we cannot help bringing to the decision of every question, is the creature of our past, and into our past have been woven all sorts of frustrated ambitions with their envies and hopes of preferment, with their corruptions, which long since forgotten, still determine our conclusion. A wise man is one exempt from the handicap of such a past. He is a runner stripped from the race, he can weigh the conflicting factors of his problems without always finding himself in one scale or the other.

Let me give you a recent example of the insensitivity of the research community to the issue of conflict of interest, or the perceived conflict of interest, because it is equally important. NIH appointed a committee due to Congressional pressure to investigate allegations against Dr. David Baltimore, a Nobel Laureate. The Magazine section of the Washington Post last Sunday was about Walter Stewart and Ned Feaders, two of my colleagues at NIH who are called "fraud busters," who have been after it for four years. Let me know that I am not here to address the merits of these allegations.

The original committee appointed by NIH consisted of three people. One member was a former post-doctoral fellow and co-authored with Dr. Baltimore 14 papers. None of these papers, of course, was the one in question. The second member co-authored a textbook with Dr. Baltimore. Because of Congressional pressures the composition was, of course, changed. As all of you know, a recent draft report by NIH has claimed and pointed a finger of misconduct by the principle author of the paper, and the paper has been withdrawn by Dr. Baltimore himself. Rough estimates of the amount of questionable research, that sloppy work, ranged from 7 to 12 percent. These estimates, as one would predict, have a tremendous immediate economic impact.

In other words, we have close to $10 to $15 billion dollars a year spent on questionable research. For each expenditure of one dollar in research, we have an additional $10 to $30 dollar impact on the economy in the long range. One can see the huge annual economic impact of shoddy research on our economy. These numbers on the economic impact of continued questionable research are detached from its moral and ethical impact on our society. In this century errors, deceptions and fraud have lasted too long, as in the case of the Piltdown man--lasted 40 years or have had tragic consequences, as in the case of the Challenger disaster. It is apparent that our society cannot fully depend on the current system of extremely defused and ill-defined accountability.

The primary source of all the problems with integrity of data is the conflict of interest. The other two are complexity and remoteness. There is little you could do about them, because that is the very nature of our huge enterprise. The conflict of interest you could do something about.

On May 6-7, I am presenting a paper at Georgetown on Ethical Issues in Research. I have taken statistics for 10 years, showing that industry advisory councils are the top group at most Federal agencies. And I discovered that for the same merits priority score, these advisory groups have probability of getting funding twice. These are the people who write the programs, the direction of the program, and where the money ought to go. They can't be objective because the statistics for 10 years indicate they're getting twice the money for the same priority score.

The same thing with industry. There is no way unless they are Mr. Spock of Star Trek; he's all the time pre-programmed to be objective, right? People don't behave that way. I will not behave that way. No one does. We all have conflict of interests. And we've got to avoid it to have objective opinion. Try to get people with independent sources of judgment, who don't care what the outcome is because it doesn't affect them whatsoever. No one of us is devoid of all these connections.

There is a strong argument toward getting the most experts to be the most objective reviewers of that project. You have two issues: one is expertise; the second is the fact that if they have a conflict of interest they will exercise censorship. A great deal of creative work might be hampered and you've got to weigh the two.

I review grants for Muscular Dystrophy and the American Heart Association; I serve on the policy committee and peer review committee of several organizations; I've even been on NIH advisory for NSF. I would say that 80 to 90 percent of the proposals I have reviewed are not directly in my area. I don't know these people. I don't eat and drink and meet them all the time in meetings and know their wives and their children. I am much more objective when I don't know the person. I believe I am a competent scientist to be able to spend an extra two hours to evaluate a project not directly in my own very, very narrow field of expertise. And I think I would be much more objective than the expert, because the joke is, in science, that you can nickel and dime any proposal to death when you are an expert.

The American Heart Association uses huge councils. They review all the research grants, and 99 percent of them are not in their area. And they do a darn good job in evaluating and funding money. They've had tremendous success in funding excellent people for the past 20 years.

I want now to turn my attention to the issue of QA and peer review within the environmental data quality. I have spoken at length with about 10 people from within and outside EPA. Let me first define my terms the way I have developed them for the past 10 years from their use and the literature in all available fields of finance, research, science, health care, quality assurance, and policy analysis. By the way, the field of finance is ahead of us in terms of accountability and data audit. That doesn't speak much about the S&L crisis; but the S&L crisis is basically the failure of accountability, rather than the lack of the science of accountability within the financial field.

First, what do I mean by quality control? QC concerns itself with ensuring the quality of products and services during the numerous production or service steps in order to guarantee compliance with the originally agreed-upon specifications. Most of what I know from people--what they call QA is really QC. The specs are already

predetermined and you're trying to follow them to the letter. QA concerns itself with reviewing the quality of products and services after the products or services have been used by the consumer for a certain length of time.

What I perceive in the research and development of what is the value of QA: there are three and they are all related to R&D. And everything else emanates from these three things: evaluation of the current R&D activities, actual performance of R&D, and selection of future R&D projects. That's basically what you do most of the time. Selection of future R&D products helps you to evaluate where you should go next.

What are the generalized methods of achieving QA? This is, again, not necessarily only for EPA.

An internal QA/QC unit, in my view, should be down to a minimum number of staff. Guidelines on conflict of interest.

Training and education--that's so important in QA to all of our personnel, starting from top management. Remember, all of us were trained. But we got our college degree, or master's degree, or our Ph.D. without any concern to QA. So we are almost too late. The new generation is where it's important; as for us, we have to be retrained and retrained. Retraining is harder, just like the infant when he learns a language, it's easier to teach it to him when he's less than six years old.

Use of QA/QC consultants, use of outside independent data auditors, implementation of outside QA data auditors' recommendations, retraining and education of internal QA/QC staff, use of independent external QA data auditors whenever a new event occurs--that is, you have a new project, or a new direction in the company or in the agency.

I want to give you my definition of what a data auditor is. I have read the entire 3,000-page document of the Food and Drug Administration on Good Laboratory Practices. They have no definition of what data audit is. None of these documents have a definition of the auditor either--they just go around it. A data audit is the systematic process upon which objective evidence is obtained and evaluated as to assertions about research data and their value to determine the degree of correspondence between those assertions and values and established or predetermined criteria which can then be communicated to interested parties. This is work that took us two years. Steven Loeb is a financial auditor, one of the top in the country, and an editor-in-chief of Accountancy in Public Policy. We searched the literature from the 1930's till now, on how the word data audit is used.

John Lawrence, the Director of the Institute of Quality Assurance in Canada, said (this is going to appear in the next issue of

Accountability in Research, which is devoted to environmental data quality assurance): "The three legs of a quality assurance program: a quality assurance management plan, quality control, and quality assessment."

Here is how he defines his terms. Stringent requirements means that the entire measurement process, from initial site selection through to data interpretation and archiving must be thoroughly quality controlled. Rigorous QA procedures and protocols must be an integral part of all monitoring programs if reliable, traceable, and compatible data are to be generated. The integrity of samples must be ensured throughout collection, handling, and analysis.

Then he continues to define quality assessment. "Quality assessment is administered under the quality assurance management plan, preferably by a neutral third party." The whole thread of what I've been talking about is having a neutral third party--a source of an independent judgment, I call it. It has a management and a scientific component. The managerial component through interagency comparison study--and the audits--provides the necessary information and advice to managers on overall credibility of data and the suitability of field and laboratory protocols and of the effectiveness of internal QC.

Based on these definitions and my rudimentary understanding of the EPA program, I would like to make a few comments, first about my understanding and appreciation of the EPA peer review program. It reviews, primarily, reports; no QA program probably is in it, and no data audit is in it. It is not a focused responsibility. I'm trying to instigate you to think and get angry and ask questions because I think you need an outsider to say these things--conflict of interest issues are not clear.

The reviewers may not be neutral on the subject or the outcome. How truly independent are they? That wasn't clear to me. In house peer review, is it truly objective? That is, once you know the staff, you know everybody in the program. Peer review may coincide with the end of the program. It could, therefore, be too late, and too wasteful. It has no value--the program is finished. I guess it will help in subsequent projects which are similar.

Peer review should not be a substitute for a QA program. How binding are the peer review opinions? Otherwise, what are they there for? Is there a follow up? Is it really a single event only? How thorough could a peer review be when you only spend just a few days to examine the data? Is there truly a critical review of the data, of the raw data or original data?

I would like to make a few comments on the QA program within EPA. One: Is there a philosophical commitment of QA by everyone, the entire EPA? Is there a QA agency culture that is similar to corporate cultures? Is there such a thing? Because I believe some

pharmaceutical companies, especially the modern ones, have a true QA corporate culture within them. Two: Lack of concept of evaluation of data quality and why. Three: Does it truly audit raw data? I was not able to decipher that from all the documents I read, or from all of the 10 people I've talked to. Four: How are all QA programs integrated? Five: QA training of scientists. All these university contractors have zero QA training. They not only don't believe in it, they think it's a pile of junk. Could scientists be trained as QA officers? Six: QA, in order to be effective today, should have access to all data, including industry confidential data.

The way I envision QA is after the fact--to look back and peer review and assure the data after a time has lapsed of the services or products. Again, you have to look at the literature and how it was used by all these other fields. Once you know the specs and you've put them down in writing, and you're telling all the subordinates how to do it, that is no longer a QA program; it's a QC program because you know what to expect from them. QA is you evaluate the QC program after two or three years; you change the QC program; you make suggestions. The procedures may be wrong; new methodologies may be introduced; new science may be introduced--it's much more global in nature. That's how I view QA, rather than as primarily a check list approach.

This is based on the literature of the past 40 years. And part of my job in writing and urging a lot of people to write on this subject is to have a basis of sharing information. The Journal is one, the book is another, the conferences that I organized three years ago was one, the next one in Rome is another one, another one is going to be in Washington next year. This is the basis of why we share information. How many books or literature written, for example, or articles on the EPA QA program were read by everyone? Not a lot, and that's important. I'm inviting you to write your views, to disagree--that's what academic life and intellect is all about.

I will end by giving some bold, overall strategic suggestions. One: Scientists and QA personnel cannot run away from the implication of the data on policy and regulation. There is no such thing called pure science without an impact on other parts of our society. I heard a lot about "we're only interested in science." They should become involved in policy and regulation--you and scientists.

Two: There should be one overall QA program where peer review should be a component of QA programs. QA programs are a permanent fixture and the peer review is only a temporary event to augment an ongoing QA program.

Three: QA programs should be augmented by truly independent outside reviewers who perform a truly scientific data audit.

Four: Discovery laboratories. Exploratory laboratories that test market new ideas and are nonprogrammatic, not of the basis of any paper or a policy, but purely the private notebook of a scientist, should not be the subject of any QA or data audit. This is to protect the creative process.

In the 1990's our society will demand a greater and greater accountability for the conduct of each professional group's action. Society will not give each professional group their unchecked license to do what they wish on the principle that they know best. They will not do this for the military, doctors, accountants, scientists, or even QA personnel.

JOURNEY TOWARD QUALITY: THE FEDERAL EXPRESS STORY

Gilbert Mook
Vice President, Properties and Facilities
Federal Express, Inc.

It's my pleasure to represent Federal Express, especially to be out preaching the quality gospel. We have an opportunity to go out and talk to a number of groups about our quality program, and I've had the opportunity to meet with a lot of different organizations, both government and non-government, and I've seen some interesting things going on--a lot of positive activity.

One of the things we found is that no matter what business you're in, chances are that you have a shelf full of "how to" books. Everyone wants to know the secret of success, and we can always go to a host of self-appointed quality gurus who are willing to let you in on their secrets. Unfortunately, what works for one company or one organization doesn't necessarily work for another. And that's why many organizations, including Federal Express, employ many different techniques and methods in their ongoing efforts to define and refine their quality process.

And so, when people come to us and say, "What did you guys do to win the Baldrige Quality Award and how can we incorporate the special secret into our quality process," unfortunately we don't have a one-size-fits-all answer. What we can do, perhaps, is go over three fundamentals that have guided us.

First of all, customer satisfaction starts with employee satisfaction. Second, service quality has to be measured, and third, customer satisfaction is everyone's job. These points are the basis of what I'm going to talk about with you this evening.

Our focus at Federal Express on quality began the day that we began. For although we were really a maverick at the time in the distribution industry, our objective then, as it is now, was to provide timed, definite delivery for high priority documents and packages. Fred Smith, our founder and CEO, was first to apply the hub-and-spoke concept for distribution practices. At the time there were no precedents to guide us because this was a unique approach; consequently, we had to create practices and processes as needs arose. Though many of these processes have changed and our operations have expanded over the years, the focus has always been on delivering quality service.

When we began operations in 1973 we shipped eight packages on our first official night of operation. From these humble beginnings, we've become the world's largest air express transportation company, delivering over 1.6 million items to 127 countries around the world each working day. Our fleet today consists of more than

400 aircraft, which includes Boeing 747s, DC 10s, 727s, F-27s, Cessna 208s. On the ground we have more than 35,000 computer and radio-equipped vehicles. Also, we have 94,000 employees to support our worldwide operation.

To expand so far and so fast, we've had to continually reassess our policies, our procedures, our logistics, everything. In fact, our focus has always been on 100 percent customer satisfaction. From the beginning we've been guided by a simple but profound three-word corporate philosophy: People, Service, Profit. And this is as relevant today as it was nearly two decades ago. The philosophy guides the setting of our annual corporate goals, and we have one goal for each of these three elements.

Our measurable people goal is the continuous improvement of our management leadership index score, which we track through our annual Survey Feedback Action program. I'm going to tell you a little more about that in a few minutes.

Our service standard is 100 percent customer satisfaction. We had to guide our efforts. In order to do that, we've created a unique measurement system of service quality indicators. This index measures our weekly, monthly, and yearly progress toward achieving our 100 percent goal.

Our profit goal, much like any other company's goals, is fundamental to our long-term viability. If you don't make a profit, you can't sustain growth.

To sum up our People Service Profit philosophy, we believe that if you place your people first they will, in turn, deliver an impeccable level of service, which is demanded today by our customers, and that profit will be the consequence.

The essence of our people-first policy is that customer satisfaction begins with employee satisfaction. Let me share with you some of the methods that we use to demonstrate our commitment to a people-first philosophy. One of our most important programs is our annual Survey Feedback Action (SFA) program. SFA has been a part of our quality process for the last 11 years. The survey gives people the chance to express their feelings about their managers, their service, and about pay and benefits.

Once a year every employee within every work group anonymously fills out this survey. A portion of the survey includes a series of statements concerning the immediate manager's leadership abilities. One such statement may say, "My manager asks for my ideas about work." Or another: "I can tell my manager what I think." Or: "My manager tells me when I do a good job."

In each case, the person filling out the form may respond either favorably or unfavorably. While the individual responses are kept

confidential, the overall results of the survey are passed onto each manager, who then must meet with their group to develop an action plan for resolving any actions that were identified in the survey. So the survey gives useful information regarding individual managerial strengths and weaknesses.

Just as importantly, all work group results are integrated into an overall corporate leadership score. These scores are then used to diagnose the corporate-wide leadership problems and in addition become part of management's overall objectives. And here's the rub: this is how they get your attention, because these scores are then tied to incentive compensation for both managers and professionals throughout the corporation. In fact, if the company's wide leadership score isn't as high as it was the year before, no one in management receives a bonus. That's incentive. So the survey feedback action encourages strong, even-handed leadership and open two-way communication.

Another people program is our Guaranteed Fair Treatment (GFT) Program. The aim of the GFT process is to maintain a fair environment in which everyone who has a grievance or a concern about his or her job, or who feels that he or she may have been mistreated for whatever reason, can go through and have these concerns addressed through the management chain. A team of management weekly reviews GFT cases that have not been resolved and have progressed up through the three-step internal process to the final stage, which we call the appeals board. What we've found over the years is that this is not the fastest way to address an issue, but we think it is the fairest.
Both the Survey Feedback Action program and the Guaranteed Fair Treatment program promote open communications. By creating this environment we have found that people are more apt to take part, to make suggestions for improvement, to question decisions, and to surface concerns. We work hard at keeping these lines of communication open within and between divisions, departments, management, and the front line worker.

For example, we have an 8:30 a.m. operations meeting every day and this serves as an example of some effective cross-divisional communication. At these meetings divisions representatives from our various divisions around the world come together to discuss major operational problems encountered during the previous 24 hours. We run essentially an entire war plan every 24 hours. So people are gathered around the table or participating via world wide conference call--these people will determine who is going to solve each problem that's been identified, how it's going to be done, and all these action plans must be developed and implemented within 24 hours.

This continuous check on quality of service enables us to find ways to reduce failures. It's also another way to communicate effectively.

One of the things we've found over the years is that gone are the days where senior management used to be able to sit down and face the entire work force to discuss problems. Today we've gone to the high tech solution. We now have a technology to share information quickly and effectively via our satellite link television network, FX-TV. New information is quickly and effectively shared through live phone-in question-and-answer sessions between top officers of the company and employees. This front line feedback is vital to the quality process. Today all major presentations are broadcast over the FX-TV network for employee viewing. Effective communication is critical to keeping everyone aligned with our goals.

Training is also fundamental to the success of our quality process. Employees must know what's expected of them and be given the proper training in order for them to be effective in their jobs. At Federal Express all customer contact people receive extensive training before they assume their jobs and deal with customers. For example, our call center agents are given six weeks of intensive training before they'll ever take the first call. Senior agents provide one-on-one coaching to help the trainees become familiar with the computer terminal and its functional screens.

Every six months couriers and service agents and customer service representatives must participate in a job knowledge testing program. These tests are online and can be taken at any one of our over 25,000 terminals around the world. After the tests are completed, the computer tallies the score and stores it in the employee's training record. Within 24 hours the agent or courier receives the pass/fail results of his test. Along with the test results, each person receives a personalized prescription that targets areas requiring review. It gives them a list of resources, training materials. and interactive video lessons to help them get back up to speed.

We're very serious about training. If, for example, a customer service agent were not to pass the test, he or she would be relieved from duty for eight hours of remedial training. This training can be obtained through interactive video lessons. By going through this training, employees would progress at their own rate until they're ready to take the tests again. So all our training directly supports the continuous improvement in the quality of our service.

We also have a variety of reward programs that encourage people to work toward providing the highest possible quality of service. Pay for performance is written into everybody's job description from myself as a senior officer, down to the courier that you may meet in your workplace. A manager can bestow what we call a Bravo Zulu Award, which is U.S. Navy jargon for "well done." This can be bestowed on the spot. This commendation is given for clearly going above and beyond one's job responsibilities, and can bring with it monetary reward in the form of a check, or a non-cash award, such

as tickets to a dinner or theater tickets. For the non-management employee we have what we call the Golden Falcon Award, which is a recognition of service above and beyond. Teamwork is applauded through a monthly Circle of Excellence Award given to the top performing work unit or station in the field.

We've found that when people have the autonomy to make decisions that affect their performance and its outcome, and they have their ideas listened to and acted upon, they have greater ownership in their job. I'll give you an example. We didn't just create a tool like the Cosmos Super Tracker and hand it out to our couriers for them to use. We asked for their input. We asked them to help us design it and work with us to make it better before we even rolled it out for the first time. By providing real time information through our Cosmos Tracking System, we are proactively trying to reduce customer dissatisfaction.

One of the things we've discovered is that a customer not having information about a package is equally, if not more frustrated, than receiving a late package. According to studies that we've made, 70 percent of customers with complaints don't complain, they just go away--often for good. To avoid this consequence, we believe that you must quantitatively measure service quality.

Many of us who have studied quality have read of W. Edwards Deming. He said that you cannot manage that which you can't measure. For many years we measured our service levels by measuring our success rate, the percentage of on-time deliveries. And, indeed, we found out that 99 percent looked pretty good. But in 1985 we realized that if we really wanted a true picture of our performance, we needed to begin our performance by our customer's standards and perspectives.

We initiated customer satisfaction studies that afforded an in-depth look at the way our customers perceived our service. We set about interviewing, quarterly, a sample of our customers who shipped with us--some exclusively, some with our competitors. They were each asked to participate in a 20-minute interview covering about 50 areas. Two years into these studies we realized that while we were becoming more aware of customer needs, we were missing the mark because we were falling prey to the law of large numbers. One of the things we found is that even at a 99.1 percent success rate, this translates into 2.5 million failures a year. That's 2.5 million customers who may go away.
By 1987 we decided we needed a more rigorous method to measure the quality of our performance. So we turned our measuring stick upside down. We stopped measuring the percentage of our success and began measuring the number of actual failures. Our tracking system provided the data base. From this we developed our Service Quality Indicators. We call it SQI.

SQI is a service measurement index which tells us exactly how much

improvement we've made in reducing our errors across 12 critical categories of service. Here's how the system works: Weights are assigned to each component, from one to ten points per failure, according to how bad these failures would frustrate a customer. For example, a late package is weighted at one point, and this, indeed, is less upsetting than a damaged package that's weighted at 10 points. The nature of the failure is just as important as the total number committed.

What we've done is to go out and measure all the things that annoy our customers and then measure ourselves against that. A missed pickup is a pretty big hit. That's when someone calls and says, "Hello, I have a package." And no one shows up. That's an egregious error. We also have lost packages. What could be worse? Damaged packages. So these points are assigned to each one of these sins as we go through.

One of the things we found is that often a customer may not even be aware that we've failed. For example, suppose we guaranteed a priority one service by 10:30 the following morning. If we were to deliver that package at 10:31, our system that counts the delivery knows it's a failure, even though the customer may not even notice it. Why would we go to the trouble of docking ourselves for packages delivered just one minute late? The answer's quite simple. One hundred percent customer satisfaction is our goal and nothing less.

All of these efforts, which involve the setting of clear goals, the creation of a people-first environment, the cross divisional communication, the extensive use of technology, training, rewards and recognition systems, and sophisticated measurement systems, have been encouraged and developed so that people are prepared to deliver quality service.

Part of improving our process has been the development of Quality Action Teams (QAT's). And through the years we've seen more and more people from all areas participating in these QAT's. The critical success factor is that no one comes closer to the expertise about a particular job as the person who is doing the job. We now have a process of measuring quality efforts, and once a quarter each division goes through an internal selection process in which they choose their best quality success stories. Teams chosen are considered to be the best of the best. We have a ceremony; team members present their quality success stories to management; and some of the results have been astounding from all levels.

One of the things that I've had a difficult time preaching to people about quality is that every person in every job is an expert about his particular area, and it's those little things that add up. Those are the real expressions of quality, as opposed to coming in with some sweeping managerial changes.

Last year, for example, we had a QAT from our Memphis Super hub. They developed a recycling plan. We are now recycling such things as steel, batteries, plastic, wood, pallets, tires, waste oil, paper, and the results in one year--just in this group--are that they saved over $200,000. Now this program is company-wide and we're recycling all over the world.

We talked about our 12 service quality indicators. Well, we formed what we call 12 root cause teams to enhance the quality process which looks at each one of these service quality indicators. And although each one of these teams is led by a corporate officer, there's really no star quarterback. As with all the quality action teams, every member is equally empowered regardless of whatever his position may be in the organization. So everyone, especially our frontliners, has the option, the time, and the power, to deal with customer problems. That empowerment translates into better service and more satisfied customers.

We formed quality action teams across divisions to improve responsiveness to our internal relationships. When analyzing the way people rely on one another throughout our operation, one of the things that we found is that everyone's job is to support someone else. That someone else may very well be their internal customer. So, if you can do a good job in providing service to your internal customer, when that service reaches the external customer, satisfaction is built in at every step and it then becomes a permanent fixture.

What models did we use at Federal Express? We had a quality guru organization come in and give us a list of procedures. Basically it was a language. It seems to me that the most important thing is to get everybody talking the same language so that they can communicate. And that's all it was. Our corporate quality structure is an Executive Quality Board and a Quality Advisory Board.

The key thing in getting the quality program going is that it has got to be bought off and demonstrated by the top management. It's not something that you can send down and say, institute this quality program. Because if the people don't see the top guys doing it, they're not going to buy it. And that, to me, is worth a thousand books on quality. You've got to preach it if you want to get other people to buy into it.

Everybody wants their organization to run better. Everybody wants to have a more profitable organization. And one of the things that we found--and this is an example of why management would buy into this thing--is that we spend an inordinate amount of money ensuring 100 percent customer satisfaction. We charter extra airplanes, we run people overtime, and it costs a lot of money. The cost of quality is very expensive. What you find going through the design phase and finding something to change is that it costs maybe 10

dollars. But if you change something once it's operational and out in the field, it costs you 100 dollars or more.

The real truth is not that we were blessed with any more wisdom than anybody else, but when it gets right down to it, quality was a tool that we thought we could use to make our company more profitable. And that's what gets people's attention.

Management puts the procedures in place. I am the quality disciple in my division. We do have some quality professionals but I don't have any in my division. And the reason I don't is because it's always been my theory that as soon as you have somebody else to come in and perform the task, management then assumes that they're off the hook to be accountable. So we don't have any in our organization. Everybody's got to do it. And everybody's measured by it. Not measured by the number of events, but rather by the performance of their jobs and it's got to continually improve.

People talk about the quality process--that's a scary word. Quality process can be a group of people who run around with clip boards counting are you using the right language. Our quality philosophy is that everybody buys into the fact that if I communicate with somebody, and if we have a customer supplier alignment, then I know what's expected of me.

We've got a form that we fill out. In one column is "How do we think we're doing in providing service to this customer?" The other side, the side the customer fills out, asks, "How is this guy really doing?" And guess what? The numbers aren't the same. So the idea of the customer supplier alignment is to get his perception and your perception the same thing. And then you make a contract and you write it up. And then you are measured by meeting the elements of that contract. And it works. It gets people's attention.

Our well-communicated focus on customer satisfaction saved the day for one of our customers. A fellow by the name of Michael Davidson of Atlanta was unable to meet the cutoff date of his business service center, so he ran the Atlanta Hartsdale airport with 150 packages that needed to go out. They happened to be his company payroll and he was very interested in getting it out. He came charging in here during what was the busiest time of the shift for the young man who was accountable for getting that aircraft out and loaded. His name was Mr. Augustus. Realizing the time constraints on this one guy, he shanghaied a service agent and a couple of pilots and together they worked to code the package so they could get the correct sort designators and get the freight on its way. All this was done, by the way, without jeopardizing the on-time departure of that particular Newark to Atlanta flight that Mr. Augustus was assigned to get out. Thanks to his dedication in getting this job done, he did earn the Golden Falcon Award that we talked about earlier. For Mr. Augustus and all of us at Federal

Express, quality is an objective that leads to 100 percent customer satisfaction.

Driven by this quality-focused mind set, we then applied for the Malcom Baldrige Quality Award, even though we were struggling through a very challenging year. We had just integrated with Flying Tiger Lines and had opened up a whole new segment of our business. Going for the Award and winning it has been quite an educational experience for all of us at Federal Express. And naturally, we're all proud of being the first service company to be named as a recipient. But we're really only as good as our latest pickup. So whatever loyalty we have earned in the past it must be preserved, because loyalty in a competitive marketplace is a very fragile commodity.

We found that the real value of the Malcom Baldrige Award is the opportunity to rigorously evaluate our own company. Our quality processes have improved as a result of going through this. Applying for the Malcom Baldrige Quality Award will do the same for any company that's willing to undertake the challenge. One of the other things that concerned us upon receiving this award was that we would run the risk of everybody saying that we have now solved the quality problem and let's go back to the regular way we've been screwing up the business for years. It's in many ways a mixed blessing.

With all this in mind, we do keep a watchful eye on our Quality Service Indicators and an open mind as we look into the future. We in industry today are fighting for our existence in a global marketplace where our competitors are ahead in the quality arena. We can go through a long list of industries that are no longer with us or no longer viable because of this. And so, while some may see the Malcolm Baldrige Award as a culmination, it certainly is not to us--it's only just another landmark on our journey toward achieving our objective of 100 percent customer satisfaction.

Fortunately, it's not a journey that we at Federal Express take alone. The example is this meeting here today. Today countless corporations have begun to align themselves with suppliers who share their penchant for quality. These organizations realize that quality performance is becoming a necessity for survival. The quality improvement process at Federal Express is aimed at 94,000 employees believing that our goal of 100 percent customer satisfaction will always be the key to our continued prosperity.

Thank you very much.

GOOD AUTOMATED LABORATORY PRACTICES
PANEL DISCUSSION

Moderator:

Kaye Mathews
EPA National Enforcement Investigation Center

Panelists:

Jeff Worthington
TechLaw Inc.

Joan Fisk
EPA Office of Emergency and Remedial Response

Rick Johnson
EPA Office of Information Resources Management

Kaye Mathews

We will be focusing our attention on the trend toward computer automation in the laboratory and EPA's progress toward addressing these trends with its draft guidance "Good Automated Laboratory Practices: Recommendations for Ensuring Data Integrity in Automated Laboratory Guidance."

Joan Fisk

I'll be talking about Good Automated Laboratory Practices Guidance: A Perspective for Superfund Data Collection Activities. By way of background for those of you who aren't familiar with Superfund's Analytical Operations Branch, we have quite a few responsibilities related to analytical services under our cognizance. We provide environmental service assistance teams to each region. These are contractors within each region who do things such as data review, analysis of samples, and reviewing QA plans.

We also are the coordinators for developing guidance for data review or data usability. We are the leads generally for Superfund methods development in coordination with the Office of Research and Development. We also maintain an extensive database called the Contract Laboratory Program (CLP) Analytical Results Database Card. We also provide large routine analytical services through the CLP and special analytical services.

We are very much involved with quality assurance (QA) oversight and quality control (QC) programs for Superfund. We work with Duane Geuder, Superfund's QA Officer, and our QA Coordinator, Jim Baron. We are involved in the QA oversight of the CLP and are also trying to get into other areas where analyses are being done outside the

CLP. We're in the process of making every effort we can to put performance evaluation (PE) materials into the regions for all these uses.

We've seen this Good Automated Laboratory Practices (GALP) as being very important in looking beyond the traditional in our QA oversight because of the changes that have happened in the industry over the past few years. In the last few years, the laboratory community has become heavily computerized. There are many reasons for this. The market pressures with all the environmental legislation--the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) or Superfund, the Resource Conservation and Recovery Act (RCRA), the Clean Water Act, Clean Air Act, and Safe Drinking Water Act--are such that there's an enormous amount of analytical work to be done out there. Fortunately the technology has marched along with the need so that the facility is there for the laboratories to be automated and therefore able to get their jobs done.

However, along with all the benefits that come with automation, we have gotten a new set of problems to deal with. We have many things that affect or compromise data integrity. In the old days we used to worry about things as simple as manual transcription errors. Now we have to worry about computer errors. We're talking about things such as data entry errors, computers talking to each other, storage of data, and electronic transfer of data whether it be on magnetic media like diskettes or over the telephone lines. So we have additional sources of error such as sampling errors, analytical errors, and operator errors.

In addition, we've had another problem, which is that alleged fraud is compromising the integrity of our data. It's become much easier to cheat in the laboratory community because of all these neat things you can do with computers. We find that there have been instances where laboratories have manually edited their data just to meet the contract requirements and there was no technical justification for doing this. All this has happened because it has gotten much easier.

We believe that the GALP guidance will promote data integrity within the analytical laboratory community. We think it will assist us in ensuring the quality of data. It will not guarantee it, but we believe that following the guidance will give us a better chance at success.

It's important that the laboratory not look at the document at face value. They can use it as a foundation for data management/ automation practices, but it's important that they look at it as a minimum set of requirements of things they must address. This does not mean that there are not other things that need to be addressed. They have to establish within their own laboratory the systems that have to be in place in order to meet the requirements they set up

for themselves. It's important that you have a system in place to know when it's working and when it's not. You have to have checks in place. And you also have to be able to have a system where you're going to correct your problems when you find that you haven't met success.

In connection with the fraud issue, we believe that if you institute some of the things in the GALP document, such as some of the ideas on security or audit trails, it's going to be more difficult to commit fraud. It may be at the point where it's easier to do it right the first time, or cheaper to do it over again than it is to go through manipulations with the data just to make it look right. While this is not going to prevent fraud, it will make it more difficult.

The laboratory community is familiar with this document. Rick Johnson gave a talk at our annual data management caucus last July and the audience was very enthusiastic. The lab community has been anxiously awaiting this document ever since. We plan on having another data management caucus this upcoming December. We'd like to think there will be people using it by then, and we'll be able to have some success stories related to it by the lab community. We do plan on providing the GALP guidance to our community when it's available for release. I think it probably has to undergo a revision before that.

We have included some data management requirements and tenets of the GALP in our existing CLP contracts and I believe that our special analytical contracts have also included some of these GALP tenets. We have put in hardware and software requirements; we have added personnel that were not ever listed in our contracts before; and we've clearly defined some of the security levels that are absolutely necessary. We've required something that's essential to us in looking at data, and that's the audit trail. We think that with these security things in place it may make fraud more difficult. As it makes it more difficult to access the data system, you can eliminate the number of people that have access and limit the potential for people who are going to do bad stuff to your data.

Also, as far as the audit trail goes--if it's required that you identify where you've made a change, you qualify the data as having made a change and you have to signify. You may be more reluctant to go in and make that change if you do not have a technical justification. So we do think that these things will impede, though not prevent, fraud. We have added some items to our repertoire that reflect data management issues. We think we can improve on it, and we are going to be requesting assistance from Rick in helping us perfect our audit process so that we would be good at doing the QA oversight job on data management practices of our community.

I consider the GALP guidance as a great breakthrough for EPA. It was not written specifically for Superfund, but it does provide a basis for providing data of integrity from computerized systems that are critical for Superfund decision-making. I believe it is in the mutual benefit of the laboratory community and the EPA clients to take advantage of the GALP in our mutual striving to improve data quality and integrity.

Jeff Worthington

I'll be providing a testimonial to some of the types of observations we've seen in laboratories over the last five or six years. First, I want to give you some information about where our experience and background came into this type of observation. TechLaw provides support to the Federal government primarily as the Contract Evidence Audit Team (CEAT) contract to EPA's National Enforcement Investigations Center. We have been doing this from 1980 to the present. We have conducted 850 evidence audits (field and lab). We also participated in the environmental survey as well as the Love Canal habitability study. I think probably in some of the study areas is where we first saw, for instance, the use of electronic data transfer.

Besides going in to audit laboratories that are providing data to EPA, we've also assisted in litigation support in over 500 cases. The type of support sometimes entails helping prepare samples and sample evidence for trials for EPA or Department of Justice attorneys. In addition, we've conducted audits of PRPS' search reports that have been developed by other contractors. TechLaw also has some technical enforcement support, which is along the lines of litigation support as provided under the CEAT contract. With the Department of Energy we've recently spent some time designing document management systems and preparing technical and evidential audits. We've also worked as expert witnesses for the Department of Justice in assembling environmental data.

One of the trends that we're seeing in laboratories is increased use of laboratory information management systems (LIMS). In 1985, when we were looking at laboratories, many of the laboratory directors would try to drag you off to the side and say, "Don't you want to see my nice new toy, my new LIMS?" And we'd say, "No, we want to see your papers." And over time we've started to see the paper disappear into the LIMS and to understand that the evidence is starting to enter into computer systems.

The second trend that we've observed is the use of electronic data transfer systems by laboratories. They're doing this for several reasons. The first reason is to facilitate transfer of data. These can be used for quick turnaround, and it's a good marketing tool. Some of EPA's programs and other clients are asking for this type of service as a deliverable.

The third trend is the replacement of handwritten records with direct computer data entry. This started first, probably, with the analysis area. Many people who are most comfortable with computers--the analysts sitting at their GC or GCMS--began to think, "Why do I need this log book; why don't I just start putting this information directly into the computer?"

You sometimes see that same activity in the preparation area and sometimes in sample receiving. But when you look at information generated by a laboratory, both on handwritten records and information inside a LIMS, sometimes the information disagrees. This is for a variety of reasons. Sometimes the LIMS is not designed as a QC or QA tool; it's designed just to track information within the laboratory. For that reason people use it to say, "Was this thing prepared or was this thing analyzed?" Often those records conflict, because maybe the laboratory manager went to the LIMS two days after samples were prepared and then punched in all the samples that were analyzed, and maybe used different initials and names. Often when you're preparing evidence, you see that the information that's summarized in those systems doesn't always agree with the handwritten records. That's something that needs to be reconciled. It's not necessarily a problem for the evidence.

Also, there's a lack of written procedures for the use of software and hardware systems, both in laboratories and in field operations. There's seldom any life cycle documentation of software development. I think that problem is universal across all businesses, not just EPA and its contractors. Often you will not find the software within a life cycle documentation. Many times there is no clear definition of the responsibilities for the functions related to software and hardware systems.

There is also no check on data accuracy. That depends very much on the type of business, but often in laboratories and field operations there may not be anybody who actually checks to verify that the information is accurate.

We could almost think of the evidence as actually moving into computers--the papers are disappearing in some cases and that's where the evidence is. There's more and more reliance on computers, and not just in the laboratory. And with future cleanups being the thing of the 1990's, maybe we'll see more use of electronic data transfer to transfer information into the field and people's decisions will rely on the data that is transferred. People are addressing these concerns now.

In conclusion, there are several things I'd like to touch on. First of all, guidance is needed for this area. The GALP is an example of a guidance document that covers the laboratory areas. I would also suggest that other areas such as field or sampling analysis plants--anywhere there's a computer that's being used,

either in the collection and generation of data or by any other contractor--need to address many of the same types of issues.

Secondly, if you're in the process of having a computer replace your handwritten records now, or you're working with somebody who does, print out your computer record in a timely manner. For instance, if it's an analysis activity, have them print out their GC log, look through it, verify that it's accurate, and then sign and date it.

Lastly, as Rick Johnson presents the GALP, I'd like to ask the audience to consider both computer software and hardware guidance for potential inclusion in any QA program or project plans in the future. It's being addressed in the EQA-1 draft document now and we strongly support that.

Rick Johnson

Those of you who aren't particularly computer literate hang on because the problem that I'm going to describe is not a bunch of technical issues as much as it is an overall set of procedures and understandings in management--practices in the laboratory to make things better than they currently are in a number of labs. My purpose is to describe our program for ensuring the adequacy and integrity of computer resident data. What I'll do is give you a feel for the basis of it--where we got into it, why we got into it, what it's all about, and where we think we are with it today.

I'm on what's called the Scientific Systems Staff. The Scientific Systems Staff is in the Office of Information Resources Management, one level below the Administrator. There are basically five program offices that report to the Administrator. There are several others, and then all of the Regional Administrators. Our mission is to help the Agency out in the area of information technology, anything from providing the resources for hardware and software development to overseeing contractor's work in this area to developing and managing all the Agency's information assets to promoting data sharing and integration. This last one turns out to be something that's important to all of us here at hand, because this is what Good Automated Laboratory Practices are all about--the issue of data sharing and data integration.

Why did we ever start on this in the first place? About two and a half years ago we started becoming clearly aware that there was a rise in automation in the laboratories. Problems were beginning to surface. The auditors that audit for the GALP program and also in the CLP programs were beginning to wonder what to do with all of the automation that was coming into the laboratory. There was no uniform set of EPA principles to guide laboratories as they automated. People were making expenses in hardware and software that clearly were not meeting perceived needs that were developing as the Agency moved forward in its information management policies.

In addition to all this, there were a number of activities going on in the way of development of requirements for information management and information dissemination.

Collectively all of these things looked as if this was something we wanted to check into and see if there was some genuine need for the assistance of our office in this area. What we did is put together a program to identify as much information as we could in various areas to be able to assess whether or not we needed to go any further with it.

It was a several-pronged program. The first was to go out, and through a combination of site visits and a questionnaire survey that was sent out to about 200 labs, assess what the state of automation was in laboratories, and if there was a problem, determine if we needed to get involved with it.

Secondly, we wanted to examine all the existing procedures that were around and not go about re-inventing the wheel. Automation has been in the banking arena for a number of years; perhaps there are some lessons there that we could learn. Perhaps we could also find out things from the clinical laboratory industry. Forensic toxicology and stuff like that have been around for a number of years, and they've put together a set of principles and practices in their laboratory and are also automating. Why not go to them and see what they've done, and find out if there are lessons to be learned from there?

Third, we wanted to look at state-of-the-art hardware and software technology as it applied to laboratories. Perhaps there were some readily available fixes there. There are some things that can be done...capitalized on...utilized. Perhaps there's software in the labs that vendors are selling that could do a much better job, and maybe there are some hardware fixes, simple things that could make a lot of sense.

Since the Good Laboratory Practices (GLP's) have been around for a number of years and the computer is already under the aegis of the GLP's, why not look into the GLP's and see, in fact, if there aren't some lessons to be learned that we could capitalize on as well. They've withstood the test of time; they've been under review by the scientific community for some 10 years and were finalized about two years ago by EPA. They'd been in place by the Food and Drug Administration for a long time. Why not look into those and see if there are things that make sense and apply to the computer when it's put into the laboratory?

An important consideration was the fact that there were existing requirements already on the books that we should probably be incorporating into whatever guidance we come out with.

Finally, there were a number of requirements underway that could

also affect laboratories--the electronic data transmission standard, some of the system design and development guidance, the computer security act, and a number of other things.

These were basically the areas we charted out. We had people with different capabilities looking at each one of these things over the last couple of years. And what we found out, first of all, was that the state in the laboratories, regarding their use of the computer, was not as good as we would like to see it. Physical security was typically lacking. You could easily walk into a laboratory in many cases without any ID--without any checks or balances.

System access was not protected. People could get on the system, log into it, and there were no passwords in place or voice recognition. I think this was the case in about 50 percent of the labs.

Probably one of the biggest areas where problems occur is in data verification. We are moving from the area of laboratory notebooks and people are beginning to key in on the computer all their information--setting aside the fact that it's also now being electronically transcribed from instrumentation. There were very few verification procedures in place in a number of the labs. There was no double check, for example, to see that data were right or blind entry. Generally, if there was a problem across laboratories that was immediate to impeding data integrity, it probably was the verification.

Documentation was sketchy. A number of the labs that we went into had no idea what version of the software was used to create what data sets. In a number of cases they had none of the versions of the software available, yet they were relying on this data to make decisions and provide the Agency with environmental information.

And then there were a host of other things--anything from the lack of competent staff available to the adequacy of the staff. In some cases we saw a couple of labs where people were working 70- and 80-hour work weeks. I don't consider that to be adequate resources for a lab, but some people may.

When we looked at automated financial systems we learned a number of things. They've been in place for about 10 years. One of the first things they do is perform a security risk assessment. They look into the environment of their operation and determine where various breaches to the potential integrity of the data are, analyze them, and come up with an overall schematic that lays out where the problems are. Then they go through what's called a risk management program, where they effectively respond to each one of the security needs that they found out about. Some of the components of that system were access management programs: varying the password; requiring people to make periodic changes to it; when

somebody leaves the organization, their password is automatically dropped; verification procedures; double entry; and sometimes blind keying in the second entry. Audit trails were standard, as was hard copy retention.

When we looked at hardware and software technology we found that generally there is no single guarantee that ensures data integrity in either hardware or software areas. And surprisingly enough, there were no established software standards for data integrity in laboratories. There are a number of laboratory information management vendors selling a lot of different software, yet there were no standards in place. Some LIM systems, for example, had password protection, some of them didn't. Some had certain data backup and data recovery features, others didn't.

They can customize software to meet whatever needs you want; the problem has been that nobody's ever had a clear understanding of what was needed or what is needed. So when people went in to determine what it was they needed they came back to the software vendors and had a prescription that in many cases was probably good for what their perceived needs were, but that lacked the requirements for an information system. I blame that in part on us as much as those folks that are dealing with us, because we never really had in one place a common compendium that lists out all of the requirements and understandings of what we feel constitutes good management practices in the laboratory to ensure data integrity.

I'd say the software manufacturing business is in bad need of some overall standardization. And I think we really found it out, particularly in the laboratory environment. There've been countless amounts of investments made in off-the-shelf LIM systems that many companies have been sold a bill of goods on.

Some other interesting things we found out were that some of the advancing technology that some of you bump into now in the grocery stores--optical scanners--can be adapted to automation in the laboratory and ease some of the problems in our transcription errors. Also, magnetic ink readers have become standardized across the entire banking industry, virtually worldwide. And "smart cards"--they're like the strip of information on the back of your banking card that can hold an entire portfolio of information and can be updated as you move from various points in the lab to others. That's not out of the question at all any more.

We looked at our GLP regulations that are in place now and found out a couple of things. One of the GLP's that was in the toxics program and the pesticide program, which had been adopted by other EPA programs, allows for raw data to be just about anything you want it to be. "Raw data may include...computer printouts, magnetic media...and recorded data from automated instruments" (54 CFR 158 & 160.3 [FIFRA] and ibid 792.3 [TSCA]).

Wherever the data are first recorded, that is considered the raw data, but there is no requirement that the raw data have to be recorded in any one form or the other. Laboratories have the latitude to choose what media they use and how they go about it, but once they do it and decide on it, that is raw data. Then, depending on the medium that it's retained on, there are certain requirements regarding the retention of that raw data.

The issue of what constitutes the raw data for the laboratory--wherever the data are first recorded and however they're first recorded are considered the raw data. That raw data then must respect the data change requirement, the data entry requirement, and the data verification requirements which are spelled out in the GALP. In the case where you have information sitting somewhere and that information generally will be considered the raw data, the computer information should not be relied on. The person who's in charge of the machine should be attached to that raw data when that raw data were entered the machine identification for that information. There are all sorts of specifications for acceptance testing of software and hardware configurations that are required.

Finally, the testing of facilities encompasses those operational units that are being used or have been used to conduct studies, e.g., the computer. Therefore, if the computer is being used in the conduct of the lab, it also must come under the GLP requirements.

A couple of other things--the GLP requirements apply to automated systems. There are also requirements for the documentation of personnel qualifications, oversight of QA, and standard operating procedures (SOP's).

Regarding existing requirements, we had a couple of them in place. EPA's Electronic Data Transmission Standard now makes it possible for people to report data electronically to the Agency, with the standard in place to allow people to do that, and with an understanding of what needs to be in each one of the transmission records. We also have a number of things going on in the Information Resource Management Policy related to such things as system design and development to documentation.

There were a number of requirements under development at the time we put this together. The Federal Electronic Reporting Standards were being pushed into all the Federal agencies and they must have a general standard for the electronic transmission of data. EPA beat Congress to this by about a year. The Federal Computer Security Act specifies various levels of security that must be in place for certain types of data as defined within the Act itself. Finally, we are continually involved in changing our System Design and Development Guidance.

What all this meant collectively to us was that we probably needed

to do something. It looked as if there was clearly a reason to do it. There were a number of things under development, and we needed to bring it all together. We decided that we needed a registry of principles--what we subsequently called the Good Automated Laboratory Practices--and then to help folks to implement the GALP, implementation guidance as well. We wanted to not just lay this out to people and tell them that they should do it, but to give them some feel for what we expect them to do, and some understanding of why it is that they should be doing it. We also wanted compliance guidance for the auditors to enable them to determine that they are, in fact, following specifications.

Recognizing all this and putting together all this information between late '89 and early '90 and collecting it all, we finally came up with the draft Good Automated Laboratory Practices. Then we went one step ahead and put into it Implementation Guidance. **Figure 1** shows you relationships to various principles within the GALP. The bottom line here is that nothing's new. Everything that's in the GALP is already there in one place or the other. The Federal Computer Security Act is dealt with; EPA's Information Resource Management (IRM) Policy is there; the Good Laboratory Practices are incorporated in the GALP; some of the statutory requirements from several different programs are incorporated. Retention requirements that the Federal government mandates all Federal agencies to do and the types of media are all addressed there as well, and others such as the electronic data transmission standard are also included.

The Quality Assurance Unit has oversight over such things as the standard operating procedures (SOP's), the operation maintenance of the computer system, and security. In addition, this Responsible Person (RP) has to report to management that everything is going according to plan. Or, management can assume the role of the RP if they want.

Figure 2 shows some of the different areas of the GALP and the different citations to the different statutes so that you can cross reference back and forth. This includes areas dealing personnel and qualifications, the personnel training, such as what laboratory management should do, the role the RP should have in the laboratory, what the QA Unit should do and what operational roles it should have, the facilities and what govern them, the equipment, security specifications, standard operating procedure, software requirements, data entry, raw data definition and records and archiving. Again, these all relate back to any one of the different statutes I showed you earlier.

Section 7.14 covers comprehensive testing periodically done on the system to ensure that, with any of the changes that have been done with the system over time, the system is still fully capable. I think we specify that in the GALP at least once every two years, as I recall.

Under section 7.10, data entry, there are two areas: integrity of data and data verification. Under integrity are three separate requirements: tracking person--that's who entered the data, or who was handling the machine at the time the machine entered the data into the system; the equipment that was being used, the identification information on the equipment, and the time and date that it was entered; and data change. This is one of the 82 principles in the GALP and it relates to changing data in the information system.

There's nothing new in this requirement; it's in the GLP's. It's been in fundamental accounting principles for a number of years. What this does is let somebody know that the data have been changed, who changed it, when they changed it, and why they changed it. This is very important. It seems, on the surface, like something anybody would want to be able to do and have in place.

A number of software vendors have sold software to laboratories, advertising that they have an audit trail in the system. In many cases it does not meet one or the other of these requirements. It doesn't, for example, tell the auditor or somebody going back through it that the data had been changed. It does preserve the original data; it dumps it off onto a tape somewhere and writes the new data in. But there's no indication that the data were changed.

In other cases, it doesn't tell who changed it, why they changed it, or when it was changed. But it may show that it has been changed. The full compliment of requirements here are only met right now by about three (that I know of) commercial software vendors. A number of labs on their own have built systems to meet these specifications.

So in an effort to help people, rather than just telling people what to do, the guidance is formatted like this: it shows the icon at the top, gives you a specific statement of the individual requirement, attempts to explain what the requirement is, why it is wanted, gives you an example of it, and then it shows a coding in here for who is suggested to take on the role of managing that particular area of the GALP.

For example, with regard to the data change requirement, please look at **Figure 3**. Here you'll see the data change requirement restated, an explanation of what this is all about, what is meant by it, an example, and who's responsible for it, and there's an underlying principle called audit. There are six basic principles behind the GALP and six basic operational roles that are assumed in the guidance.

Finally, a special consideration--where we can we've tried to show a picture. If the picture's right, it's worth a thousand words. For example, **Figure 4** shows a picture of what comprises an adequate audit trail according to the GALP principles. You'll notice that

there are additional notes as well that can refer you back to various types of documents and various EPA requirements that are already in place. In this case you have the Toxic Substances Control Act (TSCA) and Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) regulations that are already in place and specifically require that. And you have a number of background assessment documents we've done leading up to the GALP that are also referenced. This requirement is already in place in the clinical industry; it's already in place in the financial industry; and it's a requirement in our GLP's as well.

Where we are with it today: the document was sent out for review and comment in early February. We asked that the comments be back by the end of March; we're still waiting for some offices. What we intend to do over the next several months is look at the comments. I've hired a couple of folks to take a careful analysis of the comments and go out and make some laboratory visits and quality checks on them. Following the completion of that, we will come out with a paper that shows each comment, how we've addressed it, what we consider about it, what we're doing with it, and where changes to the GALP are indicated. It may be out by early December.

We struggled with whether or not to require this of all the Agency's programs via Administrative Order, or to package it as recommendations to Agency programs to adopt, or call it guidance for Agency programs to adopt. We spent about a month and a half back and forth considering those two options. It was deemed at the time that the merits of the individual GALP will stand for themselves and that the EPA programs can then, by merit of the individual GALP principle, adopt those within their framework so that the integrity of the individual principle will speak for itself and the Agency programs can then pick it up.

You'll see in a number of cases for a given principle that it may say a "shall" or a "will" or in some cases it speaks in very general terms. Those are specifically written that way. If somebody's going to adopt an Agency program, they're going to adopt one of the GALP principles. Then the language in there is very specific to that effect. If they're going to adopt a principleone place. Then we go on to the next site. And we can put all of the site by site planning in one place and separate the lab standard procedures and the field standard procedures and incorporate them by referencing them--get them separated from the issue of planning.

I want to make a point, which is emphasizing existing terms and

another 20 or so programs in the Agency that have already adopted many others. And there are a number of programs that have a mish-mash of them. If we went out with requirements, one of the problems we would have is that they would be viewed as a duplication of those folks who are having to establish them. They already have them on the books; why do they have to do them again?

There also are individual interpretations and some of the different areas that different programs have for their statutes that we feel the integrity of which had to be maintained. So at this point we are packaging them as guidance or recommendations, providing ways in which someone can achieve compliance with them in the document and giving examples of how one can achieve compliance in a number of cases where special considerations can come into play. But again, it is going to be up at this point to the individual EPA programs to decide which of the elements they want to adopt and which ones they don't.

The document, by the way, has not just been distributed to EPA. There are about 250 organizations inside and outside of EPA. I know that the U.S. Department of Agriculture, U.S. Department of Energy, the Food and Drug Administration, and the associated people in those organizations have all been given copies of it and were involved in the program from the very onset.

Figure 1

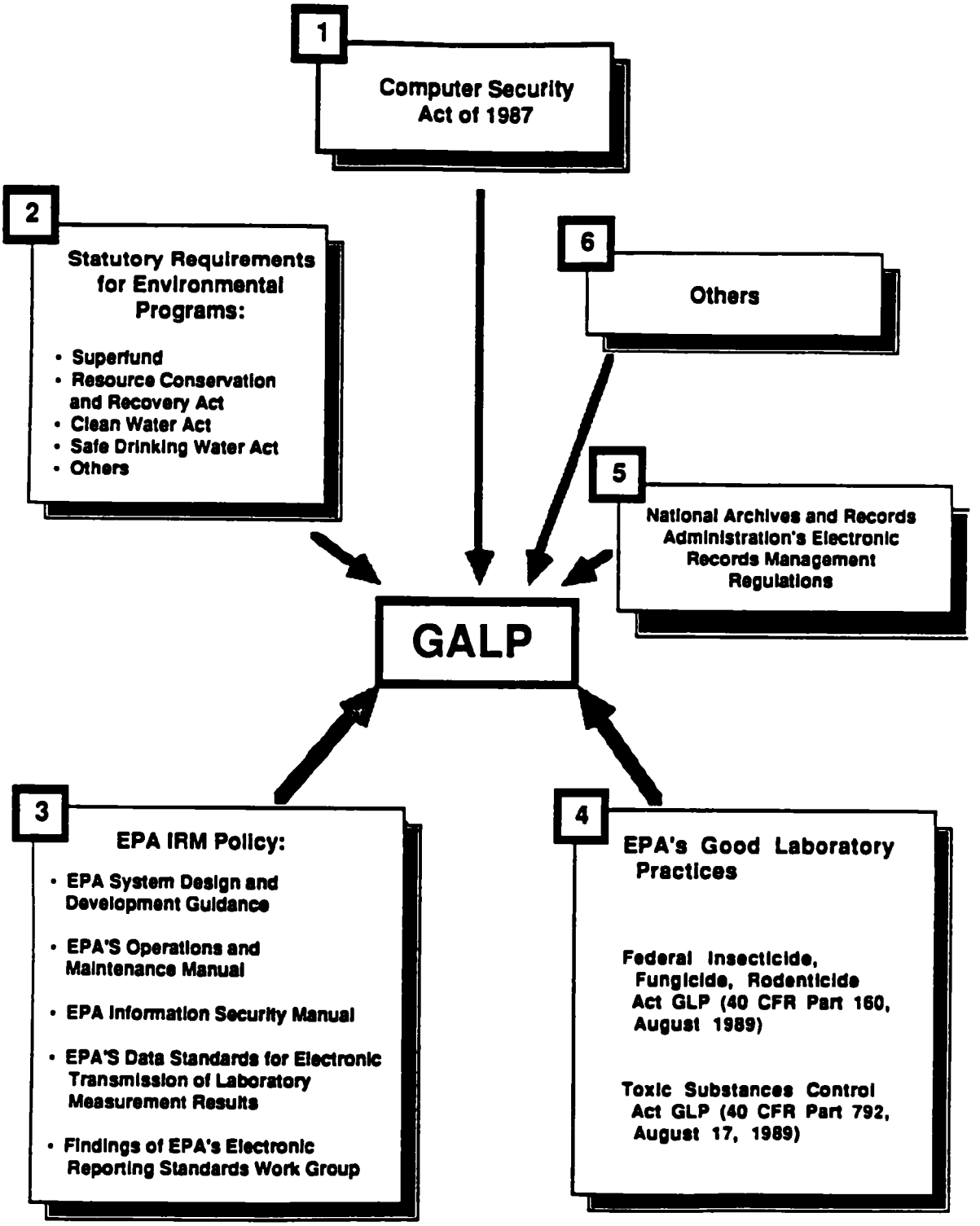

1
Computer Security Act of 1987
2
Statutory Requirements for Environmental Programs:
• Superfund
• Resource Conservation and Recovery Act
• Clean Water Act
• Safe Drinking Water Act
• Others
6
Others
5
National Archives and Records Administration's Electronic Records Management Regulations
GALP
3
EPA IRM Policy:
• EPA System Design and Development Guidance
• EPA'S Operations and Maintenance Manual
• EPA Information Security Manual
• EPA'S Data Standards for Electronic Transmission of Laboratory Measurement Results
• Findings of EPA's Electronic Reporting Standards Work Group
4
EPA's Good Laboratory Practices
Federal Insecticide, Fungicide, Rodenticide Act GLP (40 CFR Part 160, August 1989)
Toxic Substances Control Act GLP (40 CFR Part 792, August 17, 1989)

Figure 2

APPENDIX A: INVENTORY OF COMPLIANCE DOCUMENTATION

RECORD	PURPOSE	SUBSECTION	REFERENCE
Organization and Personnel			
Personnel Records	Ensure competency of personnel	7.1	FIFRA GLPs 160.29 TSCA GLPs 729.29
Quality Assurance Inspection Reports	Ensure QA oversight	7.4	FIFRA GLPs 160.35 TSCA GLPs 792.35
Facility			
Environmental Specifications	Ensure against data loss from environmental threat	7.5	FIFRA GLPs 160.43 TSCA GLPs 792.43
Equipment			
Hardware Description	Identify hardware in use	7.6 7.12	FIFRA GLPs 160.61 TSCA GLPs 792.61 EPA Information Security Manual for Personal Computers
Acceptance Testing	Ensure operational integrity of hardware	7.6 7.12	System Design and Development Guidance
Maintenance Records	Insure on-going operational integrity of hardware	7.6 7.12	FIFRA GLPs 160.63 TSCA GLPs 792.63
Laboratory Operations			
Security Risk Assessment	Identify security risks	7.7	Computer Security Act
Standard Operating Procedures	Ensure consistent use of system	7.8	FIFRA GLPs 160.81 TSCA GLPs 792.81
• Security Procedures	Ensure data integrity secured	7.8	Computer Security Act
• Raw Data Definition	Define "computer-resident" records subject to GLPs	7.8	FIFRA GLPs 160.3 TSCA GLPs 792.3

Figure 2 cont.

APPENDIX A: INVENTORY OF COMPLIANCE DOCUMENTATION

RECORD	PURPOSE	SUBSECTION	REFERENCE
• Procedures for data analysis, processing	Ensure consistent use of system	7.8	FIFRA GLPs 160.87, 160.107 TSCA GLPs 792.81, 792.107
• Procedures for data storage and retrieval	Ensure consistent use of system	7.8	FIFRA GLPs 160 81 TSCA GLPs 792.81
• Procedures for backup/recovery	Ensure consistent use of system	7.8	EPA Information Security Manual for Personal Computers
• Procedures for maintenance of computer system hardware	Ensure consistent use of system	7.8	FIFRA GLPs 160.63 TSCA GLPs 792.63
Standard Operating Procedures			
• Procedures for Electronic Reporting	Ensure consistent use of system	7.8	Transmissions Standards Electronic Reporting Standards Workgroup
• SOPs at bench/ workstation	Ensure consistent use of system	7.8	FIFRA GLPs 160.81 (c) TSCA GLPs 792.81 (c)
• Historical Files	provide historical record of previous procedures in use	7.8	FIFRA GLPs 160.81 (d) TSCA GLPs 792.81 (d)
Software Documentation			
Description	Identify software in use	7.9	FIFRA GLPs 160.81 TSCA GLPs 792.81 Computer Security Act
Life Cycle Documentation	Ensure operational integrity of software	7.9	System Design and Development Guidance
• Design Document/ Functional Specifications	Ensure operational integrity of software	7.9	see above

Figure 2 cont.

APPENDIX A: INVENTORY OF COMPLIANCE DOCUMENTATION

RECORD	PURPOSE	SUBSECTION	REFERENCE
Life Cycle Documentation			EPA Information Security Manual for Personal Computers
• Acceptance Testing Testing	Ensure operational integrity of software	7.9	see above
• Change Control Procedures	Ensure operational integrity of software	7.9	see above
• Procedures for Reporting/Resolving Software Problems	Ensure operational integrity of software	7.9	see above
• Historical File (version numbers)	Ensure reconstruction of reported data	7.9	FIFRA GLPs 160.81 TSCA GLPs 792.81
Operations Records/Logs			
Back-up/Recovery Logs	Protection from data loss	7.12	EPA Information Security Manual for Personal Computers
Software Acceptance Test Record	Ensure operational integrity of software	7.12	System Design and Development Guidance
Software Maintenance (Change Control) Records	Ensure on-going integrity of software	7.12	see above

Figure 3

7.10 Data Entry

1) Integrity of Data

3) Data Change

When a laboratory uses an automated data collection system in the conduct of a study, the laboratory shall ensure integrity of the computer-resident data collected, analyzed, processed, or maintained on the system. The laboratory shall ensure that in automated data collection systems:

3) Any change in automated data entries shall not obscure the original entry, shall indicate the reason for change, shall be dated, and shall identify the individual making the change.

EXPLANATION

When data in the system is changed after initial entry, an audit trail must exist which indicates the new value entered, the old value, a reason for change, date of change, and person who entered the change.

EXAMPLE

This normally requires storing all the values needed in the record changed or an audit trail file and keeping them permanently so that the history of any data record can always be reconstructed. Audit Trail reports may be required and, if any electronic data is purged, the reports may have to be kept permanently on microfiche or microfilm.

CODE

Responsibility: Responsible Person
Principle: 3. Audit

SPECIAL CONSIDERATIONS

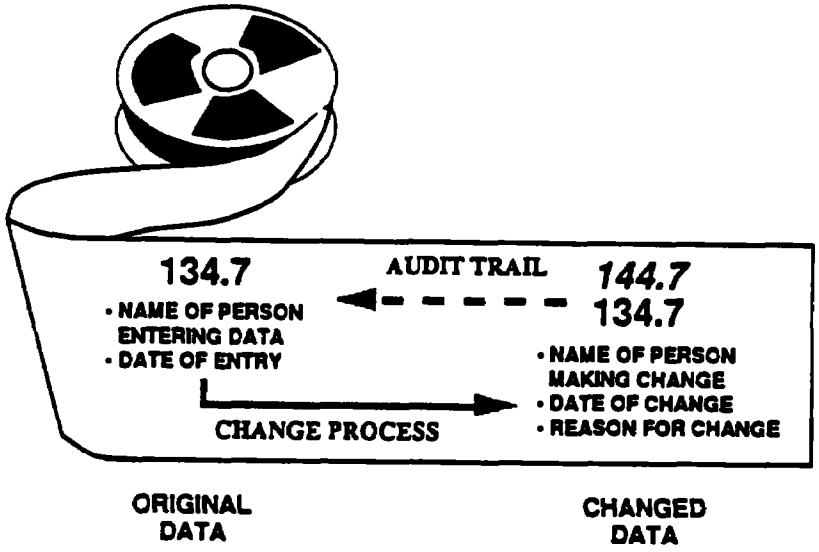
Laboratories may consider adopting the policy by which only one individual may be authorized to change data, rather than implementing a system that records the name of any and all individuals making data changes.

Figure 4

7.10 Data Entry

1) Integrity of Data

3) Data Change



Notes...

For additional guidance, see: *FIFRA GLPs 40CFR 792.130(e); TSCA GLPs 40CFR 160.130(e); Automated Laboratory Standards: Evaluation of Good Laboratory Practices for EPA Programs, Draft (June 1990); Automated Laboratory Standards: Evaluation of the Standards and Procedures Used in Automated Clinical Laboratories, Draft (May 1990);* and *Automated Laboratory Standards: Evaluation of the Use of Automated Financial System Procedures (June 1990).*

HAZARDOUS WASTE SITE REMEDIATION

PANEL DISCUSSION

Moderator:

Gary Johnson
EPA Quality Assurance Management Staff

Panelists:

Thomas Morris
Martin Marietta Energy Systems, Inc.

Duane Geuder
EPA

Marcia Davies
U.S. Army

John Edkins
U.S. Navy

Gary Johnson

I'd like to give you a little background on the proposed National Consensus Standard that is being developed through ASQC. Then we will have presentations by our panelists on their view of the issues that need to be addressed in order to make an acceptable National Consensus Standard work for their organizations. We'll tell you a little about the origin of our efforts on this.

This effort occurred because of concerns expressed over QA requirements for hazardous waste management clean-up activities. We found that there were multiple sets of requirements out there. There was EPA guidance in several forms. The now infamous QAMS-005/80 which has been out there since December 1980 has not been revised since the "interim guidelines" were published.

Other organizations have other sets. Probably the most common set of requirements that has been applied to these activities has been NQA-1. This was a set of QA requirements developed primarily for nuclear facilities. In fact "N" means "nuclear" in NQA. Its application to environmental concerns has been somewhat successful in some areas, but not without some difficulty. There were not only these different requirements, but also the fact that those in the regulated community often had to respond to multiple requirements--both EPA and NQA--since they were not fully compatible. And this has led to duplication of planning documentation; it's led to rework; and both have led to added time and cost, which neither we in government nor the regulated

community can afford to allow to continue.

Harmonization began as an effort of the ASQC Energy Division. We began this effort just a little over a year ago, in the winter of 1990. The participants included EPA, DOE, DOD, Nuclear Regulatory Commission (NRC), various EPA and DOE contractors, and private consultants. This has been solely a voluntary effort by a group of your peers--fellow quality professionals who recognized that a need existed to bring more consistency and standardization into the way we go about QA in environmental work. Our purpose as we began this effort was to harmonize the current multiple QA requirements into a single set for environmental programs.

No current standard exists for environmental programs. A standard should provide a clear statement of what QA elements are needed, allow flexibility on how and by whom requirements are implemented, enable more consistency by everyone doing the same things, and enable use of the good work already done to harmonize QA requirements.

When you think of a standard, probably you're thinking in terms of a performance standard. What we're talking about is a requirement standard. In the Agency we do not have a current requirement standard; we have EPA Order 5360.1. That is not a requirement standard. We have guidance, such as the now defunct 004 and 005. Those are guidelines, not requirement standards. In fact, there is no requirement in EPA right now that anyone should implement a QA project plan. All the contract regulations say is that you have to prepare it and get it approved--they do not say you have to implement it.

We need a clear statement--a good solid foundation--for quality assurance in our Agency. What we've heard over the last 10 years is that you've had a lot of frustrations in trying to deal with carrying out and institutionalizing a QA program in your own organization. Our recommendation that went to the ASQC group was that a standard is a pretty good idea--that perhaps we can provide this clear statement of the things that we will do in a QA program. But at the same time, we emphasized that flexibility had to be provided to the organizations implementing this standard to determine how the requirements would be implemented and by whom.

Everyone recognized from the very outset that we could not write a prescriptive requirements document that would have any prayer of working in EPA--given the diversity of our programs--nor in any other Federal agency engaged in environmental work. But we felt that if we could get everybody at least doing the same things and talking about the same things, then we could begin to bring more consistency and ultimately improve the way that we're carrying out QA activities in our respective organizations.

We also recognized in this group that a lot of good work had

already been done. We have to give credit to the NQA Committee of the American Society for Mechanical Engineers (ASME), because there are some really good things in NQA-1 that our committee felt was appropriate to include. And so our philosophy was, "steal shamelessly" because there are a lot of good ideas out there. And so we solicited ideas from whatever sources we could and we haven't stopped soliciting those ideas.

Now, to briefly describe the structure of the proposed standard. It has three parts. Part A deals with management systems. The intent here is to define what you need for an effective QA program in terms of the structure and framework. In other words, what do you need to be able to carry out day to day activities on specific technical projects? Part B, characterization of environmental processes and conditions, is primarily environmental work--environmental monitoring, sampling and analysis activities. Part C deals with design construction and operation of environmental engineering systems. This part deals with the technologies that we use in pollution control, remedial design, remedial action, and Superfund. Part C addresses an area that the Agency has not completely addressed, and so we felt there was an opportunity there to address that. In particular, we found that a lot of the work that had been done by DOE and DOD provided us with a wealth of information which, through the standard, we could create good, concise, clear statements of what would be needed.

Figure 1 shows the sections of Parts A, B, and C.

To quickly show you how Part A is constructed, visualize this as an umbrella under which everything is done. The management commitment and organization, the first statement in that standard, says that management at all levels is responsible for quality. That is an essential statement; it's an essential part of this entire process.

The QA program could document the management's systems that you are employing. So that's really nothing new there.

As for personnel training and qualifications, we all recognize (and certainly from viewing the world from a TQM standpoint) that human resources are our strongest asset. We need to make sure that those concerns are addressed and that people who are doing work that affects the quality of the results, and therefore the decisions that you're making, have the necessary skills to carry out that work most effectively.

Regarding management assessment, it's absolutely essential that management participate in the process and that they periodically examine the effectiveness of that process.

FIGURE 1

Part A Management Systems

1 Management commitment and organization
2 QA program
3 Personnel training and qualification
4 Management assessment
5 Procurement of services and items
6 Documents and records
7 Use of computer hardware and software
8 Operation of analytical facilities and labs
9 Quality improvement

Part A requirements apply to both parts B and C.

Part B Characterization of Environmental Processes and Conditions

1 Planning and scoping
2 Design of data collection operations
3 Implementation of planned operations
4 Quality assessment and response
5 Assessment of data usability

Part C Design, Construction, and Operation of Environmental Engineering Systems

1 Planning
2 Design of environmental engineering systems
3 Implementation of environmental engineering systems design
4 Inspection and acceptance testing
5 Operation of environmental engineering systems
6 Quality assessment and response

In the procurement of services and items, we have to make sure that the services we get from subcontractors meet our criteria, or that the equipment that we purchase to monitor polluted streams or air meets our needs.

We need to do a better job in the Agency of maintaining documents and records. One of the most frequent comments that I've heard from Superfund has been the difficulty in maintaining satisfactory documentation on given sites, largely because, in many cases, we don't have a process in place to do that. So we can learn from what others have done here.

We're depending more and more on computerized acquisition systems and storage systems for our data. And so it's appropriate that we address that issue in our requirements standard for QA pertaining to the use of computer hardware and software.

The operation of analytical facilities in laboratories--it's important that these labs practice good automated laboratory practices, that this be an integral part of their operations. It was felt that highlighting this was very important, because so much of what we do depends on the products of those operations.

Last under Part A is quality improvement. We can always learn from our experiences and next time do it a little better.

In Part B we followed a very simple axiom: plan, implement, assess. The first two requirements relate to the planning that goes into designing the data collection activities. The requirements are consistent with the data quality objectives process that we have been using in EPA for several years now.

Then an interesting thing: implementing what you've planned. That's perhaps an area where we haven't been as persistent as we should be.

The next item is assessment. This refers not only to assessment of the work that's being done in process, in responding to it where responses are appropriate, but also the assessment of the usability of the results--recognizing that even imperfect data sets can be used for some decisions if we understand the limitations on the use of those data sets.

Part C deals with engineering systems. Again, the same approach: plan, implement, assess. Plan the design of environmental engineering systems that may be required for a Superfund remedy; design those systems; implement the system's design, and make sure that the components of the technology that are being constructed pass inspection and acceptance-testing requirements. You need the assurance that this system is going to work once it's actually put out there in the field. To make sure we have thought out the operation of these systems, sufficient guidance should be provided

in the form of operating manuals and the like for the successful operation of these systems.

Last is quality assessment and response--to make sure that the systems do, in fact, perform as intended, and if they do not, that appropriate response actions to correct the situation be performed.

I'm sure you are probably thinking, what's the impact on EPA? Well, for the large part, most of your programs are going to be unaffected. Because as Nancy said, over the last number of years, we've heard from a lot from you, and our responsibility has been to try to carry those concerns to the harmonization committee. I think that when you look through this document, you'll find that it really doesn't change what you've been doing very much, because the essential elements are there.

Part C does add something new, because it deals with issues pertaining, particularly in Superfund, to remedial design and remedial action that we have not effectively addressed as an agency. But there's still ample time to do so.

Our key interest in this is to be able to provide a foundation, a basis upon which new guidance for a variety of issues such as QA management plans, project plans, and audits can be developed and given to you and to the regulating community at large to use.

The current status: we believe that ultimately we can achieve an acceptable national consensus standard. But the emphasis is on the word consensus, and consensus requires your participation.

We have also presented this document to the second annual Hazardous Waste Conference in Las Vegas, which was sponsored by the ASQC Energy Division because of the particular community that would be directly impacted by this and that has a special interest in it. So the document has, at least to this date, gotten somewhat limited distribution. We have gotten a number of comments back in and I appreciate that very much.

Within ASQC the standard setting process has begun. Two weeks ago in Hollywood, Florida, the Energy Division council voted to report the standard out of committee and to request that the ASQC standards committee list this standard and report it to the American National Standards Institute as a proposed national consensus standard for environmental programs.

I've got to say a couple of words here about why that's important--it takes this out of the political arena so that no one organization feels that any particular organization is trying to enforce its own agenda. I can assure you that we've had some candid and lively discussions from the policy group and the work group that put together this initial draft. We've tried to accommodate everyone's concerns.

The pleasant thing about it all is that the group coalesced very quickly. We found that the concerns were the same. You get quality professionals together and you find out that you've pretty much got the same set of problems.

This week some of our colleagues in the committee are presenting this standard to the ASME NQA committee which is meeting in Williamsburg, Virginia. We're looking for their support and comments on it and also to express our appreciation to that group for the effort that they've put into the NQA standards through ASME, which provided us with valuable information.

The next step, as we said all along, is getting input from you. Please review it and let us have your comments. Sometime later this summer we hope to publish a revised draft in the Federal Register to allow for a formal public comment period. This will be used as input to the ASQC standard-setting process. And we're hoping that in the not-too-distant future ASQC will issue this standard which may be at that point known as ASQC Standard E-4. We're hoping that the standard will be accepted and endorsed by the participating agencies, by EPA, if it meets your needs.

In the meantime we need your help, my fellow EPA folks, to help pull together revised guidance that more closely reflects your needs and your concerns right now for where our quality program needs to be for the remainder of this decade.

For the purpose of our panel discussion we're going to assume that we can reach an acceptable national consensus standard. We're going to ask the panel to address what must be done, or what issues must be addressed to make the national consensus standard work in the organization. Through their discussion we hope to be able to bring some of these key issues to the forefront so that we'll know what areas we're going to have to identify in the months ahead as we address this.

Marcia Davies

I would like to talk to you about the structure of the Army Corps of Engineers and how the Corps views QA. The Corps since the 1940's has always had the same structure. We have a headquarters in Washington whose responsibility is policy, interface with Congress, and interface with the headquarters of other government agencies in Washington--trouble shooting and resolving differences that can't be resolved elsewhere. Beneath headquarters we have divisions that are geographic. There are about a dozen of these around the country. Each division has several districts and each district has area offices. As you go down that structure, the geographic responsibility gets smaller and smaller and smaller.

What are the purposes of all these? The worker bees of the Corps are in the districts. The districts are the direct overseers of

the contractors. The districts do the work in-house. The dam builders for civil works and so forth are at the district level: The area offices which are under the districts are construction representatives. And those are broken down to small enough geographic areas so everywhere that the Corps has a construction project going on, there is a construction representative on-site that reports to a nearby office. This was put together for the Corps' traditional civil works and military construction missions over the years.

The sole purpose of the division is quality assurance. The division oversees the work districts--makes sure all their contracts are legal, and that they're not doing under one particular contracting mechanism what should be done under another one. There's a lot of technical support at the division level: legal support, personnel support and so forth. And each division services several districts and many area offices.

I feel that the traditional structure of the Corps lends itself very well to the TQM concept. The principle of the Corps is one-step-up review. If the districts have a contractor working, the districts are supposed to have the personnel to review the work of the contractor, with general division oversight. If the districts are working in-house, than the divisions are supposed to directly oversee, technical and otherwise, what the districts are doing.

Within that structure, there are special offices that are called design centers or centers of technical expertise. The division that I belong to, the Missouri River Division, is designated as a mandatory center of technical expertise for environmental works. And so we have special missions where we oversee all of the districts for some aspects of their work.

To the Corps, QA is a government function. Contractors do QC and the government does QA. It is rather rare for the Corps to contract out its QA function. That's almost always done in-house by government employees. Sometimes we get into semantics differences with the folks in the regions or in the states in terms of what they think we should be doing and what we're actually doing.

The Corps entered into hazardous waste remediation in 1982 to support EPA in Superfund, primarily in the area of design and construction since the Corps is an engineering outfit--but an engineering outfit which had been traditionally devoted to design and construction. Since that time, the Corp's missions and requests for assistance have expanded quite a bit, so that the Corps districts currently manage remediation problems for EPA, DOE, and the Department of the Army. The Corps manages the entire formerly-used defense sites program for DOD. We do some work for the Navy, the Air Force, the General Services Administration, the National Guard, and the Department of Transportation--whoever comes

knocking at the door saying, "HELP" is what the Corps often gets involved in.

We strongly support any harmonization effort, because working for that many different Federal agencies is very difficult under the current set of circumstances. The Army Corps of Engineers recently had an internal reorganization effort. The principles under which we're slowly reorganizing internally say that the people who are responsible for the projects and programs--the managers responsible for the schedules and for communicating with the outside agencies and so forth--are in a different reporting line from the people who are responsible for the technical adequacy of the products. And so for each project, sometime down the road in the Army Corps of Engineers--I'd say within the next six months in some districts--there will be a project manager and a technical manager. The technical manager will coordinate all of the internal QA efforts for that particular project. That will be in the environmental arena as well as in military construction and all of the other areas in which the Corps operates.

The Corps QA program has all of the traditional structural elements, specific requirements for each project as well as general guidance requirements. We write QA program plans; we like to call them chemical data acquisition plans because of what our focus on QA is and we think that says better what they are.

Internal review--land validation. We do land validations; we do them out of my office. We use audit samples and we generate them ourselves within the Corps. We have our own audit sample system. And in our audit sample system we have real world soil samples, and a large percentage of the CLP labs does not pass that sediment sample on the first run. We've taught them a few things about extracting. And we do not run quarterly blinds. Instead, for every project we take government splits. The Corps has nine division laboratories and those government split samples go to our own laboratories and they either analyze those in-house, or with intensively managed commercial contracts that they hold. The news is there aren't many matrix effects out there.

So we've learned a lot of things and we feel that we have a good chemistry program going. Problems are essentially recognition. If it ain't the CLP, it ain't what the regulators want. Is it CLP-equivalent? Very frequently. But it's not the CLP. We like to standardize on SW 846; we like to require all of the internal QC that has to this date been optional in SW 846. We like to see that reported. We're probably on 90 percent of our work never going to court--maybe more than 90 percent of our work never going to court. It's quite clear who did it, when they did it, and what they've got to do about it.

I'm pointing up some problems in implementation that I see. I think the main problem that we see is lack of recognition that

there are a lot of different ways to do things and they're probably mutually acceptable. And they all work well.

Now speaking mostly to the investigation phase. Given all the things that we have in place, including geotechnical guidance, almost everything that we have we have ripped off from EPA, because we started in this arena in 1982 with a Memorandum of Understanding with EPA. We have very few wheels that we've invented that weren't already somewhere mentioned or suggested in existing EPA guidance, including the split sample concept,. which as far as I know, we're about the only ones who implement.

Because we've been a design construction organization for a long time, we have in place a number of things with respect to specs or guide specs for building slurry walls on contaminated projects, and landfill covers that are compliant with rec river requirements, that are helpful to our field people, who are overseeing projects but don't really have the time or the technical ability sometimes to sit down and go through all of the legalese that's in the guidance in the Federal Register. So we tend to develop pieces of guidance that translate those things into field directives for our folks. And we have been doing this on the design and construction site for quite a while. I think that we may have something important to contribute in that area as an organization to that part of this new standard.

A couple of the specific problems that we have are, for example, on studies: Who reviews? Who trusts whose reviews? When have we reviewed enough? How many agencies do we have to review? How long does it take, and how much money do we spend on this? I'm not downplaying review; review keeps us alive--it's a very important part of the activities of the office from which I come. But some of the projects we review, the Department of the Army reviews. We pay the states and the regions to review; the contractors review. And you've got these massive numbers of people in essence all saying the same thing, and I would bet you a dollar that if you and I sat down next to one other and you're a chemical professional in this area and we review the same document for chemistry, we wouldn't come up with the same set of comments.

So I think that the review process needs a lot of work. And I think that it needs to be addressed in the standard in greater detail and I think that we need to figure out a way to get on with this process. DQO's are wonderful things; I endorse them heartily. I felt that the little two volume set on DQO's that came out of EPA really turned the lights on. That was great. But they're not implemented. You can use data quality objectives all you want, but you're going to get to a regional Federal facility project manager who's going to say, "You've got to do it over, guys. This isn't the CLP and that site's on the NPL list." Those decisions are not being made by quality professionals. If we could talk to the quality professionals I suspect we wouldn't come up with the same

decision.

There are things like that which I feel the standard needs to address--and address in greater detail in terms of what's happening and who does what. How much uncertainty are we willing to accept in data? Well, we're not willing to accept bad data. So we want the contractor to accept the responsibility for the analytical, and if most of it is flagged, he's going to do it over. And so we don't have contracts that allow them to flag it and give it back to us as acceptable. Consequently, we've run into problems because our data's not flagged. And it's not flagged because we didn't accept the flags, whether it's SWA 46 or whatever type of analytical method that they're using.

I think we need to pay a lot of attention to DQOs on all the analytical levels and that we need data validation guidance for level one, level two, level three, level four--the concept of level four needs to be expanded to include more things than the CLP. I think we need to figure out a way to do this work cheaply, smartly, on schedule, by doing a whole lot more interagency cooperating than we do now. The Corps would welcome the opportunity to do that. And I think that we need to address redundancy of effort among Federal agencies.

I want to say that the brightest light in the past year, and the thing that I think will help us a great deal as it gets down the road, are the actions of the Environmental Monitoring Methods Council. I was excited when I heard about that and I think it's wonderful. And that's about all I have to say.

John Edkins

I'm going to agree with almost everything that Marcia said and then act as a ground wire for some rudimentary problems that we have in the Navy--perhaps a general agreement for a harmonization effort for the same reasons that Marcia described and a plea for help because of the particular resources problem that we have. I'm not a QA professional; I'm a geologist. I've been doing this for about four years, so I have had to deal with some very basic problems in starting with this, and through my friends at the Quality Assurance Management Staff, gain a basic perspective.

I want to say something about our structure for environmental compliance. The Naval Facilities Engineering Command in Alexandria, Virginia, responds directly to the Chief of Naval Operations. Then that structure is broken down into eight engineering field divisions, which is the operating arm for cleanup of Navy shore facilities. Then the Naval Facilities Engineering Command has several other smaller support organizations, namely ours, where we were formulated originally as a small multidisciplinary group. As far as compliance with CERCLA is concerned, somewhere around 1980 all of the original Navy property

assessment was done out of our office. When the engineering field divisions plunged into the problem of investigating the environment with multitudinous drill holes and collecting environmental data and QA became an issue, our command office then turned back to us and said, all right, give us QA, because you're the multidisciplinary group.

That's how we happened to fall into this picture. We have a shortage of resources. We tend to buy everything. When I got into QA in late 1987 the first thing that I attempted to do was bring to the attention of my management the need to restructure everything that the Navy does to make it sound, look, act, and taste like EPA guidance. I realized that we were not going to get accepted on a local level unless we had those key program elements and names in our program.

We now have some 2,000-plus sites. They're small sites. We identify the individual pesticide rinse aid area and a fuel spill as individual sites in our program language, although we do have the large landfill with the multi-types of waste present. A common Navy site will be a PCB waste discharge area. Typically one Navy base, a Naval air station for example, will have from 12 to 15 sites identified of that nature. To give you an idea of our resources, our Navy engineers that act as remedial project managers--the people that drive the contractors--may have as many as three Naval installations and perhaps upwards of 50 sites for which they have responsibility. These people typically will be one or two years out of graduate school and just be becoming integrated into the process by the time they are hired away by our more well-to-do industrial brethren.

So my thesis today is one of a procurement-based problem and also the idea that there is indeed nothing new under the sun. I took Gary seriously about barriers to harmonization, and I could only really come up with one barrier. It was communication, without a doubt. We have a multi-disciplinary industry and terminology from many disciplines. We've got toxicologists trying to talk to engineers who are trying to talk to bio-ecologists, and now I find that we are trying to talk to procurement specialists about what all of this is that we're trying to buy in terms of environmental data and QA services for environmental data.

We have a lack of general industrial standards or standard operating procedures. Many of the procedures that we use don't have very strict source referencing requirements for contractors. Many times in the Navy we have seen instances where EPA guidance documents have been used in lieu of good contract standards or good contract specifications. In other words, a statement of work will say, take these guidance documents and those regulations and comply, comply, comply. A contractor is out there performing his own interpretation of guidance, which can sometimes be ambiguous and does lack these kinds of small critical elements as the source

referencing requirements. Guidance tends not to identify by whom individual or specific actions are to be taken. When you get in a procurement milieu you find out very quickly that that becomes important.

The fact that we are trying to turn a lot of good ideas in Federal guidance into a procurement system, and then trying to adapt to sometimes changing a revolving guidance and revising our procurement system to address that, becomes a problem for us and creates a lot of redundancy and waste.

Certainly Federal guidance has a lot to say for it. It does tend to standardize and provide a lot of good elements for us. The ideas of redundancy and streamlining have been recognized and these guidances are continuously improved. The very concept of DQO's I heartily applaud--the think before you leap approach. That was a badly needed concept early in the industry when "characterize the site" meant go out and get data on just about everything and then figure out later what you were going to do with it. Also, on the very idea of risk-based decision making I heartily approve.

The concept of harmonization itself--the standardization of national programs for environmental clean-up and compliance--is something that's going to benefit everyone. We have the same structural problem that Marcia alluded to in that our Navy field divisions are roughly the same in size and number of geographic acreage as EPA regions, but they don't coincide. So we'll have one engineering field division with possibly as many as three different EPA regions that they are responding to, not to mention state and local governments.

The work that's been done by QAMS and DOD-sponsored annual QA meetings and the ad hoc committee on quality and environmental measurements, ASQC Energy Division work, has resulted in the EQA-1 effort. All of these things are definite progress, and I want to not focus too much on those but go on to something that I'm very interested in, which is the individual method standards, because I'm a firm believer in building blocks.

Standards for data collection and interpretation include EPA guidance and standard operating procedures (SOP's), state standards and SOP's, and contractor and other agency in-house SOP's. Some other people that I have talked to in these meetings have indicated a joy in collecting SOP's--we call this piracy--but actually many of these procedures the government's paid for probably 16 times, so we ought to be able to pirate them, especially in the contractor area. Looking for all sources of standards, I sifted through EPA and came up with a batch several years ago and then turned around and plugged those into ASTM Committee D18 Soil and Rock, for which I'm an active member. I got sucked into that process with a great deal of joy, mixing myself with industrial interests as well as other government agencies and local government agencies.

I'd like to focus just a little on D18.21 standards. These are consensus standards and my initial charge was to develop field QA to correspond with lab QA, and it turned out that we got into a lot of different things. But just to mention a few: the surface and borehole geophysics and vadose zone monitoring, everybody's favorite .."how to put in a monitoring well," soil sampling practices, pump testing for hydraulic purpose and ground monitoring well design and construction, monitoring well maintenance, and rehabilitation and decommissioning.

We typically decommissioned monitoring wells by cutting them off at ground level with a backhoe or bulldozer, becoming lost in the records and also conduits into subsurface lower layers, a real problem. The American Society for Testing and Methods (ASTM) is looking at this. This one, which I'm particularly involved with, I think is very important because this gets into some of the aspects of DQO's: how to design an experiment for a site and how to interpret the data. These are very important issues and I wanted to raise our involvement in the building blocks aspect of it.

I'm going to talk about what more we can do. We need to recognize and focus on QA as a procurement-based problem. We also need an increased recognition by people of data as the primary product. We need more model contracts requirements documents and standards for contractor action, right down to the building block level. We also need to look at some long-standing technical terms and determine how we might clarify existing program language.

QA/QC seemed a very simple concept, at least originally. As I said, I'm a geologist, not a QA expert. It took me a while to figure it out, because when you ask people what QA/QC is you get as many different answers as you ask people. QA in terms of procurement is inspection and acceptance. As for the in-house problem, it seems that a motor company can have a staff that decides they want to sell this to our perceived customers and set up a series of specifications, and then another engineering staff will design those into tools and set up a manufacturing line. QC has a responsibility for making sure that the product that comes off the line conforms somehow to the specifications that were set up by QA. As soon as the QA expert leaves the motor company and goes to work for the Federal government, there gets to be a very sharp line between the two. It's a procurement line; it's a contractual line; it's a no conflict line--buying products on behalf of the American people.

I did some checking around on definitions and there are a couple of things that were interesting. QA implies inspectioning acceptance on behalf of the government, confirming that a product conforms to contract specifications, whereas QC is ensuring that it conforms to specifications. But in both cases we have the implicit specification already there. We presume that we have

specifications in both QA and QC. Also, the interesting thing here too is that it's very clear that QA is a government responsibility and QC is a contractor responsibility.

I did some reading on inspection acceptance in the Federal Acquisition regulation. They basically defined higher level contract quality requirements as those which apply to critical and complex procurement, and the definitions of complex and critical were given. Complex means that the product has quality characteristics not wholly visible in the end item. Critical means that the failure of the item could injure personnel or jeopardize a vital agency mission. I looked at those and said, That looks like data to me. It's very hard to say that I've got a high quality piece of data when I look at it. And it is critical, too, because we have human lives that are at risk in this environmental cleanup business. The thing about a higher level contract requirement is that it puts an increased onus on the government to not use contractor inspection of product. It puts an increased onus on the government to have a non-conflict inspection except as a process.

In wrestling with the problems of QA, I ran into the fact that we didn't have any standards. In talking to contracts people, they presumed that we had standards and specifications for what we were trying to buy and I said, no, we don't have any. And they said, that's not QA. And I said, well, what is it? Well, that's acquisition support--to develop those specifications and standards.

One of my co-workers, Barbara Johnson, helped me with this one. I think that this appears in EQA 1 under the heading of Quality Improvement. It says that you look at what's wrong with what's coming off the assembly line and decide how to re-specify it so that you continuously improve.

You've got to have all of these things happen in order to get quality data in a new industry. Yet we've got a procurement system that's already written up in a Federal Acquisition regulation that we have to communicate with whoever thinks QA is just inspection/acceptance. So we've got to look at these issues and determine how to communicate with these people and get them on board to our issues and on our side.

I want to emphasize one last thing: the acquisition process has nothing to do with the people who are generating the data. The Navy buys everything--we buy QA program plans; we buy QA project plans; we buy the whole business. The contractors are over here; they're producing. We're over here figuring out, well, we'll get their product in here and we'll inspect it.

I wanted to touch on the recognition of data as a primary product, and I argued this in our Naval Facilities Engineering Command. I have people that want to refer to this as construction, and I said,

That's fine, but you don't know where to clean up; you don't know to what level to clean up; and you can't verify that you indeed cleaned the area up without data. How do you reassure the neighbor across the border line that you got rid of a part per billion of benzene out of the ground when it's an invisible situation? Data supports your decision. You stand or die by data. We all know this, but it's something that I have to keep hammering away at in my own shop.

We need an increased focus on these contracts requirements documents, individual methods standards and SOP's, and model work statements, which could be almost in any form for every step of the process, for planning documents, for reporting, for execution of work for feasibility studies, for remedial designs, you name it.

We need standardized planning and reporting formats. In a way, a lot of our problem is on format. We can provide the same information with the same substance, but if we call it something slightly different, or label it in a slightly different order because we're buying these things so quickly that one engineer out there procuring a million dollars worth of contracts services in a very short time provides that to a region, and the region looks at it and says no, that's not acceptable, that's not what we're asking for, you don't have a QA program plan here or whatever it's called. And so we're required to redo the effort or revise it. That's very expensive.

Referencing is something that I think we need to have in guidance documents, in our model work statements, and in our contracts requirements. We all track information. We buy a lot of redundant information in the Navy. I'm sure you've all seen that problem before.

It was very complex for me to try to convert a very good piece of EPA guidance into a streamlined procured work plan for the Navy. One of the things that I noticed was that the QA project plan is very similar to something that we designed also. The project plan guidance 005/80 consists largely of standard operating procedures. When I looked at some of the things that had to do with sites and the objectives for measurement, I had to sweep all of these things that were site-specific over into one place, because, as I said, often we have 15 sites on one Navy base, but that usually will be one contractor as well. The same procedures for drilling wells will be the other contractor on all sites. What we have here is site one, with all of its conditions, its data quality objectives and scoping, and its risk-associated elements put in one place. Then we go on to the next site. And we can put all of the site by site planning in one place and separate the lab standard procedures and the field standard procedures and incorporate them by referencing them--get them separated from the issue of planning.

I want to make a point, which is emphasizing existing terms and

trying to pull in as many existing terms to define program language as we can--in terms that other people in the industry might recognize. There's nothing inherently wrong with acronyms in themselves, but they tend to get a life of their own if we don't pull them back to long-term technical terms.

DQO is one of my favorite acronyms because I really like the concept. However, when we get on a small site scale, I think a lot of people would recognize these sorts of things: hypothesis development, hypothesis testing, experimental design, and errors and controls. We need to go for all of these and we need to use these words to tie together these concepts.

I've now defined QA as government responsibility in a procurement-related system, with planning being something different from standard procedures. We had a contract provide a QA plan which named these program plans and project plans, but since it planned to have QA, this very much looked like a plan to plan the planning plans and we had no actual planning there at all. We can spend a lot of money on these kinds of documents. So I'm advocating a terminology problem where we need to tie these back together somehow against the Federal Acquisition Regulation and the problems of procurement, and that will help. We can keep these terms if we give them a little more clarification and definition.

From the Navy perspective we are looking at standard procedures; we're looking at building blocks; and we're looking at procurement tools. We have a need to provide engineering field divisions with things that buy good services just by the plug-in sort of factor, so we have a very baseline sort of attitude on this. Any guidance that comes out that will be useful to us will help name those relationships, especially for contracts and government responsibilities. QA is procurement to us.

Duane Geuder

My major concern in being almost last on a panel like this is that almost everything has generally been said. Fortunately I'm not last, so I still have a chance. For any number of issues that I address, approximately half of them have already been addressed either by Nancy or Gary or John or Marcia.

What I want to start out with is to give credit to Gary and anyone else involved in the generation of this document because I think it's a quantum leap forward. Obviously a lot of time has gone into it. I hope we can, in fact, get it to a point of implementation.

Two things jumped out at me from the document: first, the advocacy of plan, implement, and assess; and second, to foster a no-fault attitude. Many times the QA community is looked upon as the policeman and we have difficulty doing our job because people think we're looking for fault as opposed to trying to improve the

process. The plan, implement, and assess was at least in Superfund. We're pretty good at implementing but we really haven't done a good job in the planning and assessment.

With the fraud issue in the CLP, or the fraud issue in the lab community, what I'm hoping is that the diplomacy among the federal agencies will continue and that that diplomacy will pervade not just the Federal agencies but all of the organizations within the Federal agencies, because we in Superfund and elsewhere have to deal with numerous organizations within Superfund that all support the project. And likewise, with implementation of this guidance that it would minimize and reduce all opportunity and inclination for fraud in the lab community or elsewhere.

Anyway, I understood my mission in a slightly different way from Gary. I think it's not terribly off track, but I was attempting to answer two questions: What could a single QA standard mean? and what are the issues for implementation? I think we mostly dwelled on the second, but the first, which was addressed by Robert Layton, was the question of terms, definitions and acronyms which the Navy is so fond of--EPA and Superfund are enamored with acronyms. When I first started with EPA, it took me three weeks just to learn the acronyms and that was in water enforcement. Superfund has another order of magnitude of acronyms. At any rate, this standard guidance would certainly help to standardize our language, our terms, and our definitions.

The guidance will provide a standard process that will ultimately facilitate review and audit by EPA or by Superfund or Federal facilities or contractors and most importantly, Potentially Responsible Parties (PRP's). Again, more acronyms. By definition it will eliminate barriers, both in its development and in its application. The barriers among the agencies are already falling; I hope that the barriers within the agencies will tumble in a similar manner. The buy-in by the agencies and the sub units will, in fact, eliminate the barriers. If each entity has a buy-in, some ownership of the product, which is what Gary has emphasized, then certainly it can't fail. It'll provide a yardstick, especially in Superfund, for cost recovery.

We need some kind of yardstick, some measure of what the PRP's or any other entities should be doing at a remedial site--what is an appropriate level and how many samples, because we go after cost recovery. If EPA says you should do more than is necessary, then we're not going to get all our costs. If EPA says less, then the project won't be done properly. So, definitively a yardstick for cost recovery and in some instances we can go for triple damages. In that instance we definitely need a very viable, documentable yardstick to measure the activities. You can't get away from it. Clearly, resource implications come out from this. Increased resources are unlikely; therefore we're going to have to do things smarter with the resources we have and reallocate those resources.

It's been mentioned by Nancy, Gary, and others that we're going to need tools and guidances. But they're going to have to be customized; they're going to have to be user-friendly. Hopefully they'll be automated. We at headquarters have heard from the regions numerable times that there's too much guidance--we've heard this in some of our audits and reviews. Therefore, whatever guidance is forthcoming, we'd better be careful to keep it terse, to the point, and as user-friendly as possible.

Last, but not least, this will provide a significant improvement to EPA's, and I hope to the other, QA programs--the other Federal agencies. Significant improvement, because it emphasizes a cradle-to-grave approach where you do QA through the upfront planning, you do through implementation, and then at the tail end you do the proper assessment to make sure everything has worked and what you can do to improve it.

These are the issues for implementation. Resources--we can't get away from it. I mentioned it already. I can see that if we have a full fledged audit or review process within Superfund, the resource implications are dramatic. We currently don't do a lot of field and on-site auditing. If we are to do so, significant resources are going to have to be shifted from some other activity if we're not going to get additional resources. The other thing: we plan two or three years in advance, so they are now providing input to the '93 budget process. I've done so already. If we're going to change, or get additional resources, we won't see anything until '94 at best, based on this particular process.

Nancy mentioned that there's always resistance to change. This will require dramatic change, especially in where we have our QA resources applied presently. We've emphasized the analytical component; we've minimized the upfront planning and scoping; and we've minimized the review and audit process. Marcia mentioned that data quality objectives (DQO's) are great, and they are. But within Superfund and within EPA there's a DQO syndrome. It carries a bad taste, unfortunately, with too many of the engineers because of some of the problems in its infancy with implementation.

We also have a QA syndrome that we have to deal with, where the engineers and a lot of the data users are not QA advocates; they want to get out with their shovel and re-mediate the site. So we have those two syndromes to deal with.

We also have the issue of true implementation. We can write program plans and project plans until they come out our ears; if they are not fully and accurately implemented, they're of minimal value, except as an exercise and profit for the contractors. We need more than lip service and we need true upper level management commitment to this guidance. Once it's in place, management has to understand they're going to be wed to this and it's going to cost. Others have mentioned education and training. I put it as

enlightenment education and training, especially for the engineers and the data users that we have to deal with in the QA community, so that they understand that QA is not a necessary evil, a hurdle, a barrier, but a useful management tool and a mandatory management tool.

Last, but not least, are analytical facilities and labs. I think we need to develop among the Federal agencies a minimum standard that the labs will ascribe to all data. If the user needs more, the DQOs will get it. If you can accept the bare minimum then it's taken care of within all of the laboratory community.

Tied in with that, we need to do a lot more in addressing performance-based results as opposed to method-based results. We often encumber ourselves by being wedded to particular methods that don't always work. The CLP is a good example. We have very rigid requirements that can't work in every instance. There has to be some flexibility.

There are two related projects going on in Superfund presently that will dovetail very well with this standard. One is called DAS for those who love the acronyms; it's tied in with the long- term contracting in Superfund and it is the Delivery of Analytical Services. That component was left out of the strategy; it's currently being addressed. Clearly the chemistry in the analytical services required by Superfund will be a major component of this standard.

The other is that we presently have an ongoing review of the Superfund QA\QC to look at the program in its entirety, to find out where there are shortcomings and where there can be improvements made. This is being done in a TQM approach, so we have regional as well as other input.

Thomas Morris

In the Hazardous Waste Remedial Actions Program (HAZRAP) we have lots of customers. It's difficult because we've got the DOD people, and even within DOD, we have the Army, the Navy, the National Guard, and then we've got EPA and DOE. Everybody has a different agenda so we have a pretty difficult time of it. We also have all the subcontractors who do work for us that we oversee and do project management for. I've worked in about four different areas--all within Martin Marietta--and I fight the same battles, time and time again, so maybe I can shed some light on areas that will help in implementation of quality standards.

There are five keys to effective implementation of any quality standard: understand cultural resistance to change; demonstrate top management commitment; provide adequate education and training; be willing to define the overall objectives and process requirements at a global level; and ensure availability of

electronic user-friendly implementation techniques, tools, and processes to help project team participants.

Respect for QA I'll talk about first. I expect that you all have about the same level of respect by your project managers and your upper level managers that I have, and I don't know how we get through that. I've struggled with it for several years. I think it's changing slowly. One of the problems was that they put QA people into QA positions when they had nowhere else to put them. There are some exceptions to that--we're probably those exceptions. We have different ways we put things, and I think managers have trouble understanding it sometimes.

To understand cultural resistance to change, I think you have to analyze and pay attention to the basis for resistance. You've got to actually look back in time and say, The managers that are in power, what's their real heritage? What year did they grow up in? I think you have to get to the point of understanding what their real motivational drive is all about.

Our personnel people have done a lot of activities over the past four years or so, such as using Myers-Briggs and those kinds of tools. I had the benefit of knowing the guy in training who does those and he's plotted all of our senior managers and they're all power hungry. In seriousness, I point that out. It's real and you have to learn to understand that it's there. I think part of the reason why managers have difficulty with QA people is that we're threatening to those managers. In many cases, of course, we really do understand what we're talking about and it's not easy for them to accept that.

Break down barriers that were established as a result of ego and insecurity. That's tied to the real bottom-line needs. I think we need to start using some psychology-oriented people to better understand what drives people. You've got to deal with it.

Empower the people doing the work--that's embodied in TQM--and listen to the people who actually do the work.

Involve mid-level managers. Even when people get on board with TQM and even when the top managers speak the right words, whether they practice it or not, we seem to somehow miss the mid-level managers. They finally find out about it somewhere down the road, by hearsay, and that's threatening for them because they haven't had a part in it. The real commitment is when you say <u>and</u> do. And that's a pet peeve I have about presentations. People get up and say what needs to be done and never get down to actually doing it.

Encourage change for the better; emphasize continuous improvement.

Demonstrate top management commitment. Practice values implementation. There's a lot of politics involved in decisions,

and sooner or later politics is going to drive you down. I don't think you're going to get anywhere until you treat people like people and listen to what they say and let them listen to what you have to say.

Reward those willing to take risks and accept accountability. Nobody wants to accept accountability. I understand why, too; there's risks associated with it. There's legal liabilities associated with it. We have major problems getting people--whether it's EPA or whether it's the states--to accept accountability. Say, okay, I'll put my signature down and I'll accept the accountability for whatever method you're proposing, or accept a plan that's been submitted. And you've got to reward the people who take the risks and if they fail, they have to suffer some of the consequences for that, but on the other hand, you've got to take into account that they're willing to try and make some decisions to move forward.

Make the QA function a key step in the upward mobility chain. I think one of the things that will really demonstrate top management commitment is when they start having the QA function be a place where "fast trackers have to move through." Actually, once people get into it, they do develop an understanding of it. But when they're out on the side and you're bugging them about management systems that need to be in place, it's just a pain for them. You put them in that position and let them go through that and then let them take it out and implement it. If they actually learn it and you put them in a project position, then all of a sudden you have it infused within where the work actually takes place.

Integrate methodologies for assuring quality into a defined line organization procedural system. Within HAZRAP for our QA program we're getting all of our procedures in place for doing business. With our procedures manual, we've got a section called "Administration" and of course it's got all of the "how do you hire and interview people and how do you orient them," and that sort of thing. But in the project management system section we've got not only the things about "how do you plan a project and how do you use a team concept and how do you estimate your costs and schedule it and go through what procurement acquisition strategy you're going to do," but also things such as quality management and DQO's, "how do you do readiness reviews, how do you document non-conformances, how do you resolve problems and get to root cause, how do you apply lessons learned." Those kinds of things have always been pushed off on the QA people, but they're really a part of doing the project.

And so, we're trying to move as much of QA into the project as we can, because document control, and all of the things that go along with document control, is not a QA function but a records management function. That's probably not even a project function. We don't have document control in our project management section;

we've got it over in a section called documentation; and we let people who understand all the myriad of regulations associated with keeping documents for 75 years and microfiching take care of it. That's not a QA responsibility.

QA is an integral part of a structured and disciplined project management system, not something that some QA people do off to the side. I think you have to adequately staff and fund a QA function and train the project participants, depending on the level that you involve QA into the project. You need to say, we're going to have a QA function, we're going to recognize them as a viable entity, and we're going to fund that operation because we believe those are the kinds of management practices that need to be taken if we're going to do work, regardless of what kind of work it is.

Or, if you're going to let project participants be the people who document your non-conformances and do your problem reporting and problem resolution, then you've got to fund training the project managers to do those things. QA people have a better understanding of that, but nothing says you can't train project managers to get to what caused the problem and document it.

Respect the QA professionals' credibility and input equally. I daresay that if it's like it is in some of the organizations and programs that I've worked in, the QA person gets called in when there's a problem, or when there's something that has to be resolved or when there's been a non-conformance, and you've got to fill out a form and the project person doesn't know how to fill it out because he's never been trained to fill it out and never respected the fact that you needed the form in the first place.

Provide responsibility, accountability, and authority for function-specific decisions. Our documentation doesn't yet give us specific enough responsibility or the accountability and authority for the things that QA people are responsible for, or for the things that the program people are responsible for.

Provide adequate education and training. I think we have to teach management and project personnel what QA is, not from the standpoint of the QA requirements, but from the basic practical elements of QA. This is what document control is all about; it's about making sure that the right work plan's out in the field. I think you ought to teach the QA professionals a little more about basic project management principles so we'll have a better understanding of what the project people are facing. They're facing a lot of problems, too, with controlling costs and schedule, and overhead rates.

Teach everybody the basics of regulations, terminology, and statistics. We've got instances where states require absolutely knowing that there's not one part per billion anywhere on a site, and we'll have other states who actually will say, you can do a

statistically-designed random number-generated statistical sampling for anything. You can give me a 95 percent competence level, or 99 percent competence level or contaminant is below a certain limit, then we'll accept it. I don't think we use nearly enough statistics.

Teach DQO's. I'm a strong supporter of DQO's. We've got several hundred projects but we probably had one or two DQO's that were actually used. Yet it's a wonderful process. We're having difficulty in teaching our contractors about what DQO's are. We have to sit with them in the hotel room--they've got a contract to do the DQO's for us--and we have to say, here's some examples of how DQO's need to be done. Then they feed it back to us. It's reality.

I think we need to teach assessment and oversight to everybody, because one of the things we're moving toward is not only independent assessment such as the QA people typically do, and audits and field surveillance, but we're also trying to teach the project people to do self assessments all the way along where they're looking at themselves, even if it's just for a small piece of the activity.

I think the training courses need to be structured 25 percent lecture, 75 percent practical. I think we need a lot of DQO training and that training needs to be set so that even if it's a simple example, you can work through the forms and fill in the blanks and learn by doing.

And last, staff the training function with personnel qualified to teach the subjects. We typically have training departments and they're staffed with trainers and you can give them the slides and they can go through the slides, but if they don't understand the material that they're teaching, then they have no credibility with you. The audience probably has more knowledge than the trainer before they even begin to take the course.

Be willing to define the overall objective and process requirements at a global level. Set the program structure up in the top, but formulate the procedures from within the organization. We formulated our list of procedures for doing business in HAZRAP at the staff and department level, but now that we're assigning the preparation of these procedures for doing business, we've got secretaries doing the ones on secretarial work; we've got project managers doing the one on DQO's and quality planning--not the QA person, but the project people. We've got the people who actually do the work doing it. Now we have that separate bit of oversight in assuring that once they get a procedure together the implementation of it does fulfill the requirements that have to be fulfilled. But we try to get it written at the project level.

Drive for consistency, at least in approach. Maybe there are

slightly different requirements in CERCLA versus RCRA for the kinds of information that need to be in a QA program plan, but the general approach that you go about in doing a program plan should be standardized. Trying to strive for consistency is a difficult thing to do. But the only way that you can eat an elephant is one bite at a time. It would be nice, though, if we had a consistent approach for eating the elephant we started maybe up here instead of back here all the time. But on the other hand, I think the harmonization effort is starting to try and set up at a global level, and from then begin to build all the parts.

Build any graded application into the procedures themselves. If there's a need for a graded approach for a small site versus a large site, or a site that may be either contaminous or not as critical, you can try to build that into the procedure and have a procedure that has a graded approach in it, rather than saying that we have this QA program for this kind of site, and we have this kind of QA program for this kind of site, because controlling a document is controlling a document. If you're really talking about QA principles, at a minimum coordinate the building of the pieces of the program to maximize the strengths of each part.

There's great work that we face in all of these areas. CERCLA has a work plan, a sampling analysis plan, a field sampling plan, QA program plans, and health and safety plans. The Underground Storage Tanks (UST) program has things such as initial response measures and site characterizations. RCRA, CERCLA, UST, and NPDES all overlap, and many of the elements are similar enough in nature that I think if we could get people together and use the best parts of them, we could come up with generic statements or generic work plans.

As a matter of fact, we have a generic statement of work. We may use it internally, but we have a generic statement of work that you can pull the pieces from. It's on a computer and you can go in and fill in the blanks. As you go through it you pick the things that are applicable and pull them out, and the computer goes in and through some WordPerfect manipulation puts together a statement of work in a couple of hours instead of a couple of weeks. We're also working on a generic work plan that leads to ensuring availability of electronic user-friendly implementation techniques, tools, and processes to help project participants. Our next step in this generic work plan is to build an expert system where the screen asks a series of project related questions about a specific project in the language that a project manager can understand, and then obtains his or her answers to those questions. For example, what kind of a site is this? Is there water contamination? Is there soil contamination? Is there both? As the manager answers, the expert system automatically says okay, because there's soil contamination, these are the potential applicable standards that go with it. The project manager gets the particular words that need to be in the statement of work from a database that already exists.

Structure software to respond transparently to project manager language. We're working toward generic QA program plans, generic statements of work, generic work plans, and health and safety plans. Share lessons learned with everyone. I don't think we share lessons learned enough and we ought to share them in a user-friendly lessons-learned system of some type. One of our agenda items is to work with our contractors. We have 11 major general order contractors who work with us. We'd like to get a lessons-learned system that they're willing to share among each another. They all face the same things; they just face them in a different area of the country.

We have one region that tells us we've got to use a certain kind of decon procedure that calls for specific decontamination fluids to be used, and we have other regions that say you can use whatever is applicable including steam. So we run into the same kinds of problems that have been mentioned in some of the other presentations. Those are going to happen unless we work together and we stand to benefit, because you are our customers too. We have to deal with the regions and the states and get decisions made, so I know it would benefit us. We want to work with you, because we want to be in this business for a long time too. Appreciate it.

ECOLOGICAL MONITORING
PANEL DISCUSSION

Chair:

Robert Graves
EPA

Panelists:

James K. Andreasen
Fish and Wildlife Service

Adriana y Cantillo
National Oceanic and Atmospheric Administration

Thomas F. Cuffney
U.S. Geological Survey, Water Resources Division

Robert Graves

I am the Acting QA Coordinator for EMAP, which stands for Environmental Monitoring and Assessment Program. This talk is not going to be about EMAP per se, but rather about ecological monitoring. Nancy had asked for my talk to cover a few different objectives. One is to define what ecological monitoring is; two is to describe why harmonization standardization of QA is important in ecological monitoring; three is to give a brief overview of EPA's QA program; four is to link EPA's QA program to ecological monitoring; and five is to link EMAP's QA structure to EPA's QA requirements.

To give you a little background: from my perspective, EPA has two broad objectives: one is to protect human health and the other is to protect the environment. To achieve these objectives, EPA works within the area of risk assessment and risk management. The Agency has in the past focused mainly on risk assessment as it applies to human health. That is, we regulate contaminants for the most part, to protect the health of human beings.

However, we are now, I believe, re-emphasizing that other objective we have within the Agency, and that is to protect the health of the environment. I think we're beginning to realize that our biological resources sustain our existence, and that to protect our own health, we have to protect the biosphere in which we live. Accordingly, ecological monitoring research within the Agency is starting to get more emphasis than it had in the past, and that is one of the reasons I believe that EMAP has developed. EMAP is probably the Agency's largest ecological monitoring program.

Let me begin by giving you a brief definition of what ecological monitoring is. It's the measurement of abiotic and biotic factors in the environment to assess current conditions, that is, status, and to identify and warn of changes in biological resources, which is trends.

What are the QA objectives of any ecological monitoring program? One is to ensure that the data generated are of sufficient quality to meet program needs. Two is to ensure that the procedures and processes used are such that they will produce the desired results. Three is to ensure that all procedures and processes and data are sufficiently documented. Fourth, which I think is the crux of harmonization, is to ensure that data generated in one program, albeit EPA, are defined well enough so they can be validly compared to those data generated in other programs, that is, programs such as the National Oceanic and Atmospheric Administration's (NOAA) Status and Trends, U.S. Fish and Wildlife Service, U.S. Geological Survey (USGS), and a lot of other Federal agencies and states and other research efforts.

The purpose behind harmonization, I think, is to have data comparability. If we can have ecological monitoring programs that give us data comparability, we can then put all the data together and make some real integrated assessments.

Harmonization/standardization, the way I look at it, touches on various methods. One is sampling methods. The one thing I think is true with ecological monitoring, and it's probably true of other programs as well, is that when I speak of methods, I don't necessarily think of the laboratory methods. I think the biggest crux of ecological monitoring is to harmonize sampling methods. For example, when you go out in the field, how do you collect your samples so that the way EPA collects its samples is compatible with the way the Geological Survey collects its samples? If we're looking at fish tissue, for example, are we looking at the same tissue? Are we looking at the edible portion of the fish, are we looking at the whole fish, are we looking at livers? How do we take the fillets if we're looking at the edible portion; is it skin on or skin off? All these factors will have a great impact on whether we can pull that data in the end. That, I think, is more important than the analytical techniques used.

The analytical techniques are comparable--and you'll listen to Adriana talk about NOAA's program where they don't really specify standardized methods--in other words, what they do is specify performance criteria of the laboratory so that laboratories can use any laboratory methods they want as long as they generate data of a certain precision and accuracy. I think that's legitimate. But if we don't have sampling protocols that are standardized, we'll still never be able to pull that data in the end, and I think that's where we need to focus a lot of our attention--not only sampling methods in that sense, but also things like statistical

methods. How do we design our protocols? Are we using randomized samples or non-randomized samples? Again, I think we need to get our statisticians involved upfront to see if we take our samples in different fashions and whether or not we'll be able to integrate that data together in the end.

QA/QC techniques is another big issue. There are certain QC techniques that are mandatory, such as blanks or calibration standards. I think that from a laboratory perspective, if all the Federal agencies could agree on a certain QC program, it would make it a lot more cost beneficial for us to run samples rather than what happens right now. EPA is probably one of the worst offenders in this realm. No matter what program you're working for, it has completely different QC requirements. And most of these requirements are not requirements because they're really necessary for that particular program, but they are requirements that some manager puts in because that's their particular bias. Therefore, what happens is in the laboratory they've got to shift, as they do samples for the drinking water program and they've got to shift again, as they do samples for the NPDES programs, and then they've got to shift to QC techniques a third time when they do for Superfund, or for RCRA or for any of the others.

Method Detection Limits (MDL) determinations--I think that's another important thing. For a lot of our methods, we do list MDL's, but the way that we calculate these MDL's varies from method to method in some cases; therefore you can't get a good feel whether method A is really comparable to method B, or at least go down to the same levels.

Definitions--I think that was mentioned the other day; laboratory certification on a national scale was another one. Indicator selection with respect to ecological monitoring and computer hardware/software standardization, which I think was addressed when they were talking about GALP's.

If we achieve this, what will this buy us? What it will do is buy us integrated programs; it'll give us an integrated database. We can then take inputs from either the Federal agencies that are doing ecological monitoring, whether it be EPA, NOAA, the Bureau of Land Management (BLM), U.S. Department of Agriculture (USDA), or any other agency, or any of the state programs that are doing ecological monitoring, and other international programs, and feed it into a common database that will allow us to do integrated assessment reports.

Let's take a quick look at the QA components within EPA. The way I look at what QAMS has dictated to the rest of us within the Agency is that we have an umbrella document called a quality assurance program plan (QAPP). A QAPP more or less sets the general guidance of how we're going to operate a program. Under that we have various other documents that we're mandated to put

together, such as data quality objectives (DQO's), quality assurance project plans (QAPjP's), audits, and audit reports.

Why do we require these particular programs? The rationale is that the QA program establishes the principles and guidance. The DQO's establish what the customers needs are, and I think it's important that we go back and determine who our clients are and exactly what it is that they expect out of these programs. The QAPjP then establishes the process for satisfying customer needs. The audits, in turn, evaluate that process to improve it and to judge its applicability to satisfy customer needs. Finally, the reports are the product to meet customer needs.

How does this all tie in with respect to ecological monitoring programs? What steps does one go through when one does the planning for an ecological monitoring program? This is the scenario that I came up with, and I tried to tie that into the various elements of what's required under EPA.

First, you have the initial preparation where you define the objectives of the program. Basically, that is when you're asking questions such as what data are required, what is the end use of data, and what is the total allowable error? That is the vernacular of EPA's DQO's. Then you always have that thing called resource allocation, which is the budget--that seems to be the roadblock in most of our programs. We never have enough resources to really do what it is that we plan to do. That's a reality check and we have to pare back so that we can do our program within our prescribed budget.

The system design is where you do your research plans, your QA project plans, your design plans, data processing (you have your computer hardware/software needs), and field operations, which describes your QA project plans and your logistics plans. Analytical laboratory operations from the QA perspective is described in the QA project plans. You have data reduction and analysis and validation, and again, the procedure for that should be described in your QA project plan. You have your audit reports and your corrective action memos. System certification--you go out and do pilot studies and demonstration projects. Finally, you conduct your full scale study which is implementation. Then you have your data reporting, which is your final report.

How does this process fit into EMAP, which is the Agency's ecological monitoring assessment program? And when I say the Agency's ecological monitoring assessment program, I think I should step back, because that is not quite true. EPA is making a concerted effort to make EMAP not an EPA program but a Federal program. We're looking for partners out there in the Federal sector to work with us on EMAP. And I think we're doing a fairly good job at working with the other Federal agencies.

We did a pilot study this spring in Virginia Province which is an estuary system, and we worked very closely with NOAA's Status and Trends program. We're working closely with the BLM when it comes to arid lands, and we work with the USDA Forest Service with respect to the forest monitoring effort that was done in the East Coast this last year. We are also forming partnerships with other Federal agencies.

The EMAP process of going through this is that first we do a pilot study. The pilot study entails designing your study, conducting your study, and of course, interpreting your results. If it was successful, then you move on to a demonstration. If it's not, you go back and do a pilot study again. A pilot study is a very small study where you test all your processes and all your hypotheses to determine how you should design your study and choose the indicators to tell you what it is that you want.

A demonstration project, on the other hand, is a large-scale pilot study done on an eco-regional basis. It allows you to test things such as spatial variability to make sure that it isn't so great that it swamps out the variability of your measurements. And again you go through the same scenario, and if it's successful you move on to implementation, which is where you take it on a national scale.

One of the things, though, with implementation is that we're never quite satisfied. We don't implement it and just stick with it. We have this thing called continuous improvement, and we keep recycling back. So even though you're in the implementation phase, you've got to continually reassess what it is you're doing, relook at your indicators, see if it's telling you what you want it to tell you, and redesign on a year-to-year basis.

How does that fit in with the QA techniques that are mandated by EPA? The QA tools--DQO's, QAPjP's, and audits--are required in each stage of the process, at the pilot stage, the demonstration stage, and the implementation stage. The difference is that the content of these various documents differs depending on which stage of the project you're in. For example, let's take the QA project plan. You may at the pilot stage make it more extensive than it is at the implementation stage, because at the pilot stage what you also want to do is to test all those QC techniques out there to determine what QC techniques are needed to control those parameters that you're measuring. That way, when you go to the implementation state you can do the most cost effective QC on a national basis. When you're doing basically thousands of samples, you don't have to be doing all that same QA/QC that you did at the pilot stage when you were trying to learn and assess.

If we achieve our goals, we'll end up with a national integrated ecological monitoring program where many different Federal agencies will be contributing to the EMAP database. You'll have EPA

contributing, but you'll also have the Fish and Wildlife Service, USGS, BLM, NOAA, the states, the local government, and other research efforts that can all be feeding into that.

If we're really successful--maybe another decade out--we'll end up with an international integrated ecological monitoring program. EMAP has already made some strides in that direction. We've talked to Brazil and they do have the rain forests on one of the EMAP grids; we've also been over to Australia with the arid-lands people over there and Australia is very interested in the EMAP concept and with becoming part of the same grid system. So we are moving into the international ecological monitoring program.

In closing, I'd like to reiterate what Robert Layton, the Regional Administrator for Region 6, said yesterday. He charged this group to develop data collection processing and reporting techniques that transcend agency boundaries. I think that's really what harmonization is all about, at least on the ecological monitoring scale. We need to develop these types of techniques that transcend across the agencies so that data from NOAA and the Fish and Wildlife Service can all be pooled and put into a common database, and we can really get around to doing an integrated data assessment. Thank you.

Adriana y Cantillo

I'm here to describe briefly the National Oceanographic and Atmospheric Administration (NOAA) National Status and Trends Program, which has just started its sixth year of sampling. The QA function of status and trends is an integral part of the program and was included in the program plan from its inception. I must add that this was done to the chagrin of the potential contractors because we're dealing with a community in the marine sciences field that is used to QA, and initially the comments were: we don't need to do QA, we know what we're doing. But now they have decided that this is an excellent idea and in presentations that I have seen, they make a point of saying that they participate in the Status and Trends QA Program. So they're actually publicizing the fact that they take part in it.

The Status and Trends Program measures the current status of and any changes over time in the environmental health of Eastern and Coastal waters of the United States. It has six major pieces--benthic surveillance project, mussel watch project, biological surveys, the QA program, the specimen bank, and historical trends assessment. The major pieces that I'm going to discuss are benthic surveillance, mussel watch, and the QA program.

If anybody's interested in further information on the program, feel free to drop me a line. We have almost 100 publications on results and interpretations from the program--we'll be happy to get a list of publications to you.

Benthic surveillance collects sediments bienially in bottom-dwelling fish from around 75 sites in the United States. All analysis is done by NOAA's National Marine Fisheries Service. The sampling sites are determined by where the fish are. So over time we may have to go to different places in an estuary. The fish are collected by trawling, so we are dependent upon where the fish happen to be on that particular day. We are also looking at the incidence of fish disease and tumors.

Mussel watch is a continuation of the 1970's Mussel Watch Study that was conducted by EPA and other groups. In this case sediments and bivalves (mussels/oysters) are sampled around the country yearly at about 220 sites. Texas A & M University and Battelle are the contractors for this study. The sampling sites are governed simply where the mussel or the oyster beds are. We collect natural specimens so where they live is where we go pick them up. We don't have, again, any choice in where the sampling sediment sites are.

The QA program will document all the sampling protocols and analytical procedures used in the Status and Trends Program. This becomes very important from the fact that we have to pool samples together to get enough material to analyze. And so it's very important that the various contractors know that they have to prepare composite samples of X animals and what part of the animal they're supposed to collect and be consistent about it over time. We also want to reduce variations inside a particular laboratory and between laboratories. We want to use the QA program to eventually compare our data to the data generated by other programs.

In methodology, we're quite different from EPA. We do not specify any analytical methodology. The laboratories are free to use whatever method works. This frees the laboratory--especially the contractor laboratories--to use analytical instrumentation that they may have on hand and have the expertise on knowing how to use expertise that perhaps is not common to everybody. This is quite all right, as long as they can produce results in the intercomparison exercises that are similar to everybody else's. This is very much appreciated by the contractors and it eliminates a lot of headaches for us.

We require the use of standard reference materials in control samples. We contract with the National Research Council of Canada, and with the National Institute of Standards and Technology (NIST) in the preparation of control materials and standard reference materials (SRM's). Some of the materials that have been prepared for Status and Trends have become SRM's.

All the methodology and sampling protocols are documented. We're in the process of doing that now. It's difficult because the contractors don't seem to want to provide the detail of information that we want for the documentation documents we're preparing. We

do want to put on paper the level of details down to the part number of the materials used in the plastic ware, because we do not know if 10 years in the future that may be something that will be critical.

So we're doing a very detailed documentation of methodology. And we're looking at the addition of all the results of intercomparison exercises into the national Status and Trends database, so that anybody looking at our Status and Trends data will have available the results of intercomparison exercises, things such as detection limits, what the precision was, how the laboratories compare with each other, and how their accuracy was compared with SRM's. This will all be part of the electronic database.

The most important part of the QA program is that each year there is an intercomparison exercise that takes place and the NOAA contractors, including the National Marine Fisheries Service, are require to participate. The organic intercomparison exercise is prepared and run by the National Institute of Standards and Technology (NIST), and the inorganic by the National Research Council of Canada (NRC). NOAA does not do anything in the laboratory; we do not have a lab in the office; we contract this to NIST and NRC. So they act as an independent sort of judge or evaluator of how our contractors are doing.

Sample types in the past have included free strike sediments and extracted sediments, so that you take out that variable of the extraction, homogenized frozen tissues. They now want to explore the possibility of tissue samples from matrices, such as mussels other bivalves, fish, and also sediments from clean areas and contaminated areas. The way this works is that every year at the beginning of the year, the labs get the samples from NRC and NIST; they analyze the results; and then they send back the results to the originating organizations. They, in turn, get all the results together, and every year they have a meeting with all the laboratories and the results are presented.

Our core laboratories have been participating in the program since it began five years ago. They are doing very well in the analysis of the intercomparison exercise samples. We just opened up the QA program to other laboratories; this is a way of showing that participating in these exercises has a beneficial side effect. Our core labs do very well compared to NRC, and the new labs still have some work to do.

Every year there is a meeting in the late fall or winter once the results of these intercomparison exercises are sent back to NRC and NIST, where the laboratories that have participated and would like to go to the workshop can attend. The purpose of the QA workshop is to show everybody's results and discuss what problems there may be in common and what the probable solutions are. It's almost like a teaching situation. During that workshop the laboratories and

NIST or NRC decide what kind of samples they want to do next. So the choice of sample for the next intercomparison exercise is, most of the time, the choice of the laboratories.

In other words, they may say, we're having problems with analyzing a real clean sediment, or we have analyzed clean sediments before but we're not sure how we would do with a real contaminated sediment, so we'd like to do that. Or, we would really like to test and see what our extraction is like. Can you send us something that is not extracted so we can add that into the degree of difficulty?

It changes from year to year and that's why it's not possible to show you an improvement of one lab over time. The samples change and the degree of difficulty changes as the labs get better and better.

In future developments, some of the EMAP labs are now going to take part in our QA program, especially the ones that will be working in the coastal area. We also are going to open up the intercomparison exercises to non-NOAA contractor labs, or any Federal or state government lab that would like to participate.

The response to this has been overwhelming. We have about 30 labs already that are going to participate in the inorganic intercomparison exercise. The organic exercise is completely full and we have a waiting list of about 25 labs. A lot of the comments from the field are that we're doing such and such analysis but we're not sure whether we're doing it right. So the response has been very good.

We haven't been able to open it up to more labs simply because of funds. It's very expensive to do this, but probably slowly we'll be opening this up. We have found that for marine environmental samples there isn't that much QA available. The marine chemists are an independent breed and a lot of them have become chemists because they need to determine something in the marine environment. So they don't see the need for QA and don't like to do it. But very slowly the point is getting across.

We're also beginning to work with international groups. Right now we have the International Mussel Watch that is scheduled to begin in the Caribbean, probably this year or next, and they will be part of an intercomparison exercise since we also do Mussel Watch. Slowly we're spreading and trying to get the word out. If anyone would like to participate in the trace metal intercomparison exercise, please give me a call.

James K. Andreasen

The mission of the Fish and Wildlife Service is to conserve, protect, and enhance the fish and wildlife resources of our country

and their habitats. I want to briefly describe an ongoing marketing program that we've had, tell you a little about some of the results of that program, and then discuss a new effort that we have started.

During all this I'd like you to consider how this all interacts with the QA requirements. Consider the complexity of the environment, the number of different species that are out there that should be monitored in order to say something about the health of the environment. Think about how diverse those habitats are and the difference between the life history of each of those critters we're trying to collect, different collecting methods that are needed, storage techniques, and everything else that goes along with that. Maybe you'll get some idea of why we think there is a tremendous need for having harmonization within environmental sampling.

Like EPA, we're a strongly decentralized organization. We have seven geographical regions in the country plus a separate research division. It makes another level of complexity on top of the whole thing.

The Service has responsibility under several Federal laws and international treaties to manage migratory birds, threatened and endangered species, anadromous fish, and certain marine mammals and lands that are under the control of the Service, such as our National Wildlife Refuges and National Fish Hatcheries. Currently there are about 475 wildlife refuges around the country and this consists of some 89 million acres of land. We are in the process of developing a monitoring program for each one of those sites.

These are some of the resources that we're charged with protecting: migratory birds, endangered species, and brown pelicans. We have our various wildlife refuges and they're all being assaulted by various kinds of environmental impacts. All you have to do is open up any newspaper and you'll see that there are daily new problems coming along that are going to affect one of those species. A lot of things we found in our previous monitoring efforts that showed the impact of environmental contaminants on natural resources were from our irrigation drainwater program which we've had functioning throughout the west. We saw impacts from the Alaskan oil spill, not only the critters being killed by the oil directly, but the secondary effects on bald eagles from eating those oiled birds. We're looking at a lot of these things, not strictly for the direct impact on the critters, but rather the fact that a lot of these birds and other fish eat smaller things that are in the environment, so we're concerned about the impact on the birds consuming contaminated prey in some circumstances.

I want to describe briefly a program that was originally called the National Pesticide Monitoring Program (NPMP). It was set up by Congress in 1967, right after Rachel Carson's book hit the stands.

Originally there were many agencies involved in the project. Gradually, over the years, most of them dropped out. The Fish and Wildlife Service kept the thing going and we're still collecting fish--not primarily pesticides any more--but we're looking at the whole suite of environmental contaminants similar to the list that the National Marine Fisheries Service is using for the Mussel Watch Program. We're looking at that same suite of contaminants still. We're going for pesticides, PCB's, and a suite of metals.

When we originally set up the stations for this program, we tried to look at selecting areas that would be fixed stations, there over time, and that would integrate a large watershed area in the fish part of the program. We originally also looked at whole body starlings, and we looked at duckwings. Those programs, because of the extreme migratory nature of birds, were not as successful as the fish program so we've dropped those in the last few years; but we are going to reinstitute another sampling in that work for birds. We've tried to pick sites so we could integrate a lot of watershed areas but yet not be impacted by a point source.

This is what the network ended up looking like. There are presently 112 stations in the program. Samples are collected on a two-year cycle, and we analyze these samples in-house or at the Columbia National Fisheries Contaminant Research Lab in Columbia, Missouri. It takes about two years to get this many samples analyzed. Here again we can only sample the species that are there, but we tried to establish criteria for each one of the different kinds of sites. It was cold water, warm water; we tried to look at a predator species and another species that was more tied to the bottom.

Over the years we've decided that we would only sample fish for whole body residues. We don't do fillets for this program because we're more interested in what the consumer organisms are eating and the impact on their health, not so much on human health, although this data set has been used in several publications to try to get some idea of what the impact might be on human health.

We look at composite samples. Our directions specify that at each station we would collect two samples of a bottom dwelling fish and one sample of a predatory species. There will be five fish in each composite of the sample. They were to be selected for uniform size. We established the criteria; the fish weren't supposed to be flopped around on the bottom of the boat where they got a lot of oil and grease on them. We took them wrapped, froze them immediately and then shipped them off for analysis.

All the samples in the field are collected by our own biologists. We have about 60 field stations around the country and 110 or so biologists that work in the program. They do things other than just collect these samples. So we are collecting in-house; we do the analysis in-house also. Common carp is one of the species that

we've collected at almost all of the sites in the country. They're an introduced species, but they're now ubiquitous in the country. Also large mouth bass.

Over the years, looking at the number of stations we've collected from and the number of samples, we have well over 3,500 individual composite samples of fish in this program, and cumulatively we've collected at over 1,000 locations.

One of the problems with QA in the program has been that there's been a difference. Analytical techniques have improved over the years. When we first started, people didn't know there were PCB's in the environment; therefore our early organic chlorine residue data also included PCB's. We were later able to separate that out. Same thing with toxaphene--we didn't know about toxaphene originally. Toxaphene has been detected at stations in watersheds where it was never used, indicating aerial transport of the chemical.

Generally, over the program, there has been a decline in the concentration of some of these things in the environment. Isomers of DDT and dieldren show a good decline over the years. The same thing with PCB's. We've seen a pretty good decline in PCB's. They're not quite as dramatic; but as the technology has improved, we're more sensitive to what's out there.

Some of the elements, though, don't show this same kind of a decline. We haven't seen a decrease in selenium concentrations across the country; its residue seems to be staying about the same. The program has been very successful in showing declines of some elements and of some compounds. There's been a statistically significant decline in DDT, PCB's, and dieldrum between 1976 and 1986; this indicates that the ban on these chemicals has been effective in removing them from the environment.

The data also indicate that there's a geographic spread of PCB's and toxaphene in the environment. Toxaphene was never applied around the Great Lakes, yet we're finding significant residues of toxaphene in Great Lake fishes. I think this is primarily due to aerial transport, something that we hadn't considered before. PCB residues continue to be a problem in parts of the country. In Hudson River fish, concentrations are greater than 10 parts per million, while PCB residues in other parts of the heavily industrialized northeast are somewhere between 2 and 5 parts per million. The data set has pointed out the need to do more intensive studies in some areas where residues have been high over the years. We've gone back in and done more intensive sampling.

In order for a monitoring program to remain effective, it has to be able to adapt to new and previously undetected compounds. It has to be able to respond to new locations that are needed, and we need to be able to adapt to new management perspectives for what kind of

data are needed. With that in mind, the Fish and Wildlife Service has designed a new program that we're calling Biomonitoring Environmental Stats and Trends, or the BEST program. We have completed a design document. This has gone out for review across the country. BEST is going to be the overall umbrella for our program which will be site specific sampling. It'll be probability based, but within fixed stations. We're hoping to be able to integrate all these different things into one program that will answer the questions that are being asked of us by Congress.

The Fish and Wildlife Service has also signed Memoranda of Understanding (MOU) with EPA for the EMAP program. We're involved with EPA on several other programs that involve monitoring and doing assessments for nonpoint source pollution through our drain-water irrigation and quality program. We're partners with USGS in their National Water Quality Assessment (NAWQA) program, which you'll hear about next. And we see a need for having harmonization of these collection programs across all the different programs in the government.

We're hoping that there's a new day dawning for the environment. Through all these various programs we will have a greater concern for our resources.

Thomas F. Cuffney

It's a nice feeling to be able to come and visit with EPA and give a presentation. But I must confess that I was a little uneasy to come here and address this group. For one thing, I am not a Quality Assurance Officer, though I am and have been involved with our branch of QA, particularly Dave Erdman, Bill Shampine, and Tom Maloney. In addition, I'm not a chemist. And beyond that, I'm not an engineer. So the question comes up, what am I? Well, I'm an ecologist. I am one, as I understand it, of only two people with that job description currently in the U.S. Geological Survey (USGS).

I'm also going to be talking about something I think is very different from what has been talked about in terms of QA here-- QA applied to biological programs, specifically programs that are not involving chemical measurements. In addition, I come from an agency which has no regulatory responsibility and which neither owns nor manages any lands. This actually has a lot of advantages associated with it.

I do come from an agency that has a long history of providing high quality and long term data and interpretations for its customers. My function in the National Water Quality Assessment (NAWQA) program is the development of protocols for the ecological surveys. These QA programs that I'm going to talk about are interesting in the fact that they're being driven by the science and not by any type of regulatory requirements. I put this talk together before

I had an opportunity to read the harmonization document. I ask that you focus on the intent and content of this talk relative to the harmonization document and not on the vocabulary.

The objectives of NAWQA are to provide nationally consistent descriptions of current water quality conditions, to define long-term trends in water quality and finally, to identify, describe, and explain, to the extent possible, the major natural and human factors affecting water quality conditions and trends. So three themes are running through this: description, trends, and cause and effect studies.

There are three large scale components of NAWQA: surface waters, ground waters, and biology. The surface water and ground water components each have chemistry and hydrology involved in them. The biology is basically tissue surveys, which most people here are probably comfortable with, and also the ecological surveys.

NAWQA is a large scale, long term program. We have 60 basins across the United States, including Alaska and Hawaii, which are being studied. The focus of the study will take at any one time 20 basins under intensive studies. It will take 10 years to complete an entire cycle involving all 60 study units. And each basin in there is a study unit.

We're dealing with a hierarchy of water quality issues within the NAWQA program. At the study unit, or the basin level, it's the level at which the data collection occurs. Data collected at that level will be used to look at issues at a variety of levels increasing in spatial content: local water quality issues, regional water quality issues, and national water quality issues. So in terms of QA, we need to be producing data which can be applied across those different levels. In addition, looking at harmonization across Federal agencies, it will be nice that we can provide information compatible with other programs that want to use this information at different levels.

The goal of the ecological surveys is to characterize the distribution and relative abundance of biological communities. We're looking at three community types. One is the benthic invertebrates, which I am most involved with; the second one is the algae; and the third is the fish communities. In these communities, looking at the distribution and relative abundance of these communities in terms of water quality parameters, there are three elements involved--distribution, which implies spatial characterization of communities; relative abundance, which implies enumeration; and the biological communities, which imply taxonomy.

The QA/QC needs for benthic invertebrates are that we need a consistency in field collections. If we're going to compile data across regions, across basins, we need to be dealing with consistent field collection methods. We need consistent lab

processing--in other words, sorting. A lot of what goes into processing these samples is physically removing organisms from a matrix of organic material and sediment. We need accuracy and consistency in identifications, not only at the time that the samples are identified, but also because the science of taxonomy is constantly changing. What is listed as species A this year may be species B next year. You have to keep on top of those changes if you're going to have data which are truly timeless. We also need accuracy and consistency in the enumeration, in the actual processing or counting of these invertebrates as they are collected.

The way that we are trying to get to these objectives within the NAWQA program is to develop consistent approaches for field and laboratory processing. There are at least five parameters listed for QA for our field collections. The first item is standard protocols. That's what I'm involved with at this point, with developing sampling protocols which can be used across the nation in teams of different sizes. We typically use the term protocol and don't use SOP's, though they pretty much serve the same function. I want to make a point about harmonization across Federal agencies and that is that we should be more concerned with the intent and content and less with the vocabulary of what we're using. It's probably very difficult to get another agency to change what they're calling an item. It's probably far easier to get them to include extra material in a protocol that would satisfy your requirements for an SOP.

We're also involved with formal training through our Denver Training Center, where we will train the project personnel who will be collecting the samples. Training involves more than just teaching these individuals how to go out and physically collect the sample. We need to train these individuals in the philosophy behind why the sample is being collected, and also in some of the theories about the operation of streams so that we can obtain from them feedback in terms of what's going on in the field and better design the program as we go along.

Documentation, of course, is a key issue. We take copious field notes in the survey. The problem with field notes is they're seldom seen again. We have standard data forms which we are using, which also tend to get away. This lack of accessibility for field notes is a problem.

Under our new computerization scheme, which is our National Water Information System II, we are working toward incorporating documentation into the database itself, even to the point where we're discussing the possibility of scanning field notes into the database so that if you were working with this data and you needed to call up that information, you could access it. In this current day and age, if it's not in the computer, it doesn't get used. And we need to work toward better computerization of our support

information for the data that actually goes in the database.

Another important QA issue here is our interstudy unit communication. We have regional biology teams which serve as advisory boards for each of the study units; we have a Fish and Wildlife person who will be part of that biology team. In addition to the biology teams advising the study units, there will be study unit liaison committees, which will be made up of people from Federal, state, and local governments, as well as university people who will help the projects develop their work plan.

Sample processing QA/QC for these benthic invertebrate samples becomes somewhat tied up with the whole issue of contracting. What we are looking for is to achieve some standardized contracts which involve putting into those contracts QA/QC checks that are provided by the contractor and can be used by all the study units.

We also are working toward implementing a contractor evaluation or certification process so that we can identify laboratories which can provide us the services that we need and also develop a formalized process by which we can weed out those organizations which bid on a project, but do not have the capability to provide us with the services we need.

We're also looking at regionalizing contract laboratories so that contract laboratories in a specific region with a specific expertise in a taxonomy will be receiving the samples. This will help us, I think, both in terms of logistically controlling the contracting process and oversight for the laboratory, but also ensure that these people are familiar with the fauna across the country, which varies considerably.

We're instituting a USGS QA/QC laboratory oversight, which will involve actually putting together a laboratory with people to monitor the contractor compliance of the samples so that we can monitor how well these contractors are doing in processing the samples and ensure that we're getting accurate and consistent information. We're working with the computerization of taxonomy, also QA/QC checks and sample tracking, so that as information is entered into the computer, it will tell us that that's a valid name, or flag the information to tell us that that name is not valid, the authority with that name is not valid, or that that species may not even occur in that region of the country. This is an important check for us. This, along with the QA/QC checks and sample tracking, will be in our National Water Information System too.

We're also trying to develop a standardized taxonomy database employing the NOAA National Oceanic Data Center Species Codes. There's an interesting story about harmonization here. This body of taxonomic information is maintained by NOAA. It contains information on everything from antelope down to protozoa. The

information related to marine taxonomy is very good and very well maintained. The information related to fresh water biology is not very well maintained. As you can imagine, NOAA does not have as much interest in the fresh side as the marine.

But the USGS and EPA are both interested in using this database and incorporating it into their databases to keep track of the taxonomy. So the USGS is funding a NOAA person half-time to update this list. EPA is also cooperating with that.

Another way to ensure quality is to deposit voucher specimens in outside collections. The voucher specimens are physical organisms which represent the name that you're attaching to them. And you put the speciman out there in an outside laboratory, a museum, or university somewhere, where other people who are specialists in this field can look at that specimen and decide whether you've named it right and inform you of any current changes that have occurred in the nomenclature. I think that this is a very important component in getting credibility for your identifications.

In addition, we will be curating study collections within the USGS, which will be available both to the survey personnel and to people outside of the survey who wish to look at these.

When you put this all together, the striking thing is the Biological QA Group of NAWQA. NAWQA is making a big effort to ensure the quality and timelessness of this biological information so that when we meet again, 20 or 30 years from now, that information will be just as good then as it is now. I think there's room for a lot of harmonization and a lot of interagency cooperation in developing these types of protocols.

DISCUSSION SUMMARIES

After hearing the preceding panel discussions, participants at the meeting met in small groups to discuss how they felt about implementing a national consensus standard for EPA and other Federal agencies with environmental programs. Each group then chose a spokesperson to report on the nature of the discussion.

Quality Assurance Management Staff member Gary Johnson summarized the break-out discussion sessions.

Question 1: What are the indicators for success in this effort? What benefits could your organization anticipate by implementing a new quality framework/standard?

Group 1 determined the Indicators of Success to be: 1. General acceptance (stated in writing, use of other agency's data, outside group accepts and uses data) and 2. Reduced litigation.

The benefits of harmonization were catagorized in four sections:
1. Cost/Schedule/Performance (improved allocation of resources, increased efficiency, reduced frustration level of multi-agency requirements)
2. Cost/Schedule (less repetition of work, less time and money spent, reduced time for inter-agency negotiations)
3. Cost/Performance (large data base)
4. Performance (common language, better quality products, consistent products, defined set of compliance requirements, better staff buy-in, clear definition of objectives across agencies, enhanced assessments).

Group 2 concluded that Indicators of Success were: 1. Interagency Acceptance/Recognition (at all levels, regulator accepts product, regulated community accepts guidelines and standards) and 2. Elimination of redo's (realization that Accrual of Benefits = Indication of Success).

Benefits of harmonization were seen as: 1. Data Comparability through application of standardized criteria (review, scoring, index values); 2. Reduced Redundancy/Paperwork (project and program); and 3. Translation to Management/Management Buy-in (data quality = data utility).

A data quality "hierarchy" was discussed in the following order: Data (measurements and numbers); Information; Interpretation; Knowledge; and Decision-making. Panelists also determined that NIST has a role to play in harmonization.

Question 2: What are the roadblocks to implementation of a new standard in your organization? What actions/changes will need to

take place within your organization in order to implement a new standard?

Group 3 regarded the roadblocks as the absence of a common language, displacement of old guidance, resistance to change, and "not invented here." Suggested actions included educating affected users, keeping open communications, and tailoring marketing strategies.

Group 4 discussed six roadblocks to implementing new standards: 1. Changing how people think--priority changes; 2. Ineffective communications; 3. Lack of Standard Data Comparability; 4. Fixed budget needs a good DQO, but lacks funds; 5. Management takes holistic stance; and 6. Resistance to change. Panelists agreed that several actions/changes needed to take place: the addition of training programs, "selling" the idea (P.R. "benefits" and payoffs, marketing, cost savings), more effective use of communications, general acceptance of change, and having states "buy in" on the idea.

Question 3: What factors within your organization will facilitate acceptance of a new standard? What information/interaction from other groups or agencies would help to pave the way?

Group 5 agreed that the degree of acceptance is proportional to the perceived benefits, that user implementation must be brought into the decision-making process, that the standard must be a practical tool for the user/implementer, and that senior management must be involved in a substantive manner.

Panelists talked about the need for "consensus" from agencies other than EPA, the need for a mechanism to establish true interagency harmonization, and the requisite for a consensus to set performance criteria for environmental monitoring.

Other observations included: 1. the document needs to be written in plain English, not technical jargon; 2. there must be sufficient specificity to minimize the range of interpretation; and 3. enforcement and litigation efforts must not be restricted.

NATIONAL PROGRAM OFFICES

From a summary by Marty Brossman
Quality Assurance Officer, Office of Water

The National Program Office Sessions included: the joint session with Regional Offices on the EMMC, a session on Quality Assurance Program Plans--guidance and implementation, and a session on Qualifying Data for Specific Uses. A tentative panel was proposed on TQM--concept and implementation, but time constraints precluded this session. The issues to be discussed in this session are of importance to the continuing success of TQM and QA in the Agency; accordingly, they are briefly summarized in discussion of the sessions.

Quality Assurance Program Plans (QAPP)

The QAPP is recognized as an important management level document at each Office, Regional and Laboratory level of EPA. It describes the QA policy, roles, responsibilities, and plans for implementation of the Agency and specific Office, Regional, and Laboratory programs. The QAPP, as signed off by a top management official, the QA manager, and with concurrence by the Quality Assurance Management Staff (QAMS) of the Agency, is equivalent to a EPA contract. Meeting that contract effectively is important to the success of a QA program.

This session was designed to address issues of QAPP development and implementation to improve effectiveness. The difficulties in developing an effective QA Program Plan were addressed in detail. They included: the need to gain command of widely diverse studies and programs; management's lack of acceptance of its responsibility for the quality and defensibility of its data; the isolation of some program offices from the data acquisition tasks imposed on Regions and States; and a lack of understanding of the need to define the customer and data use.

Two effective tools to reinforce the QA program were discussed. The utilization of Management System Reviews (MSRs) has proven a useful tool in evaluating a QAPP in place. Short falls become apparent when performance is evaluated against specific commitments and responsibilities. In addition, the QA Annual Report is also a useful tool. This report, prepared by the QA Officer as a part of his QA Program Plan, provides a vehicle to discuss accomplishments and short falls with management, and gain agreement for the next year's plan.

While action items were not developed as a result of this session, opportunities were described to provide recommendations to improve the QA Plan development and implementation process in the new guidance being developed by QAMS.

Qualifying Data for Specific Uses

This session was designated as an "umbrella" session to cover a wide range of issues related to data qualification and use. Issues raised by **Larry Keith** of Radian Corporation and **Wendy Blake-Coleman**, Immediate Staff, Office of Water, brought forth extensive discussion.

Larry pointed out that with the commonly used Limit of Detection (LOD) or Method Detection Limit (MDL) set at Standard Deviation (SD), there is a 50% probability of a false negative detection, but less than 1% probability of a false positive detection. He suggested that whenever false negatives were important to the Agency, the LOD or MDL should be set at 6 SD, where the probability of false negative and false positive detection is equally low (less than 1%). Because of the high reliability of detection assignments at 6 SD, it was suggested that this be called the Reliable Detection Level.

Mr. Keith also suggested that a distinct difference be made between laboratories reporting data and users/requesters taking laboratory data and presenting it in final form. He recommended that laboratories report all data unless requested not to do so by the user/requester of the data. He further pointed out the potential liability of the sometimes current practice of reporting "Not Detected" (ND) rather than "less than MDL or LOD" when an analyte is detected, but less than the MDL or LOD. Mr. Keith therefore suggested that "ND" should only be used when there is no measurable value and not when the value is between 0 and 3 SD. Technical issues of this type are extremely important to the Agency since many toxic materials are harmful and below our ability to detect them. Accordingly, agreement on detectability definitions and related issues directly impacts the Agency's ability to regulate and defend its controls.

Wendy Blake-Coleman addressed a range of data issues-some impacted by the Office of Water's recent reorganization. As a preface, she described the reorganization and the new locations of the Office's major environmental data bases. She also described the new role of the Policy and Resources Staff in data base and information resources management. Issues being addressed include the STORET Modernization program, integration of GIS into the data systems, and development of QA data and usability guidance. The concept of minimum data set was then discussed with particular reference to the ground water data base. The ensuing discussion centered on whether the data elements were primarily descriptive and not quantitative. The range of issues addressed were so broad that individuals decided to follow up specific areas of their interest with other discussions.

Total Quality Management

Time demands precluded follow-through on this session. Some of the issues planned for discussion in follow-up sessions, however, are summarized here.

The current Agency and National focus on Total Quality Management provides great potential for progress in the QA and TQM programs--if managers understand the direct relationship. TQM has developed from within the QA/QC field represented by such professional organizations as The American Society for Quality Control (ASQC). Principles formerly applied to customer requirements in hardware and data have now been applied to other goods and services. Thus, it is apparent to many that managers cannot "buy-in" to a TQM program without having automatically endorsed the QA program. We should explore opportunities to market the QA program to Agency managers as a good example of TQM in practice.

REGIONAL OFFICES

From a summary by Dale Bates
Chief, Environmental Services Support Branch

This afternoon session focused on drinking water regulations, field quality assurance and quality control, the Environmental Monitoring & Assessment Program, statistical support needs, and Superfund's Enforcement Survey. Highlights of the discussions are presented below:

Drinking Water Regulations

Al Havinga and **Herb Brass** briefed the group on the following topics:

- Draft corrections to the January 1, 1991 notice in the Federal Register that will be published in July.
- Regional concerns on regulatory issues.
- Participants in the workgroups on lab issues (with representation from Regional Offices, Environmental Monitoring & Support Laboratory - Cincinnati, and Office of Ground Water & Drinking Water (OGWDW).
- OGWDW will provide the Office of Regional Operations (ORO) with a listing of current workgroups.
- Comments on the new Chapter 5, Laboratory Certification Manual should be forwarded to Nancy Wentworth by May 1.

Nate Malof explained the Privatization & Cooperative Research & Development Agreements (CRADAs).

Field QA/QC

Llew Williams identified and discussed issues of concern and training on Field QA/QC.

Environmental Monitoring & Assessment Program

Marcus Kantz identified the need for coordination of activities with Regions.

Bob Graves volunteered to encourage EMAP personnel to enhance communications.

Statistical Support Needs

Kent Kitchingham discussed the need for expertise and training in Regions, and the need to develop strategies with positive impacts.

Superfund Enforcement Survey

Region 2 revealed significant resources utilization in support of the Superfund Enforcement Program.

OFFICE OF RESEARCH AND DEVELOPMENT

From a summary by Allan Batterman
Quality Assurance Manager
Environmental Research Laboratory

Quality Assurance in Modeling Projects

This session focused on methods used by QAMS and modelers to address QA in modeling projects. A draft document was presented for review, and panelists edited the document for general ORD input and approval as a guidance document for modeling QA/QC. The key question for review was: How is modeling QA/QC addressed in Agency model development and use? Five presentations were given, with discussions of each following.

Definitions of Modeling (overhead transparency) provided two acceptable definitions of modeling: 1. Experimental data gathering that provides information to test hypotheses--computer programs implement the models which are environmental compartments. Processes and water relationships; 2. A mathematical equation or set of equations that describe relationships between variables of interest. QA of Models (overhead transparency) suggested that modelers consider up front and in writing, points that are necessary to assure validity of the model. Panelists determined that the validation of a model is easier when a written plan with guidelines and expectations is developed beforehand.

Purpose of Modeling Document (overhead transparency) addressed topics such as providing documentation of procedures, applicability, and reliability. Points of discussion were: making sure creativity is not stifled when implementing QA into model development; changing the QA approach to appropriately reflect a changed model; asking the questions, Is this to satisfy the QA officer? Is QA suitable for the scope of the project?; the importance of stating the intended purpose/objective of the study up front; realizing that endpoints are descriptive of a process and interpolation may be necessary; understanding that suitable modeling for risk assessment may require specific QA; and the importance of research planning.

Modeling Project (overhead transparency) discussed the process of developing a concept, validating and establishing an existing model, applying the model and verifying it, and using the model as part of data analysis or interpretation. Panelists raised several issues: documenting the accountability--determining if the modeling project should proceed; the necessity of avoiding bad models by deciding the purpose of the modeling study and evaluating and examining all possible variables of the model; and that QA should apply to the computer issues of the model, including the computer codes. The U.S. Geological Survey determined that

modeling should be different than other investigative processes in the QA arena because creativity is required and examples of good case histories are needed.

The last presentation, Computer Code, (overhead transparency) focused on evaluating models, suggesting corrective action if necessary, and testing computer models. Panelists determined that the computer code, how the computer manipulates the data into subsets, is subject to human error and must not be assumed to function properly at all times. Error checks must be made, as well as a range of acceptance set up in which samples should fall within. In addition, all errors must be documented through the use of "acceptance reports." Acceptance reports determine what data fall out of range, and adjust calibration if values are higher or lower.

Members of the panel also agreed that models taken from scientific documents and publications may not have been through QA; therefore, it was important to rely on the professional judgment of project personnel to determine that procedures were addressed properly. If the model did not work, new variables would have to be studied, reassessments figured, and corrective actions taken.

QA PLAN
(Documentation)

Types of Information Considered

A. Project Description/Resources
   - scope and goals
   - project personnel

B. Model Description
   - model equations
   - purpose/relevance
   - limits/parameters

C. Data Quality
   - calibration/parameterization
   - types/quality data needed
   - evaluation of data
   - source/acceptance/format/data uncertainty

D. Model Uncertainty
   - sources of uncertainty
   - assumptions
   - sensitivity analysis
   - comparisons

E. Computer Program
   - code verification

- records of code versions
- programming documentation
- user documentation

Privatization of Quality Assurance Reference Materials Using the Federal Technology Transfer Act (FTTA) Cooperative Research and Development Agreements (CRADAs)

The focus of this session was on EPA-certified QA reference materials: what is available, how to make them accessible on a continual basis, and where to obtain them. The discussion also included EPA's oversight role, if materials would be EPA-traceable, and questions about accreditation.

The goals of the session were to: 1. Minimize disruptions in existing operations; 2. Reduce ORD expenditures but assure dependable study, timely development of new products, high quality, and a reliable distribution system; 3. Encourage competition through accreditation; and 4. Maintain a long-term program to meet Agency needs.

EPA's oversight roles were determined to be: 1. If wholesaler does not produce compound, EPA will furnish to the wholesaler, who will distribute; 2. Two analyses in-house; 3. Analyzing and verifying the lot before a sale; 4. All "EPA certified samples" will be stability tested.

$12 million, 7 Years - What Have We Learned? (Applying DQOs to a National Survey)

The purpose of the session was to examine a case study for potential areas of improvement in applying the DQO process; the outcome was to get recommendations for successfully applying the DQO process to large surveys.

Lora Johnson, QA Manager, National Pesticides Survey, discussed the survey results and two approaches for evaluating the success of the survey in achieving DQOs. Dean Neptune then led a discussion among participants on the difficulties of implementing the DQO process for large surveys.

QUALITY ASSURANCE MANAGER OF THE YEAR AWARD

Introduction by Nancy Wentworth

We have a significant honor to bestow, the Quality Assurance Manager of the Year Award. For those of you who are new to the EPA community, we have, for the last three years, presented an award to an individual from EPA's QA community who has been nominated by one of his or her peers, supervisors, friends, or someone who has seen the value of the work. This year we received nine nominations. We had individual nominations and group nominations, or a number of people nominated as a group, I should say. We invited three senior managers from the Agency to serve as the award review panel. This is what we consider to be an Agency award and therefore we sought advice on the selection from senior managers.

The reviewers were Richard Guimond, the Office Director for the Office of Radiation Programs and in transition to the Deputy Assistant Administrator in the Office of Solid Waste and Emergency Response; Tim Oppelt, the laboratory director at the Risk Reduction Engineering Lab in Cincinnati; and Bill Rice, the Deputy Regional Administrator in Region 7 in Kansas City. They were, as a group, very impressed with the nominations that we received from across the agency.

I'd like to take a moment and credit the people who were nominated and give you a little background on who nominated them and what their accomplishments were that warranted the nomination. Then I will make the presentation of the award.

First, Jeanne Hankins, who was the quality assurance manager in the Office of Solid Waste and is now on a one-year assignment on the EMMC Laboratory Accreditation Panel, was nominated by the Office Director of the Office of Solid Waste, Sylvia Lowrance, for her work in Chapter One of SW 846, which is the methods and field manual for the Solid Waste Program. She was also credited with her work in the formation of the RCRA Advisory Committee for Environmental Data, the RACED as it's known, which has been a real affirmative step toward improving the relationships with the regions and improving communication within regions on issues relating to the implementation of the solid waste law.

Second, Rick Johnson from the Office of Information Resource Management, was nominated by Jeff Worthington from TechLaw, for his work on the Good Automated Lab Practices program.

Third, Dr. Henry Kahn was nominated by Ramona Trovato, Office of Water Regulations and Standards, for his work in F1 Guidelines in the application of statistical methods to the development of industrial water pollution control regulations and his work in the statistical design of the national sewage sludge survey and the

dioxin and pulp and paper mill effluence surveys.

Fourth, Brenda Grizinski and Don Sandifor were nominated by Bill Fairless, the Environmental Services Division Director in Region 7, for their combined effort in the development and implementation of a statistically-based sampling procedure for use in dioxin cleanup sites. This is a project which many of you have heard about, which was an application of the DQO process in Region 7 at the request of Region 7 and which has resulted in a very significant savings of money in a waste cleanups on a dioxin contaminated site in the region.

Fifth, a group of individuals from the Office of Underground Storage Tanks in Region 6 were nominated by Bob Layton, the Regional Administrator. These people were William Ray Lindale, Mike Scoggins, John Sernaro, Herb Sharo, Jim Duck, and Audrey Lincoln. They were nominated for their use of TQM principles in the development of the regional program and of the state programs for underground storage tanks. They set up quality action teams; they worked with each of the states to develop an underground storage tank program that was best suited for their legislation, their politics, and their environmental circumstances.

Also from Region 6, Mary Ann LeBarr and Judith Black were nominated by Bob Layton, the Regional Administrator, for their work in implementation of field and lab quality auditing programs in the Superfund program in the region.

Seventh, Bob Graves, who was nominated by John Winter, the quality assurance division director at the Environmental Monitoring Systems Lab in Cincinnati, who nominated Bob for his work in the development of the QA program for the Ecological Monitoring and Assessment Program. This is the largest ecological monitoring program that the Agency has ever undertaken and is an extensive program requiring coordination of quality programming among and between about five to seven of EPA's ORD laboratories and a number of other agencies including NOAA, Fish and Wildlife, and USGS, so it's been a significant effort on his part to bring all of the quality community together for the common goal of the EMAP program.

Next, Marty Brossman of the Office of Water Regulations and Standards, who was nominated by two of his QA compatriots, Barry Towns, the QA manager in Region 10 and Jerry McKenna, who is now the lab chief in Region 2, both of whom are previous winners of this award. Marty was nominated for his work on customizing QA documentation for Office of Water Regulations and Standards projects, for his work as a regional QA liaison, taking special time to work with the regions on QA issues, for his work in the development of data quality objectives in their regions in the water programs, for looking into the issue of quality in computerized data bases and his work in the design and implementation of the National Dioxin Survey and National

Bioaccumulation Survey.

And the last nominee was Elizabeth Leovey who is in the Office of Pesticide Programs. Elizabeth was nominated by Susan Wayland, the Deputy Office Director in the Office of Pesticide Programs; Michael Cook, the Office Director in the Office of Drinking Water; and Gene Briskin, the director of the National Pesticide Survey. She was nominated for her work in the National Pesticide Survey, including encouraging and setting up a pilot survey to see if the planned activities would work, the invitation for management system review to see if the processes they had in place for the survey would yield the data they needed for their decisions, and for working to assure that the follow-up field and analytic QA programs would, indeed, meet the needs that they had defined at the beginning of the survey. I think we owe a round of applause to all of these people.

The winner of this award receives a check and a plaque. And there is a historical plaque with all of the award winners and the individual that wins it will also get his name engraved on the plaque outside of my office in Washington. The winner: 1990 Quality Assurance Manager of the Year, Martin W. Brossman, in recognition of outstanding accomplishment in the field of quality assurance planning and management.

ACCEPTANCE SPEECH BY MARTY BROSSMAN
QA Manager of the Year

I'm just flabbergasted and thrilled. And I think you know this is the real highlight of my work for EPA. So I might as well stop now. But I do feel very strongly, and I know all of you I've worked with know that I mean this, that this award is an award I share with QAMS, who've been my guiding light through all these difficult years and with, primarily, the regional QA Officers who've made it all possible for me to see things happen. That combination is really the reason I was able to do anything. And I'm inspired by the type of people that we've been able to work with over the years: this has been a tough game, to convince management that this was worthwhile and necessary. The spirit and the competence of the people that I've been able to work with, QAMS and particularly all my regional pals who have helped me carry out the kind of things that we wanted to see happen in the real world, are really the recipients of this and I thank you all. Thank you.