CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

TRIP REPORT

SUBJECT: American Society for Quality Control Energy Division Second International Waste Management Conference (Account No. 20-3702-042)

DATE AND PLACE: March 17-20, 1991, Las Vegas, Nevada

AUTHOR: Bruce Mabrito

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PERSONS PRESENT:

A partial list of attendees is attached. Representatives from the NRC included Robert Bernero, Ken Hooks, Teek Verma, Larry Pittiglio, and John Gilray. The U.S. EPA and DOE were represented in rather large numbers, as were state governments. The international "flavor" was emphasized, however only a small contingent of non-U.S. representatives were in attendance. In addition to the formal listing (which, interesting enough, failed to pick up my name on both the original attendance list and the addendum, making one suspect of the quality system they utilized), I am photocopying business cards of some of the persons with whom I spoke.

BACKGROUND AND PURPOSE OF TRIP:

This Second International Waste Management Conference, attended by about 300 persons, was roughly the same size as the first conference held in March, 1989. Persons working in the waste management fields attended this conference, with many being connected through their project management responsibilities or quality assurance ties. The purpose of this trip was to represent the Center at the Conference, meet with our NRC counterparts in attendance, and learn more of the methods and techniques utilized by others in the HLW business to control their processes, ensure appropriate quality levels, and assess product quality.

SUMMARY OF PERTINENT POINTS:

The presentations given were well suited to the audience and several of them had applicability to the Center and one dealt with Total Quality Management which is of interest to SwRI Management and the Quality Assurance Committee. Abstracts for those presentations of potential interest to Center staff are attached to this Trip Report. Copies of certain presentation viewgraphs are being circulated to Center staff with a specific interest in the subject. The Center Library has a copy of all the conference abstracts in an ASQC notebook.

SUMMARY OF ACTIVITIES:

Numerous informal discussions were held with conference attendees, the majority of whom worked for the EPA or DOE, or were contractors of those agencies of the government.

IMPRESSIONS/CONCLUSIONS:

It was a valuable opportunity to meet individuals involved in the waste management industry and hear about their approach to achieve "Quality from the Project Manager's Perspective," (the conference theme).

PROBLEMS ENCOUNTERED:

None

PENDING ACTIONS:

None.

RECOMMENDATIONS:

None.

SIGNATURES:

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REFERENCES:

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SESSION A

TOTAL QUALITY MANAGEMENT (TQM) IN WASTE MANAGEMENT: ITS TIME HAS COME

Carol Greebler
Adtech Energy & TQM Plus

TQM is a management philosophy and organization-wide approach that is being embraced by organizations worldwide to continuously improve and innovate all processes, products and services. Significant increases in quality and productivity and significant reductions in overall costs, rework, time delays, and interpersonal conflict have resulted. TQM has been successfully implemented in both the public and private sectors, in manufacturing and service industries and specifically in energy and R&D.

TQM is not a program nor a fad. It is a new way of doing business, of thinking, of managing, and of relating to people. It is a scientific approach to management that applies statistical methods and tools to assess and improve all of the processes within an organization, assuring that the needs of the internal and external customers are met, now and in the future. TQM involves the establishment of an organizational culture of teamwork, trust, continual learning, and total participation of all members.

The application of quality assurance (QA) requirements to waste management projects hold a special challenge because the objective to be achieved relates primarily to the quality of research and data, an ongoing process of discovery. Conventional QA programs may be inadequate as they are usually geared to the quality of hardware, a defined and measurable product.

Many of the scientists working in waste management are negative about QA, QA regulations, and the abundant paperwork required for contract or procedural changes, planning, and documentation. A psychological barrier has been constructed between the scientists and the QA organization.

TQM can help solve these problems by (a) tearing down barriers and resistance to conventional approaches to QA, (b) creating an environment where people are motivated to achieve quality, and (c) achieve a balance between scientific creativity and the confines of QA regulation.

While there are some inherent differences between a traditional QA approach and TQM, it is the partnering of the two, rather than a replacement for one for the other, that is the goal.

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SESSION A

TOTAL QUALITY MANAGEMENT IN THE FEDERAL SECTOR

Jack Strickland
Federal Quality Institute
Office of Personnel Management

Declining budgets and increasing demands are forcing management in the public as well as the private sector to look for ways to achieve improved products and services with fewer resources. A Federal commitment to Total Quality Management is key to making government service synonymous with excellence and customer satisfaction.

Total Quality Management is a strategic, integrated management system which excellent organizations are adopting to improve the quality of their products and services. It is a way of managing the organization which focuses on achieving customer satisfaction by involving all employees in improving the work processes of the organization. Organizations use measurable data to determine that customer requirements are being met and that improvements are continuous. Organizations work to change the culture so that Total Quality Management is the system of management.

The Federal Quality Institute was established in 1988 by the Office of Management and Budget (OMB), the Office of Personnel Management (OPM) and the President's Council on Management Improvement (PCMI) to be the change agent for fostering the implementation of Total Quality Management in Federal agencies. The Federal Quality Institute provides services to Federal agencies in five major areas: coordination; training; start-up assistance; information, referrals; and model projects.

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SESSION C

RESEARCH AND DEVELOPMENT IN A REGULATORY ENVIRONMENT - THE ROLE OF QUALITY ASSURANCE

R. J. Herbst
Los Alamos National Laboratory
Yucca Mountain Project

The selection of a site for the construction of a repository for high-level radioactive waste disposal is proceeding in a highly regulated environment. EPA and NRC regulations and DOE internal orders all require the application of a comprehensive quality assurance (QA) program to work in support of this important national initiative.

Repository siting and construction are without precedent. What was originally thought of as a conventional civil work has been shown to include an unconventional, research-and-development-(R&D) intensive, site characterization phase. The R&D products of this phase must survive the scrutiny of groups, including the general public, and agencies with regulatory, statutory, or de facto oversight responsibilities. QA may impute to these products attributes that are essential to survive this scrutiny. However, scientists, engineers, and technologists have experienced difficulty adapting NQA-1, the national consensus standard applicable to the construction of nuclear facilities and preferred by the NRC and DOE, to the site-characterization-phase activities and products. Is NQA-1 appropriate to this purpose? The development of a QA program that is approved by the DOE, accepted by the NRC, and applied to Los Alamos National Laboratory's contributions to characterization of the candidate sites for high-level radioactive waste disposal will be reviewed in an attempt to answer this question.

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SESSION C

IMPLEMENTATION OF QUALITY ASSURANCE TO EARTH SCIENCE INVESTIGATIONS WITHIN A NUCLEAR REGULATORY ENVIRONMENT

Larry R. Hayes
US Geological Survey
Yucca Mountain Project

The development and implementation of a U.S. Geological Survey "nuclear regulatory type" Quality Assurance Program (QAP) is a mandatory requirement for earth science investigations conducted as part of the Department of Energy, Yucca Mountain Project study. The widely accepted understanding of what constitutes a qualified nuclear QAP evolved from experiences gained during the design, construction and operation of nuclear power plants over the last 30-40 years. The end result of this evolution is a set of regulations and applied interpretations that appears to have served the civilian power plant industry very well.

Can these same regulations be applied to the earth-science investigations of a potential site for an underground waste repository program with acceptable results? Should management simply accept the adage that "old rules applies to a new game" is the best way of achieving the intended goal? From the earth-science investigation point of view, the answer to both questions often is "No." We must modify the old regulations or develop a new set of regulations that take into consideration the unique aspects of the requirements of earth science investigations and widely accepted scientific practices.

Technical management has primary responsibility for implementation of a qualified QAP for scientific investigations. Complying with QAP requirements that may or may not be viewed as beneficial to achieving the best possible technical product is the dilemma of the manager and the scientist. A QAP can be perceived by them to be: (1) an effective tool in accomplishing the job; (2) a hindrance that detracts from the goal but should be implemented because, "There is no way out;" or (3) something to be fought, resisted, and challenged every step of the way.

Regardless of one's view of the value of a QAP (specifically, in site characterization), the implementation of a qualified QAP is essential to the acceptance of the results of scientific investigations by the U.S. Nuclear Regulatory Commission and others. Even though excellent technical results of scientific investigations could be produced without a formal QAP, the need to publicly substantiate (e.g., adequately document in the legal environment) scientific conclusions requires a qualified QAP.

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SESSION C

QUALITY ASSURANCE IMPLEMENTATION EXPERIENCE IN THE YUCCA MOUNTAIN PROJECT TECHNICAL ACTIVITIES AT LAWRENCE LIVERMORE NATIONAL LABORATORY

Leslie J. Jardine
Lawrence Livermore National Laboratory
Yucca Mountain Project

An NQA-1 based quality assurance program has been established and implemented in the Lawrence Livermore National Laboratory Yucca Mountain Project (LLNL-YMP) during the past two years. Significant progress from the establishment of this program to its acceptable implementation in a research and development environment has occurred. In October 1988, the Department of Energy audited the LLNL-YMP and concluded, based upon many findings and observations, that the Project's quality assurance program was ineffective. LLNL management clarified and communicated it commitment to both quality and acceptable quality assurance program, and the LLNL-YMP was again audited in June 1989 for compliance with the quality assurance requirements. The Department of Energy auditors reported no findings and two observations. Subsequent audits, surveillances, and independent management assessments have verified that the LLNL-YMP continues to implement an effective quality assurance program. Key elements contributing to the successful change as well as current implementation difficulties are discussed with respect to the LLNL academic atmosphere, leader involvement, and staff experience.

The University of California operates the Lawrence Livermore National Laboratory (LLNL) for the Department of Energy and currently supports the Civilian Radioactive Waste Management Program through the LLNL Yucca Mountain Project.

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SESSION F

QUALITY PROBLEMS AND SOLUTIONS FOR THE HANFORD HIGH-LEVEL WASTE TANK FARM

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US Department of Energy
Richland Operations Office

Around the world, we nuclear types prioritized our early quality efforts toward nuclear reactors and their fuel supply. Next, attention was given to fuel processing, and last to waste management. For whatever the reasons, the Hanford high-level waste (HLW) tanks were the last of the last to get attention. Imposing NQA-1 requirements in the summer of 1990 was impossible, because not even rudimentary management systems were in place. This paper describes "getting into quality - 1990."

The practices and equipment in the Hanford Tank Farm area were 1940s, 1950s and 1960s, with some being 1970s. The HLW liquids from three different processing plants became highly mixed, and specific composition of materials in a particular tank was and is most unknown. Instrument calibration was deficient, and in most cases, original equipment is still in use. The program was underfunded and equipment maintenance was spotty, and preventive maintenance was basically non-existent. Most importantly, several tanks exhibited characteristics which were clearly safety problems, but which were not recognized as such by management. Hanford Tank Farm notoriety became widespread, involving the Department of Energy at Washington, D.C., and the U.S. Congress. The states, local governments, Indian Nations, local and national media, the public, citizen's groups because concerned and involved, and several panels and task force groups began to actively study the tank safety problem.

A goal was established to obtain a quality operation in the Tank Farm as quickly as possible. Simple steps were taken to obtain the basics of quality in the operation.

The activity was "projectized" under one manager who reports directly to the top corporate structure (DOE-Richland and DOE-HQ, and the contractor). Activities are focused toward the field - DOE people are stationed in the field. Additional money was provided to the contractor, and a requirement for a program "baseline" was formally required. This means the scope-of-work with a resource-loaded schedule and control points are established. Plan-of-the-week meetings were instituted, using the schedule as the management tool for

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SESSION F

QA LEARNING CURVE FROM THE NRC'S PERSPECTIVE

Ken Hooks
US Nuclear Regulatory Commission

The U.S. Nuclear Regulatory Commission (NRC) is responsible under the Nuclear Waste Policy Act of 1982, as amended, to review and evaluate the U.S. Department of Energy (DOE) application for a license to build a High-Level Waste (HLW) geologic repository when and if such an application is submitted. In the pre-application (site suitability) phase, the NRC reviews DOE's activities and advises DOE of deficiencies identified through this review (i.e., pre-licensing consultation). One of the areas in which this pre-application review has been focused is Quality Assurance (QA).

The DOE is required by Code of Federal Regulations (CFR), Title 10, Part 60, Subpart G, to implement a 10 CFR 50 Appendix B - type QA program, as applicable, for all systems, structures, and components important to safety and barriers important to waste isolation. The requirements of Appendix B were written and have been implemented on numerous commercial nuclear power plants, including site selection and evaluation activities; however, they have not previously been imposed upon a process essentially restricted to earth science activities.

Although the NRC staff believes that the requirements of Appendix B are sufficiently broad and flexible to be applicable to earth science activities, it is obvious at this time that interpretation and implementation of these requirements has often been frustrating to participants in DOE's HLW repository program. The NRC has attempted to provide guidance concerning Appendix B requirements in the form of NUREGs and discussions with DOE and participants, and through encouraging and participating in DOE QA workshops to identify and resolve problems in QA program implementation. To date, these QA workshops have not identified any problems with Appendix B requirements, but rather problems in interpretation and implementation by DOE and the participants.

In retrospect, it appears clear that much more effort should have been placed on familiarization, indoctrination and training in both the reasons for QA and QA concepts and techniques, and on involvement of scientific and technical personnel. People with a background in the commercial nuclear power plant business grew with QA; in general, people in the

situation analysis. Experienced people were imported by the contractors, and tank farm people were provided training and performance expectations. Management demonstrated key interest by frequently visiting facilities and by talking to workers. More frequent communications with the regulators and the media were established. Weekly status conference calls kept DOE-HQ, DOE-Richland, and contractors informed and interactive.

One general definition of quality is "...doing business in a business-like manner." Following this basic quality step, NQA-1 was formally introduced in the Tank Farm Program. This process will be described in the paper.

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SESSION F

STATUS OF THE HIGH-LEVEL WASTE PROJECT AND PUBLIC ACCEPTANCE

Carl P. Gertz
US Department of Energy

Throughout 1990, the U.S. Department of Energy Yucca Mountain Site Characterization Project made significant advances. The advances include initiation of new field programs and the continuation of ongoing site studies. While most components of the surface-based investigation program are on hold due to our inability to get appropriate permits from the state of Nevada, we drew closer to initiating those studies in two ways: first, the Project took numerous steps to assure plans, procedures and personnel are fully prepared to go to work when the time comes; and secondly, the 9th U.S. Circuit Court of Appeals ruled in the DOE's favor on the permit issue. While Nevada is appealing to the U.S. Supreme Court, the 9th Circuit ruling got the legal process moving toward an eventual resolution.

This paper will highlight Yucca Mountain Site Characterization project activities that have occurred in the preceding 12 months. After a brief "big picture" overview of the Project, the discussion will focus on accomplishments such as completion of the prototype drilling program, collection of data from existing holes and trenches, quality assurance program implementation and the Project's interactions with the public. Since the progress of our surfaced-based investigation program hinges on the outcome of litigation, the DOE's legal battle with the state of Nevada will be covered. While Yucca Mountain Project technical studies are moving forward in a restricted manner, our efforts to provide an open line of communication with the public are going full-tilt. A few highlights from our public outreach activities are included in the paper.

HLW repository program were unfamiliar with formal QA programs, and failed to understand either the need for an Appendix B-type program or how to implement it.

The NRC, the DOE, and the HLW repository program participants are all still climbing the QA learning curve. Although it is not possible to return to the beginning and establish a different, perhaps better, curve, the following concepts can still be used to improve the rate at which we climb the curve:

- Explain QA as a tool to improve the work process. Concentrate on explaining how QA can help, not hinder, scientific work, and assiduously avoid adversarial situations.

- Explain the reasons behind QA requirements until they are understood; do not impose the requirements from above.

- Try to speak about QA in language which can be understood by earth scientists; many QA problems appear to be rooted in semantics.

- Develop work procedures around existing work practices, with the involvement of the responsible workers. Add QA requirements only as necessary.

- Insist on the line organization taking responsibility for doing and documenting work in accordance with their procedures. Work with the line organization to make the procedures reasonable.

- Start audits and surveillances early, and use them as learning experiences. Emphasize the necessity for effective corrective actions.

- Be open to feedback from the earth scientists, but insist that their complaints be specific and contain suggestions for improvement.

- Do not allow QA to become a management tool to impose non-QA requirements on line organization. Separate QA and administrative controls.

- Always remember that QA is the tail, not the dog (although a tail may be required to win the prize).

I believe that a QA program which considers these, or similar concepts, will result in a QA learning curve which is easier for everyone associated with the HLW repository program to climb.

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SESSION J

REVITALIZING QUALITY ASSURANCE

Frank Hawkins
US Department of Energy

Historically, the Department of Energy has set nuclear safety requirements through the Department's Directive System and through contractual arrangements with the companies that operate its facilities. But recently, DOE's nuclear safety requirements have been criticized because they (1) do not reflect today's body of knowledge regarding nuclear safety, (2) lack specificity, (3) are not enforceable under the provisions of the Price-Anderson Amendments Act, and (4) are not perceived to result in a level of nuclear safety comparable to that of the commercial nuclear industry.

In answer to these criticisms, a new conceptual framework for nuclear safety has been proposed. The framework will provide policy, technical, and administrative direction to the DOE staff and its contractors. It will also provide the foundation and impetus for ever improving performance and establish an environment in which a viable DOE nuclear safety culture can grow. One component of the framework is the development and implementation of formal rules to be published in the Code of Federal regulations. In phase one of the Department's rulemaking activities, there are 11 proposed rules, one of which addresses Quality Assurance.

The primary goal of the QA rule is to establish Department-wide quality assurance requirements which apply to the broad spectrum of nuclear activities which contractors perform on behalf of DOE. The rule's 10 generic quality assurance criteria provide the technical and philosophical foundation upon which contractors' quality assurance programs are to be based. The rule contains three major precepts: (1) management provides planning, organization, direction, control, and support; (2) the line organization is responsible for achieving quality; and (3) overall performance is independently reviewed and evaluated using a rigorous verification process.

This presentation will summarize the Department's rulemaking activities and provide specific details regarding the Quality Assurance Rule.

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SESSION J

5000.3A OCCURRENCE REPORTING FROM A CONTRACTOR'S POINT OF VIEW

John Croes
Science Applications International Corporation

On May 30, 1990, the Department of Energy issued DOE Order 5000.3A, "Occurrence Reporting and Processing of Operations Information," which describes much stricter reporting controls on operations at DOE facilities than have existed in the past. The order also requires root cause analysis, trending, tracking and escalation criteria for all occurrences. This presentation will cover the subject from the time the order was being sent out for draft comments through implementation by several contractors. This presentation will briefly discuss the reporting requirements but will focus most heavily on the ways management can use the information to get better control of the projects for which they are responsible. A successful approach to training in order to communicate information on this order more effectively to the workforce will also be discussed.

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SESSION M

PROJECT DOCUMENT CONTROL

Alice McNelly, Science and Technology, Inc. (SciTek)
J. Samuel Suffern, Martin Marietta Energy Systems (HAZWRAP)
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About a year ago, a program manager related a recurring nightmare: His project managers were all suddenly reassigned to Alaska, and it was up to him to reconstruct each of the projects within his program. He knew the major deliverables, but how did they get to that point? He knew that the information was there--within the walls of their offices--but could be accomplish his mission before he reached the age of 90? This program manager called his people together and issued the following challenge: Develop a simple, usable method for filing, tracking, and retrieving all project-related media. Every format must be covered, from disk copies to applicable hand-written notes and make the system a tool to aid in organizing projects from the very beginning.

Most companies have excellent procedures for controlling Quality Assurance (QA) records as required by NQA-1. Established systems are designed to provide tracking for "control documents," and most systems have excellent methods of handling incoming correspondence. The bane of every records management professional, however, is those documents that are hand-delivered to project managers, those memos containing decision points, those records of telephone conversations--any record that can easily slip through the cracks if order doesn't reign in the files of each and every project manager on each and every task.

A simple, functional, document control system has been created that will provide order for project files, then naturally flow into the more traditional company system. The combination of the two provides capture of all QA records from the very beginning of a project, aids the project manager in determining just what records are required for a project, and provides the records management personnel with complete project files. A HAZWRAP project management program at Martin Marietta Energy Systems, the Pollution Prevention Program, initiated a team effort with major input from the Program's line personnel, HAZWRAP management, and subcontractor (SciTek) personnel. The resulting system has been implemented in HAZWRAP's Pollution Prevention Program and is currently under consideration for implementation HAZWRAP-wide and for other key divisions at Martin Marietta Energy Systems. This paper will present the basic elements of the system and the methods used for implementation.

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SESSION M

INNOVATIVE COMPUTER-BASED TRAINING FOR HAZARDOUS WASTE PROJECT MANAGERS

Kevin J. Hull
U.S. Environmental Protection Agency

Mary Ann Pierce
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One of the greatest challenges facing waste program managers is to assure that all personnel responsible for quality implementation have appropriate knowledge, skills, and abilities. In many cases, traditional training approaches have not proved adequate. In developing training for the Superfund and related programs at EPA, managers have encountered such constraints as tight travel budgets, high turnover, conflicting pressures on potential trainees' schedules, and unavailability of qualified instructors. For these reasons, EPA's Quality Assurance Management Staff has sought out alternatives to traditional classroom-based instruction for delivering the message of quality.

One of the most outstanding products of this quest is a series of computer-based training (CBT) modules covering many of the key aspects of quality assurance for hazardous waste programs. The goal of these modules is to convey basic information related to data collection and analysis in a digestible and stimulating fashion. The target audience includes newly employed staff with QA management responsibilities, as well as those in need of refresher training. Since the CBT modules satisfactorily cover the fundamental points, they serve as an excellent prerequisite or complement to "live" training events focused on more specialized topics.

Each of the computer modules is a stand-alone lesson that treats a specific topic related to environmental data operations. We use graphics, animation, and games to provide an interactive visual learning environment. Modules completed to date include the following:

- Field sampling equipment
- Decontamination
- Chain of Custody
- Sample Preparation, Preservation, and Packaging
- Field Audits

Additional modules dealing with QA planning, analysis, and review are in development.

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SESSION N

THE PERFORMANCE ASSESSMENT PROCESS AND QUALITY CONTROL

Mark D. Otis
Science Applications International Corporation

Performance assessment for disposal sites is a complex process that requires managing large amounts of data gathered by specialists in diverse fields. Each stage of the process requires attention to different quality control issues. This paper presents an overview of the performance assessment process and identifies those areas which present particular challenges to the manage concerned with quality control. The two major areas discussed are data management and computer modeling.

The purpose of a performance assessment is to demonstrate that a disposal site will meet regulatory performance criteria related to environmental and human risk over the long term. It is important to keep this end use of the data in mind when establishing quality control criteria and procedures because the same data are also being gathered for other purposes. The data required for these assessments are of primary types: 1) site characterization, 2) facility design, and 3) waste inventory.

Performance assessments necessarily involve calculations of future performance modeled with computer codes. The credibility of these calculations depends on the quality of the input data and the reliability of the software used. project managers concerned with performance assessment modeling must be familiar with current quality assurance standards for computer software that impose significant documentation requirements.

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SESSION N

PERFORMANCE ASSESSMENT SOFTWARE TESTING AND CONTROL

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Formal testing and control has recently become an issue of concern with respect to performance assessment (PA) software. The American National Standards Institute and the Institute of Electrical and Electronic Engineers (ANSI/IEEE) software engineering standards have been recognized and followed for many years in industry (e.g., banking, manufacturing, etc.). On the other hand, environmental models tended to be more academic or research oriented in the past, and formal testing and control in accordance with accepted standards was not typically conducted. The need to license a High-Level Waste Repository was a primary driver in identifying the need to formally demonstrate the veracity of environmental modeling computer codes used as PA tools. Furthermore, formal software testing and control are becoming recognized as an essential element of a defensible PA for any application used to support a license application. The purpose of this paper is to describe how to evaluate the adequacy of a testing and control program for PA software.

The ANSI/IEEE standards are written to apply to many different types of software. Thus, it is important to identify parts of the general standards that would be counterproductive to try to meet for certain types of software. Furthermore, alternative approaches must be developed that maintain the intent of the original standards. The objectives of this paper are to identify areas where special requirements are necessary due to the nature of PA software and to describe how to assess the adequacy of the testing program for a PA code based on the specialized requirements. The areas of concern for typical PA software to be discussed are software development standards as applied to existing software and definitions of verification and validation testing. PA software control requirements will be briefly discussed, followed by a more detailed discussion of software testing requirements for PA software.

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SESSION N

SOFTWARE QUALITY ASSURANCE: THE JOURNEY

Mark L. Hermanson
Westinghouse Hanford Company

"Software Quality Assurance" has been referred to as "double whammy:" the black art of computer science and the arcane business of Quality Assurance--two magics rarely understood by a single individual. To a great extent, the mystery can be removed if computer programs are viewed as engineered products and if Quality Assurance is accepted as the fundamental control that guides this endeavor to success.

The history of Software Quality Assurance standards dates back to the 1960s. The American Nuclear Society first published ANS 2, Guidelines for the Documentation of Computer Programs, in 1967. The military established the first SQA administrative program standard in 1974, with MIL-S-52779, Software Quality Program Requirements. Since that time, there has been a stampede to publish software and computer-related control standards. The National Aeronautics and Space Administration, the Federal Aviation Administration, the Institute of Electronics and Electrical Engineers, and the American Society of Mechanical Engineers, to name a few, have been joined in the standards gold rush.

Traditional Quality Assurance principles applied to computer systems can be effective if they are adapted to the new language, techniques, and rapid change of automated data processing. The result becomes a careful journey to which there is no perfect end. When introducing new controls, it is very important to take into account the culture of the company, the status of the company's software, and the extent to which the company uses software. Anything else can lead to disaster, with company services interrupted or discontinued, extreme employee dissatisfaction, especially amount scientists, and a dichotomy of mandatory procedure compliance without the ability to comply. Because computer technology advancements are deployed so much more rapidly than agencies and societies can concur upon and publish rules, the standards tend to lag way behind. This, coupled with a company's own policy-making bureaucracy, can leave managers of computer systems waving flags at a rocket ship in flight. The challenge is to jump on board and navigate this information titan as it zooms into the next century.

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SESSION N

SITE CHARACTERIZATION QUALITY CONTROL ISSUES IN THE PERFORMANCE ASSESSMENT AND RISK ASSESSMENT PROCESSES

J.D. Hoover
Westinghouse Hanford Company

Quality control issues in site characterization are common to both disposal site performance assessment and environmental restoration efforts. These issues are important because they constrain the integrity of the end result and also the ability to provide verifiable protection of human health and the environment. Site specific baseline risk assessment is a site characterization effort in the environmental restoration of Superfund sites that includes all elements of the performance assessment process for current and future exposures. This provides a common basis for addressing quality control issues in most site characterization efforts designed for various purposes and waste types.

The principal issues regarding quality in site characterization efforts involve quantitative and qualitative specifications of the required quality of data based on their intended uses. The data quality objectives process for Superfund activities provides a basis for addressing issues common to performance assessment and risk assessment efforts. This process focuses on the identification of data types, uses, and needs in the context of precision, accuracy, representativeness, completeness, and comparability. Quality control issues in site characterization, therefore, extend to facility characterization and factors such as the identification and description of natural processes that impact isolation performance, waste fate, or restoration efforts.

The most important issue is implementation of quality control into site characterization activities. The extent to which data quality objectives are developed for individual activities have significant impacts on cost and schedules, as well as on the reliability of the end product. The issue of representativeness in the planning, execution, and interpretation of background characterization efforts, for example, impact the definition of contamination and performance standards, predictive modeling results, and decisions regarding facility disposition. Examples of quality control concerns in site characterization activities, and the ways in which they impact the validity and efficiency of activities pertaining to performance assessment and environmental restoration, are discussed.

SECOND INTERNATIONAL WASTE MANAGEMENT CONFERENCE
Las Vegas, Nevada
March 17 - 20, 1991

SESSION O

USE OF QUALITY ASSURANCE RESOURCES TO ASSIST IN A DATA AUTHENTICITY PROGRAM

Joan F. Fisk
U.S. Environmental Protection Agency

EPA's Superfund Program has been experiencing a series of Office of Inspector General investigations of alleged fraud in its Contract Laboratory Program (CLP) laboratories. The allegations of wrongdoing have all been of the nature of alteration of data to appear to meet contract requirements when, indeed it did not. Specifically, common allegations are:

- Turning the mass spectrometer computer clock back to reflect an earlier date of analysis.
- Manual editing of chromatographic peaks to enhance or diminish their area for internal standards and/or surrogates.
- Substitution of files to replace an unacceptable calibration with a previously generated acceptable one.

In addition to the stigma of scientific fraud, these practices destroy the very essence of Superfund CLP data - and that is its claim of being of known and documented quality.

Superfund data is used for making many important decisions that affect public health and the welfare of the environment Also, millions of dollars are spent on clean-up for every Superfund site. Therefore, the integrity of that data cannot be compromised, causing EPA to mobilize into a mode of detection of wrongdoing in the laboratory community.

EPA soon recognized that Superfund was not the only potential victim of laboratory fraud and invited the Department of Energy and the Department of Defence to join them in an effort to protect the Government from this fraud. The resulting Interagency Workgroup determined at its first meeting in June 1990 that fraud detection was not a Quality Assurance (QA) responsibility. It was considered important that the QA Program (QAP) operate on the assumption that laboratories are honest so as not to destroy the positive nature of QA feedback to the laboratories and the program that is constructive and energizes constant improvement - or a "white hat role." The

group decided to institute another program it has named the "Data Authenticity Program (DAP) to provide the tools needed to detect potential wrongdoing.

The Workgroup recognized that the resources to be applied to a DAP would largely need to come from the QAP and that many of the same tools would be used - but for a different purpose (to detect wrongdoing - "black hat role").

This presentation will describe the QA resources and tools diverted to the detection of laboratory wrongdoing, as well as an update of the activities of the Interagency Workgroup on Data Authenticity and its three subgroups - "Prevention," Detection/Indicators," and "Damage Control."

SECOND INTERNATIONAL WASTE MANAGEMENT CONFERENCE
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SESSION O

QUALITY ASSURANCE - THE MOST POWERFUL LABORATORY MANAGEMENT TOOL

Kathleen A. Carlberg
ENSECO, Inc.

Managing an environmental laboratory for profit is extremely challenging. The scientific and regulatory requirements for the analytical data must be met; the customer must be delighted with the service provided; the employees must be kept happy; and an acceptable level of profitability must be achieved. At times, some or all of these objectives can appear to be at cross-purposes with each other. The key to success is to have appropriate systems in place to manage the complex interactions and requirements demanded in the environmental laboratory setting.

Several types of systems are needed. In additional to financial and personnel systems which are required of any business, the laboratory must have a strong Quality Assurance system in place to ensure the generation of scientifically sound and legally defensible data and to ensure that the client receives the services he ius expecting from the laboratory. This view of a Quality Assurance system goes well beyond the prescriptive "checklist" approach to QA and incorporates QA principles into the organization and management of the laboratory.

Today we will discuss how Quality Assurance is integrated into the management of the laboratory; why it is important to the customer that this be done; and what the customer should expect from a laboratory's Quality Assurance management system. In addition, we will discuss the dangers associated with the "checklist" approach to QA; and how the Quality Assurance management system fits in with the currently popular concept of Total Quality Management.

Roger says "Hello" To Budhi Sagar

PERFORMANCE ASSESSMENT SOFTWARE TESTING AND CONTROL

Roger Seitz
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OBJECTIVES

- Discuss Specialized Requirements That Are Necessary Due To The Nature Of Performance Assessment Software
- Discuss An Approach For Evaluating the Adequacy Of Software Testing And Control Based On The Specialized Requirements

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GENERALLY APPLICABLE STANDARDS

- ANSI/IEEE Software Engineering Standards
- ASME NQA-2, Part 2.7
- ANSI/ASME NQA-1 (Hardware Related)

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AREAS OF CONCERN FOR PA SOFTWARE

- Software Development Cycle vs. Existing Software
- Specialized Testing Objectives

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DEVELOPMENT VS. EXISTING SOFTWARE

PA Codes Have Typically Already Been Developed

Lack Of Formal Documentation

Software Development Cycle Includes Steps That Can Be Counterproductive For Existing Software

PA Software Use Tends To Be Application-Specific

SPECIALIZED TESTING OBJECTIVES

Different Definitions For Verification/Validation (ANSI/IEEE vs. ASME NQA-2 vs. PA)

Application And Site-Specific Considerations

Requirement For Independent Peer Review??

Taking Credit For Many Years Of Use In The Scientific Community??

EVALUATING THE ADEQUACY OF PA SOFTWARE TESTING AND CONTROL

Software Documentation And Control

Types Of Testing For PA Software

Common Testing Oversights

SOFTWARE DOCUMENTATION AND CONTROL

Several Types Of Documentation Are Required
- Requirements, Testing, User's Guide, Technical Description, QA Plan (May Be Combined Or Separate)

Basic Elements of Software (And Application) Control
- Change And Version Control For Code
- Error Notification Process
- Record Of Data Files Used For Application
- ***Traceable And Reproducible !!!***

TYPES OF TESTING

Software Analysis (Programming, Complexity, And Coverage)
- Evaluation Of Actual Coding
- Not Common, But Should Be *Required !!!*

Verification Testing
- Measures Accuracy Of Numerical Approach
- Relatively Simple Problems

Benchmark Testing
- Measures Consistency With A Similar Code
- Application-Oriented Problems

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TYPES OF TESTING (CONT.)

Calibration Testing
- Measures Ability Of Mathematical Model To Reproduce Laboratory Or Field Conditions
- Fine Tuning of Characterization And Monitoring Data Used As Inputs For Conceptual Model

Validation Testing
- Measures Ability Of Mathematical Model To Predict System Behavior (Following Calibration)
- Requires Data And Time To Evaluate Predictions
- Generally Accepted That True "Validation" Is Not Practical At This Time
- Limited Studies Can Enhance Credibility Of Models

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COMMON TESTING OVERSIGHTS

Identify Parts Of Code That Have/Have Not Been Tested (Focus On Application)

Test Cases Must Address Conditions At Site To Be Modeled

Independent Testing And Peer Review (NQA-2)

Recognize Uncertainties Inherent With A PA (Maintain Proper Perspective)

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ADDITIONAL INFORMATION

NUREG-0856, *Final Technical Position on Documentation of Computer Codes for High-Level Waste Management* (Silling 1983)

NUREG/CR-4369, *QA Plan for Computer Software Supporting the U.S. Nuclear Regulatory Commission's High-Level Waste Management Program* (Wilkinson and Rinaldi 1986)

DOE/LLW-102, *Guidelines For Acquisition, Installation, and Testing of Performance Assessment Software* (Seitz, Matthews, and Kostelnik 1990)

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ADDITIONAL INFORMATION (CONT.)

IEEE Computer Society Press, *ANSI/IEEE Software Engineering Standards (4th Edition)*, Available In ~April From IEEE Standards Department, (800) 678-IEEE

SUMMARY

Specialized Requirements Address Existing Software And Testing Needs

Lack Of Formal Documentation Is A Common Shortcoming For PA Software

PA Software Testing Needs To Address Application And Site-Specific Problems

Independant Peer Review Adds Credibility To Testing

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