QUALITY ASSURANCE EXCHANGE

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U.S. Department of Energy, Office of Corporate Performance Assessment
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SECRETARY BODMAN EMPHASIZES QUALITY ASSURANCE

On April 26, 2006, the Secretary of Energy, Samuel W. Bodman, issued a memorandum on "Improving Quality Assurance." In this memorandum, the Secretary reminded all Departmental Elements of the following: "Effective implementation of Quality Assurance (QA) Programs is critical to achieving results and accomplishing the Department's mission. The Department has had several examples where the quality of work has negatively impacted the mission resulting in rework, delays, and cost growth, all in a time of limited resources. The Department must implement quality requirements to ensure that risks and negative environmental impacts are minimized and that safety, reliability, and performance are maximized through the application of effective management systems commensurate with the risks posed by the facility or activity and its work."

All Departmental Elements have been directed to report on their QA implementation by July 30, 2006. The Office of Environment, Safety and Health (EH), working with a team from the Field and Program Offices, developed and provided guidance for the report content on June 15, 2006. The purpose of these reports is to assess the status of the Department's QA programs and to identify areas in which improvements may be necessary.

IN THE SPOTLIGHT: INTERVIEW WITH AVA HOLLAND

Quality Assurance Manager

Carlsbad Field Office, Waste Isolation Pilot Plant

Ava Holland is the Quality Assurance Manager for the Carlsbad Field Office (CBFO) at the Waste Isolation Plant (WIPP). Ms. Holland is responsible for oversight of the quality assurance program at the WIPP and the waste generating sites that ship to WIPP. Oversight activities include responsibility for performance of certification audits for all waste characterization activities governed by the WIPP hazardous waste permit, waste characterization activities regulated by the Environment Protection Agency (EPA), and waste transportation.

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"HOW TO" SERIES ON PERFORMING ASSESSMENTS: AUDIT MEETINGS

Submitted by Bob Blyth, U.S. Department of Energy, Idaho Operations Office

This is the third in a series of articles containing auditing techniques and tools acquired over the years by auditors leading and participating in Quality Assurance (QA) audits across the DOE complex. These techniques and tools supplement DOE G 414.1-1A, ***Management Assessment and Independent Assessment Guide*** *and can be used to become a more effective auditor.*

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DOE CONTRACTOR RECEIVES THE 2005 MALCOLM BALDRIGE AWARD FOR PERFORMANCE EXCELLENCE

Submitted by Julianna Gallego, Strategic Petroleum Reserve

DynMcDermott (DM) Petroleum Operations Company, the maintenance and operating contractor for the Department of Energy's Strategic Petroleum Reserve (SPR), was notified in November 2005 by the Secretary of Commerce that it had been selected as a 2005 recipient of the Malcolm Baldrige National Quality Award for the business/service category. The Vice President of the United States presented the award to DM on April 19, 2006. On June 1, 2006 the Louisiana House of Representatives honored DM with a resolution recognizing them as the first Louisiana company to win this award. This achievement is just another step in the continuous improvement journey that began in 1993 when DM received the SPR contract.

V.P. Cheney presents the Baldrige Award to Robert McGough, President and CEO of DynMcDermott.

DM's quality journey began with the development of a quality system based on the ten criteria of the DOE Order (DOE O 414.1) and the implementation of a Total Quality Management Theory as a model for management improvement and transitioned to the Continuous Quality Improvement (CQI). Influenced by leaders such as Walter Shewhart, W. Edwards Deming, Joseph M. Juran, Philip B. Crosby, Peter Sange and the Baldrige Criteria for Performance Excellence, process management was introduced to DM as a management strategy to improve process performance.

Building on a strong foundation based on the "Plan, Do Study, Act" (PDSA) model of improvement, in 2000 DM became registered to the ISO 14000 Environmental Management Standard and in 2001 to the ISO 9001 Quality Management Standard. In 2003, DM evolved to an Integrated Continuous Process Improvement approach to process improvement with the adoption of a formal Lean Six Sigma methodology, Strategic Planning principles, and benchmarking initiatives for comparison with industry leaders.

DM has reduced cost and improved performance by using Baldrige as a business model that focuses on a systems perspective and alignment of resources to achieve the Mission.

To function effectively, management must understand and manage numerous interrelated systems and their processes. The model of a process-based management system (Figure 1) illustrates the process linkages and how the customer plays a significant role in defining requirements.

The Malcolm Baldrige criteria require that an organization answer questions about how business is conducted to achieve results. The Performance Management Relationship Matrix (Table 1) indicates how the criteria from the various business performance methodologies interrelate (Malcolm Baldrige, ISO 9001:2000, Six Sigma and the DOE O414.1C).

The ANSI/ISO/ASQ Q9001-2000

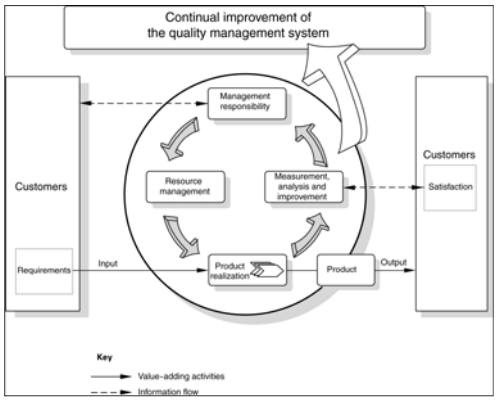

Figure 1. Model of process-based quality management system

Meeting the needs of the customer is the primary function of leadership and the management systems. Identifying all interrelated processes, understanding how these processes impact output, and constantly measuring, analyzing, and improving the steps in each process provides for a more satisfied customer.

Performance Management Relationship Matrix

Baldrige Criteria	ISO 9001 &14001	DOE O 414.1C	Six Sigma
Leadership	Management Responsibility	Program-Structure, Responsibilities, Authorities	Senior Leadership
Strategies Planning	Product Realization Quality Planning	Program-Structure, Responsibilities, Authorities	Integrated Strategic Planning
Customer and Market Focus	Management Responsibility, Product Realization	Program-Structure, Responsibilities, Authorities	Voice of the Customer (QFD)
Measurement Analysis & Knowledge Management	Quality Management System, Measure Analysis & Improvement	Documents & Records Criteria 8 Inspection & Acceptance	10x Return on Investment
Human Resource Focus	Resource Management	Program Personnel Training & Qualification	Train the Organization
Process Management	Product/Service Realization	Quality Improvement Work Processes Design Procurement	Process Management
Business Results	Management Responsibilities Quality Objectives Measurement Analysis & Improvement	Management & Independent Assessments	Business Results

Table 1. Performance Management Relationship

SQA WORK ACTIVITY #3: *Software Configuration Management*

(*This article is the fourth in a series that addresses how the software quality assurance 10 work activities in the DOE O 414.1C relate to ASME NQA-1-2000 and other consensus standards. DOE G 414.1-4 provides details for implementing the 10 work activities to meet the SQA requirements in the DOE O 414.1C.)*

Work activity #3, Software Configuration Management (SCM), identifies all functions and tasks required to manage the configuration of the software system, including software engineering items, establishing the configuration baselines to be controlled, and software configuration change control process.[1] The following four areas of SCM[2] should each be addressed when performing configuration management: (1) configuration identification, (2) configuration control, (3) configuration status accounting, and (4) configuration audits and reviews. The DOE G 414.1-1 extends ASME NQA-1-2000 software configuration management[3] tasks by including configuration audits and reviews.[4]

The methods used to control, uniquely identify and describe the configuration of each version or update of software and its related documentation should be documented. This documentation may be included in a SCM plan or its equivalent. Such documentation should include criteria for configuration identification, change control, configuration status accounting, and configuration reviews and audits.

A baseline labeling system that uniquely identifies each configuration item, identifies changes to configuration items by revision, and provides the ability to uniquely identify each configuration, should be implemented. This baseline labeling system is used throughout the life of the software development and operation.

Proposed changes to the software should be documented, evaluated, and approved for release. Only approved changes should be made to the software that has been baselined. Software verification activities should be performed to ensure the change was implemented correctly. This verification should also include any changes to the software documentation.

Audits or reviews should be conducted to verify that the software product is consistent with the configuration item descriptions in the requirements and that the software, including all documentation, being delivered is complete. Physical configuration audits and functional configuration audits are examples of audits or reviews that should be performed.[5] SCM work activities should be applied beginning at the point of DOE's or its contractor's control of the software.

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References:

[1]ASME NQA-1-2000, op. cit., Part II, Subpart 2.7, Section 203, p. 105.

[2]IEEE Std 828-1998, *IEEE Standard for Software Configuration Management Plans*, IEEE, 1998, Section 4.3.

[3]ASME NQA-1-200, op.cit., Part I, Section 802, p.16.

[4]IEEE Std 7-4.3.2-2003, *IEEE Standard Criteria for Digital Computers in Safety Systems of Nuclear Power Generating Stations,* IEEE, 2003, Section 5.3.5.

[5]IEEE 1042-1987, *IEEE Guide to Software Configuration Management,* IEEE, 1987, Section 3.3.4.

FAQ's

Q. The Contractor Requirements Document (CRD) in Attachment 2 of the Order states: "The contractor must consider QA guidance in developing and implementing a QAP. The following guidance documents…." During an assessment, what evidence is expected to be produced to adequately demonstrate that the QA guidance was considered but not used in the development or implementation of a QAP?

A. As noted in DOE G 414.1-4, alternative methods to those described in the Guide may be used provided they result in compliance with the requirements of 10 CFR 830 Subpart A and DOE O 414.1C. The evidence to demonstrate that a contractor considered the use of DOE G 414.1-4 will be determined by the DOE approval authority for the QAP. An assessment team should typically review the evidence as specified by the QAP approval authority. Evidence may be as simple as a statement in the approved QAP that the DOE G 414.1-4 was reviewed and considered in its development.

"In the Spotlight…" *(Continued from page 1)*

Ms. Holland has an extensive background in quality assurance and environmental quality at various DOE facilities and in the nuclear power industry. She holds a bachelor's degree in Mechanical Engineering Technology from Metropolitan State College, and has performed graduate work in applied statistics at the University of Northern Colorado. Ms. Holland came to WIPP in the early 90's as a contractor, and has been with the project ever since.

In a recent interview, Ms. Holland described the challenges of complying with multiple regulators and standards, the flow down of QA requirements to contractors, and the key components of a successful Quality Assurance Program.

Please share with us some of the lessons learned on having to report to or comply with requirements of several regulators (DOE, EPA, other Federal agencies) and associated national standards?

"The most important lesson is that no matter how many regulators and standards you have to comply with, a project such as WIPP needs a single quality program with a strong graded approach to provide consistency across all activities.

"Quality assurance as a discipline really addresses how we know that we're doing business consistently on a day-to-day basis: is everyone trained appropriately, do procurements get the right materials for the work, are the correct procedures in everyone's hands for use, and so forth. This concept becomes even more critical when you're dealing with several regulators. When all the cooks have their hands in the broth and are all using slightly different recipes, so to speak, it's too easy to wind up with a dish no one can eat. We found it best to use a single program that has been developed to comply with the most stringent requirements and vary the conservatism with which it is applied through a solid, risk-based grading process. This will go a long ways toward yielding a culture of compliance and will help prevent activities from falling through the cracks because someone decides that *'QA doesn't apply to this.'*

"I've encountered situations where multiple programs have been established for a single project with the rationale that this would keep the regulators contained and prevent them from interfering with things that are not under their purview. Splitting up critical management processes doesn't work that way. The regulators still will find out what you don't want them to, and your personnel wind up not knowing which programs apply to which activities. That's a disaster waiting to happen."

What are some of the challenges you have encountered with implementing DOE Order 414.1C?

"Implementing the order itself isn't much of a challenge because of the stringency of the regulatory requirements WIPP has to live by. The Land Withdrawal Act specifically requires the WIPP QA program to be based on the 1989 editions of ASME NQA-1 and NQA-3, and Part 2.7 of the 1990 amendment to NQA-2. WIPP cannot change to a more recent edition of any of these without an act of Congress. The biggest challenge has been in dealing with individuals that do not understand that I cannot reduce this program's rigor and use of NQA-1 (not all organizations include a commitment to use NQA-1 for their QA Program) and thereby risk losing compliance with Federal regulations authorizing WIPP.

Tell us about some of the challenges associated with the flow down of QA requirements to contractors, including how you verify compliance through your assessment program. How do you overcome these challenges?

"With the exception of some issues that have occurred with procurement of equipment, there have not been many challenges with flow down of requirements. The entire WIPP project is subject to the WIPP QA program as defined in the CBFO Quality Assurance Program Description (QAPD). Some of our support organizations have developed lower tier QAPDs to further define their means of compliance; some have not. It depends on the complexity of the role each organization plays and specific management needs. In any event, the CBFO assessment program to verify compliance is both broad and quite detailed. My organization performs anywhere between 30 and 40 full audits every year that cover the WIPP site M&O (Management & Operations), the supporting national laboratories, and the waste generating sites. In addition, we perform 10 to 15 surveillances as needed to cover trouble spots. This year, my audit staff is on the road on average two weeks out of every month.

"Part of the reason the WIPP QA assessment program has been so successful is that, in addition to the outstanding senior personnel leading the audits, a sizeable proportion of the audit staff are technical experts in rad chemistry, nondestructive assay, and so forth. This enables us to assess activities at a technical depth that many quality assessment programs can't meet."

Do you have any best practices to share on your Quality Implementation and corrective action process?

- ***How are your corrective action programs implemented?***
- ***How do you keep track of and verify that the corrective actions are being followed through?***

"CBFO has a classic CAR (Corrective Action Request) system: identify non-compliance or condition adverse to quality; request corrective action; plan and perform corrective action; verify effectiveness; and close. Not much cutting edge innovation there. We use it for all non-compliances that

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"In the Spotlight…" *(Continued from page 4)*

CBFO identifies through our assessment process. One thing we do a little differently from most, however, is our finding validation process. I have two senior QA specialists on staff that perform what amounts to a mini-independent peer review on every CAR that is proposed before it is issued. They take a critical look at the statement of the condition adverse to quality, the evidence, and the associated requirement, and make a determination regarding the validity of the finding and the clarity of the finding. If there are problems with any aspect of the CAR, it is fixed. Experienced auditors coming in from other programs are a little surprised by this approach and some have resented it at first. However, as a result of this approach, there is a lower level of conflict with the organizations receiving CARs over what it really says and whether it is valid."

In your assessment findings, how do you review and analyze extent of conditions? Can you share any lessons learned on this approach?

"There's an old saying: "pull the string." Funny thing about extent of conditions for this project; a condition adverse to quality may be spread out over multiple sites or multiple support organizations because of the complex interfaces and links between activities and organizations. Unless the string gets pulled sufficiently, we would not realize that the problem exists elsewhere until it pops up to bite us somewhere else."

What makes the WIPP QAP successful and in turn, the WIPP successful?

"Three things: rigor, consistency, and most of all, the dedication and knowledge of all of the people on the project across the country who implement the program every day on every task. This is a living program, and without each of these three things, it could easily become just another notebook full of paper that sits on a shelf and gets dusted off when someone wants to *'see the program.'* "

"How to Series…" *(Continued from page 1)*

Keeping your audit team on track and the audited organization well informed is essential to conducting a successful audit. Establishing and using reliable communication mechanisms are the keys to achieving these vital results.

The high-pressure situation surrounding an audit often impairs people's ability to send and receive information. Therefore, effective and open communication in the form of brief, informal meetings is essential. Basically, there are four types of audit meetings: the audit entrance meeting, the daily audit team meetings, the daily management information meetings, and the audit exit meeting. The following describes the "how to" steps to conducting audit meetings and the desired outcome of each of these meetings.

Audit Entrance Meeting

Desired Outcome: Meeting participants leave with the information they need to effectively participate in the auditing process.

Planning and conducting a multi-organization meeting without an agenda is akin to building a house without a set of plans. It is horribly inefficient and generates a product nobody likes. Therefore, it is important for the audited organization to begin an auditing process with an entrance meeting emphasizing the audit scope and the key points of contact. It is essential to note the administrative professional points of contact at this time as they will assist and ensure a successful audit from start to finish.

In addition, to help the auditing organization present itself as being prepared, organized, and professional, using presentation material in the form of briefing slides or handouts is recommended. This material is also useful as a reference to the audit team. A sample set of audit team entrance meeting presentation slides is posted on the EH website.

A typical entrance meeting agenda should include the following.

- **Introductions** – Break the ice by having everyone briefly introduce themselves.
- **Program overview** – Describe the program, work scope, project history, highlights, and accomplishments, and key points of contact. It is especially important to include administrative professional points of contact because they have comprehensive knowledge of the staff schedule and organizational procedures and are able to adapt quickly when plans/schedules change.
- **Audit scope and objectives -** Define the scope and objectives of the audit.
- **Audit team introductions with assigned areas** – Introduce the audit team with the elements and activities they will be auditing.
- **Audit protocols** – Describe the activities that will occur during the audit, such as how the team will handle the issue development sheets (IDS). The IDS should be developed as soon as possible and given to the audited organization for factual accuracy before discussing at the daily management information meetings. In addition, describe how notable practices, observations, and findings developed during the audit will be handled. For example, describe how they will

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"How to Series…" *(Continued from page 5)*

be reviewed for factual accuracy, when they will be formally issued, and what will be the process for developing, implementing, and verifying the corrective actions and their associated timelines. Finally, discuss the protocols specific to the audit, such as the location of the audit team room and specific schedules and accommodations related to the audit.

- **Scheduled audit meetings** - Note the scheduled audit meetings during the briefing as a convenience for all involved with the audit. Include days, times, locations, and expectations of the daily audit team meetings, the daily management information meetings, and the audit exit meeting.
- **Questions** – At the end of the meeting, allow time for questions to clarify areas of uncertainty, fill in information gaps, and address any audit implementation concerns/details.

Daily Audit Team Meetings

Desired Outcomes: (1) Audit team members receive input from other team members on developed issues. (2) Audit team members understand, discuss, and concur on the categorization of developed issues. (3) The audit team leader understands the audit field investigation completion status and adjusts the team assignments, if necessary.

It is very easy for auditors to become overly focused. Because of the exposure, some auditors do not feel comfortable issuing findings or concerns. By discussing developing issues as a team, these problems are minimized.

In order to facilitate team discussion, here are some typical questions to ask each auditor: Do you have any new issues? What are they? With whom were they discussed? Is there any other information you need? Do you believe this is a notable practice, concern, or finding? Ask the audit team as a whole, whether anyone else has any questions about this issue. If they do, discuss the issue until the audit team member who initially presented it has input from the other audit team members. The issue generator now understands that he/she has a decision that the team supports or that there is more work to be done.

If there are no more issues to present, then ask: How is your workload? Do you need some help, or can you give someone else a hand? Discuss and mutually agree on any adjustments in the auditor field investigation workload.

The average daily audit team meeting takes at least 45 minutes. Give the audit team sufficient time to discuss emerging issues and to help cement confidence in what they will present at the daily management information meetings.

Daily Management Information Meetings

Desired Outcomes: (1) The audited organization knows and understands the issues being developed during the audit. (2) Possible corrective actions can be verbally approved to facilitate the closure of findings during the audit.

After the auditors have identified an issue, recorded it on an IDS, given the IDS to the audited organization for factual accuracy, and discussed the issue with the audit team, the issue is ready to be presented to the audited organization. The daily management information meetings are designed to present the developing issue(s).

Have the auditors hand out copies of their IDSs at the daily information meetings. This enables each auditor to distribute copies that have incorporated the factual accuracy review comments making the presentation more accurate and credible. If there is more than one issue, each is discussed separately. Facilitate the discussion by asking the audited organization the following questions.

- Do you understand the issue?
- Do you have any questions?
- Is there a part of this we are missing?
- For findings: do you have any suggestions for corrective actions?

After these discussions, it is not uncommon that the auditor sees a need to revise the IDS. The updated IDS is emailed to the audited organization allowing them to easily communicate the identified issue internally, compile objective evidence that might be unknown to the auditor, and quickly develop corrective actions.

The discussions in these meeting can be contentious and lengthy. It is the audit team leader's job to keep the conversation focused and constructive. He/she must also be firm yet open to new information. Meeting breaks can be a good refocusing tool. It is also suggested to hold these meetings at the end of the day as to eliminate competition with other meetings.

Meeting participants should leave the daily management meeting well informed about the issues being developed. This enables the audited organization to give progress reports to management and eliminates end-of-audit surprises. Where corrective actions can be developed and implemented quickly, findings can be closed during the audit. Meeting and discussing developed issues as they arise keeps the communication channels open and helps create a collaborative atmosphere. Creating and maintaining this atmosphere speeds the corrective action process and reduces rejections of the proposed corrective action process.

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"How to Series…" (Continued from page 6)

Audit Exit Meeting

Desired Outcome: Participants leave with a summary of the audit results and an understanding of subsequent actions and their time frames.

Have the audit team members prepare their own presentation slides describing the notable practices, concerns, and findings they developed during the audit. Cutting and pasting from the IDS speeds this process. The audit team leader then combines the auditor-generated slides into a unified presentation.

At this point there should be no surprises for the audit team or audited organization. There should be no discussion as to validity of any of the issues. If validity discussions do occur during the exit meeting, areas in question can be noted and tabled. Further discussions are best done off line after the meeting.

Start the exit meeting with a quick introduction to any new participants who may be attending and a brief overview of the audit scope and objective. Although this information was presented at the entrance meeting, it helps to frame the rest of the meeting. Next, briefly reintroduce the audit team.

Acknowledgement of significant contributions or efforts by the audited organization is warranted at this time particularly if the audited organization has made significant improvements or implemented processes that are exceptionally effective.

To present the audit results, start with the major requirement group/quality assurance element in numerical order. For each element, the team member responsible for the area presents the notable practices, concerns, findings, findings closed during the audit, and an element effectiveness statement if required. This sequence makes it easy for those in the audited organization to keep a tally. Having the auditors present their summaries from their chairs eliminates the transition from auditor to auditor and keeps the meeting on a less formal basis. These are preferences that have been developed over the years and have been found effective; however, other options can be very workable.

If a program effectiveness statement is required, the audit team leader will present it after the element summaries. Using a tailored version of the summary sheet clearly tabulates the audit results and supports the effectiveness statement conclusion.

Next, explain the audit report time line (i.e., when it will be issued for factual accuracy, when these comments are due to the audit team and when the report will be issued). Committing to an issue date reduces report editing time.

The next technical topic is protocols and time frames for addressing findings.

When appropriate, and if done constructively, a little humor is a great tension reliever. The audited organization has been under the audit microscope, and the audit team has probably been working 12-hour days, making just about everyone stressed. Recalling humorous events, known previously to only part of the audited organization or audit team, can really lighten things up.

Finally, close with a question & answer session to clarify anything missing or poorly presented.

This process suggests conducting numerous meetings. The high-stress nature of auditing and the need for clear and consistent common understanding make these meetings essential. Presenting and discussing information is the best way to keep everyone "on the same sheet of music."

Credit for developing this article goes to Bob Blyth, NE; Ken Scheffter, Project Enhancement Corporation; Karen Brown, Parallax; and Tom Morgan, Idaho National Laboratory.
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FAQ's

Q. Is it required for any type of safety software to be cited in an approved safety analysis for the nuclear facility?

A. No, it is not required. If the safety basis depends on the safety software and it is implemented through plans, procedures, safety documents, etc., the safety software would be implicitly part of the safety basis. For example, a change to the software that is invoked by operational procedures would be subject to the unreviewed safety question (USQ) process.

Q. Can a developer or contractor submit software to DOE to be considered a toolbox code and to be included in the Central Registry?

A. Yes. The procedures to add, revise, or remove software to the Central Registry is documented in DOE G 414.1-4 Appendix B.

You can find more FAQs on the website at:

www.eh.doe.gov/qa FAQ_Responses121905.pdf

SAFETY SOFTWARE CENTRAL REGISTRY ACTIVITIES

Central Registry Benefits Sites

The development and maintenance of a collection or "toolbox" of highly used DOE Safety Software Quality Assurance (SSQA)-compliant codes is one of the major improvement actions supported under DOE O 414.1C, *Quality Assurance*. This collection of toolbox codes is referred to as the DOE Safety Software Central Registry. The Assistant Secretary for Environment, Safety and Health has the responsibility for maintaining the Central Registry. The implementation strategy for the Central Registry is addressed in DOE G 414.1-4, *Safety Software Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements, and DOE O 414.1C Quality Assurance.*

The Central Registry currently contains six safety analysis toolbox codes with two additional codes in various stages of consideration for inclusion. As part of the process for inclusion into the Central Registry, an evaluation is performed by a team of QA personnel. The evaluation extends beyond the review of the DOE safety software requirements to include a review of the software model's ability to implement industry accepted approaches to modeling scientific or engineering problems. The results of this extensive evaluation for potential inclusion into the Central Registry provides valuable information to the DOE users on the pedigree of the software quality and the scientific or engineering solution. Inclusion of codes into the Central Registry offers advantages to the DOE code users, contractors, and site office quality assurance staffs. Since the toolbox codes' evaluation is based upon the same SSQA criteria as the site-specific SSQA programs, once a code is included in the Central Registry and selected for use, further evaluations of these toolbox codes by the sites may be less extensive or eliminated all together.

As part of the process to include a toolbox code into the Central Registry, a guidance document is made available to DOE users to complement any user documentation and to identify limitations and vulnerabilities not readily found in either the code documentation or other publications. These guidance documents assist the DOE user in applying the codes and their results properly for DOE related problems.

Integrated Modules for Bioassay Analysis (IMBA) Software Evaluation Coming to a Close

The Office of Quality Assurance Programs is finalizing its evaluation of the IMBA Expert ™ USDOE-Edition 4.0.20 and the Professional Plus 4.0.28 software for possible inclusion into the Central Registry. Support for IMBA Expert ™ USDOE-Edition will end December 31, 2006, thus its replacement, IMBA Professional Plus, is also being evaluated. The code user surveys, code developer interviews, and the review of documents have been completed. The evaluation report and gap analysis have been drafted. A preliminary review of the final draft gap analysis report by the evaluation team was performed the week of June 12, 2006 with the final report expected to be available in July 2006.

CFAST Upgrade Addresses Gaps

The Nuclear Regulatory Commission (NRC) and DOE are cooperatively working with the CFAST developers at National Institute of Standards and Technology to include software enhancements and process improvements into the latest version of the fire modeling code. This work will address many of the safety software quality assurance gaps identified in the *Software Quality Assurance Improvement Plan: CFAST Gap Analysis*, May 2004. This work is expected to continue throughout the summer. The improvements are expected to include:

1. An update to the users' manual to include a comprehensive description of the software output, user input error messages, sample problems with input data files, output data files and a discussion of the results.
2. An installation test protocol to assure that the installed version is working properly.
3. A calculation for leak path factors values utilizing the contaminate term keyword.

Hotspot Being Considered for Safety Software Central Registry

DOE's Office of Quality Assurance Programs and the Emergency Management Issues (EMI) working group are collaborating with Lawrence Livermore National Laboratory to begin the evaluation process for considering Hotspot as a toolbox code in DOE's safety software Central Registry. Although Hotspot was created and is used to provide emergency response personnel and emergency planners with a fast, field-portable set of software tools for evaluating incidents involving radioactive material, it is also used for safety-analysis of facilities handling nuclear material. Justification for considering Hotspot as a toolbox code is being completed. If Hotspot meets the criteria for being considered, an evaluation based upon DOE G 414.1-4 will be lead by EH-31 and EMI SIG with support from staff across the DOE complex.

Central Registry Moves Forward

Since the potential for new codes and new versions of existing toolbox codes are being considered for DOE's safety software Central Registry, the Registry is moving ahead to increase its benefits to DOE sites. Internal processes and procedures for expanding and maintaining the Central Registry have been exercised and improved through the evaluation process of IMBA. More refinements will be made as the Hotspot and the new release of CFAST evaluations are performed. The improved processes and procedures will streamline adding new toolbox codes.

Existing toolbox codes are being monitored for new features and defect resolutions that will improve the quality of the code results and address the issues identified in the 2004 gap analy-

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"Safety Software Activities…" *(Continued from page 8)*

ses. EH is interfacing with each of the existing toolbox code owners or development vendors to establish open communications and provide feedback to DOE users on the latest improvements and issues with the toolbox codes. Updates to the Central Registry web site are planned.

It is important to ensure that the Central Registry set of toolbox codes meets the needs of the DOE nuclear community. EH is working with the various DOE Program Offices, administrators, and field representatives to gain knowledge on which safety software codes provide the largest benefit to DOE by being part of the Central Registry. If these codes are currently not part of the Central Registry, efforts will be initiated to prioritize and evaluate and, if appropriate, include the highest priority codes in the Central Registry. Where issues are identified with existing toolbox codes or potentially new additions to the Central Registry, funding for addressing these issues will be pursued. These activities will help to ensure that as time progresses, the Central Registry will continue to be an asset to the DOE community.

ACTIVITIES, UPDATES, AND ANNOUNCEMENTS

NQA Committee and NRC Working Towards Endorsement of Current NQA Standard

The ASME Nuclear Quality Assurance (NQA) Committee, including its representatives from the Nuclear Regulatory Commission (NRC) staff, is actively engaged in the resolution of NRC comments on NQA-1-2004. In June 2005, the NQA Committee received about 45 comments from the NRC staff on topics they believed prevented full endorsement of NQA-1-2004 by the NRC. This endorsement would help facilitate new generation activities for the nuclear power industry as they develop the license applications.

The NRC comments were based on a comparison to NQA-1-1994 (the last edition endorsed by the NRC). The NQA Committee developed a process for the resolution of the NRC staff's comments and met with them on several occasions to reach a resolution. Currently, the NQA Committee has resolved and/or approved about 25 comments for publication in the 2006 NQA Addenda. Another ten have been accepted by the NRC staff and are in the ASME ballot process. Approximately ten more are in the final stages of resolution with the NRC staff. The endorsement of the latest edition of NQA-1 will allow the commercial nuclear industry to use a more performance based approach to quality, utilize approved industry positions on Commercial Grade Items and other recent regulatory quality issues, incorporate criteria related to technology changes for computers and electronic records, and address the experience and lessons learned by the nuclear industry in the last 10 years.

The NQA Committee plans to have all comments resolved and any changes incorporated into the NQA-1-2007 edition. The NQA Committee is also coordinating the NQA changes with the ASME Boiler and Pressure Vessel Committee, Section III, General Requirements, and shall present the approved results of the NRC/NQA comment resolutions to the ASME Section III Subgroup on General Requirements at their August 2006 meeting.

ORPS Data Supporting QA Indicators

Over the past year, a task has been underway to extract Quality Assurance (QA) indicators from the Occurrence Reporting and Processing System (ORPS). ORPS, managed by the Office of Environment, Safety & Health (EH), collects approximately 1800 reports annually. The objective of the ORPS-QA Data Extraction task is to find a method to flag subtle indicators of QA management system weaknesses or even failures. These indicators may be based on minor events with low impact. However, an accumulation of statistically significant indicators could be precursors or leading indicators to more significant events.

The ORPS causal analysis data has been cross-referenced to the ten criteria listed in 10 CFR 830 and DOE O 414. These ten criteria are: Program; Training and Qualification; Quality Improvement; Documents and Records; Work Process; Design; Procurement; Inspection-Acceptance Testing; Management Assessment; and Independent Assessment. The ORPS system is also being modified to add the ten criteria as keywords. This will allow the daily EH ORPS Reports team to review the occurrences for QA indicators and tag them with the corresponding keyword. Additionally, a QA criteria field is being added in the ORPS input form for reporting organizations to provide their own judgment of how their QA program and QA criteria are indicated by the occurrence. The goal is not to have each event be proof of a QA management system weakness, but to have a statistically significant accumulation of indicators, which should cause further detailed assessment of the indicated area.

This approach will be tested through the summer and sample analysis will be conducted to compare indicators to actual events, past and present, to see if the results provide the desired precursor or leading indicator information.

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EDITORIAL NOTE:

Last issue BobToro Navaro was mistakenly omitted from the contributors list of the "How To Series" Performing Assessments On Tools and Techniques for Auditing.

If you are interested in receiving this newsletter electronically, please email your request to be added to the distribution list to qaexchange@hq.doe.gov

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Upcoming Meetings and Conferences

9th NRC/ASME Symposium on Valves, Pumps & In-service Testing
When: July 17-19, 2006
Where: Washington, D.C.
For more information: www.asmeconferences.org/nrcasme9

14th International Conference on Nuclear Energy
When: July 17-20th , 2006
Where: Miami, FL
For more information: www.conferencetoolbox.org/icone14

ASQ 33rd National Energy & Environmental Conference
When: August 27-30, 2006
Where: Loews Ventana Canyon Resort, Tucson, AZ
For more information:
http://www.asq.org/ee/conferences/doc/2006-08-27eed-conference.pdf or
http://www.asq.org/ee/conferences/index.html

EFCOG Semi-annual Executive Council Meeting
When: August 30-31, 2006
Where: DOE, Forrestal Room GH015, Washington, D.C.
Contact: Barbara Pierre at 760-745-1733 or b.pierre@cox.net
For more information:
http://host355.ipowerweb.com/~efcogorg//news/2006%20Calendar.pdf

Upcoming Courses

System Safety for Software-Intensive Systems Course
When: July 10-14, 2006
Where: Talaris Conference Enter, Seattle, WA
For more information: sunnyday.mit.edu/announce06.html

Newsletter Articles Needed

The *Quality Assurance Exchange* is intended to be a forum for the exchange of ideas and the sharing of experience among DOE field offices, contractors, and DOE headquarters in the effort to meet quality assurance requirements. Readers are strongly encouraged to contribute articles on the implementation of QA requirements, on lessons learned, and to offer suggestions.

Please forward your input to:
qaexchange@hq.doe.gov