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INSIDE THIS ISSUE:

*In the Spotlight:
Interview with
Colette Broussard,
Quality Assurance
Administrator,
Office of EM* 1

*"How To" Series
on Performing
Assessments:
Preparing for
Auditing Success* 1

*Lessons Learned:
BNL conducts 3rd
Consecutive Third-
Party Evaluation of
its Assessment
Program* 2

*SQA Work
Activity 2
Software Risk
Management* 3

*Announcements,
Updates, and
Activities* 7

*Upcoming
Meetings
& Workshops* 9

IN THE SPOTLIGHT: INTERVIEW WITH COLETTE BROUSSARD, QUALITY ASSURANCE ADMINISTRATOR, OFFICE OF ENVIRONMENTAL MANAGEMENT

Colette Broussard has extensive background in DOE as a Quality Assurance Engineer, along with experience in safety engineering and environmental management. Colette joined the DOE in 1983 as a QA Engineer at the Pinellas Plant. She transferred to Headquarters with the Office of Defense Programs in the early 90's and then to the Office of Environmental Management (EM) in 1994 where she has held various environmental restoration and waste management positions. Recently, her experience with developing the EM Functions, Responsibilities and Authorities (FRA) document has given her the honor of being chosen for the newly established position of QA Administrator. In a recent interview, Colette shared with us her experience in this newly created role. She discussed her observations from QA Field

assessments and Field Quality Assurance Plans (QAPs) reviews, the challenges in developing the EM-HQ Quality Assurance Program Plan (QAPP), the benefits of having a DOE Order on QA, and the EM Quality Assurance goals.

Describe your role as QA Administrator for EM.

"The QA Administrator is a new position that has been established by the QAPP. As the EM-HQ QA Administrator, I am the primary interface between EM senior management, the Environment, Safety and Health (EH) Office of Quality Assurance Programs (EH-31) and the Field. My responsibilities to the EM-3.2 Deputy Assistant Secretary (DAS), from the QAPP, are as follows:

- Preparing and administering the EM-

(Continued on page 4)

"HOW TO" SERIES ON PERFORMING ASSESSMENTS: PREPARING FOR AUDITING SUCCESS

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

This is the first in a series of articles containing auditing techniques and tools acquired over the years by 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 As-*

essment Guide and can be used to become a more effective auditor.

Our primary objective as participants in the auditing process is to consistently deliver high quality, professionally conducted, value adding audits. You simply can't do this without a lot of preparation. Every hour spent in audit preparation will save the audit team at least two hours of

(Continued on page 5)

LESSONS LEARNED: *BROOKHAVEN NATIONAL LABORATORY CONDUCTS 3RD CONSECUTIVE THIRD-PARTY EVALUATION OF ITS ASSESSMENT PROGRAM*

Over four years ago, senior management at Brookhaven National Laboratory (BNL) decided to subject their self-assessment program to a review by a *third party* (i.e., a team from outside of the parties on the contract, Brookhaven Science Associates and the Department of Energy). BNL had developed and been deploying a somewhat unique approach to addressing the DOE assessment requirements. However, there was some skepticism on DOE's part as to the efficacy of the new process and whether it was truly being embraced by management across the Lab. After consultation with the Department's Brookhaven Site Office (BHSO), contract measures relating to the 3rd Party Review were established and efforts were begun to select a team leader and members acceptable to both parties. The initial 3rd Party Team drafted an evaluation protocol for approval by BHSO and BNL. This protocol has been used and improved for each of the three reviews. The most recent 3rd Party Review was completed September 2005 and is available by request from Gustave (Bud) Danielson, 301-903-2954, or Roy Lebel, BNL, 631-344-3689.

For more information on the BNL assessment program, contact Roy Lebel.

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Features of the BNL assessment program

- Vertical and horizontal views of management system implementation
- Direct participation by the MS owners (horizontal view) and line managers (vertical view)
- Ownership by the Deputy Laboratory Director

Unique elements of the 3rd Party approach

- Evaluation of the assessment program's approach, deployment, and improvement
- Processes tailored to the BNL and BHSO requirements and management systems
- Results converted to numerical scores for comparison to corporate goals and past performance
- Clear path established for progressing through a defined maturity scale

Benefits realized by implementing the BNL assessment program and 3rd Party Review

- Common acceptance of its effectiveness by BHSO and BNL
- Consistent improvements and progression through the maturity scale
- Ready source of performance data for reporting on contractor assurance system

FAQ: *Why does the Order state that 10 CFR 830.120 includes radiological facilities when it doesn't state that?*

The Order is correct in including radiological facilities. 10 CFR 830 states the scope for the QA requirements is: *"This subpart establishes quality assurance requirements for contractors conducting activities, including providing items or services that affect, or may affect, nuclear safety of DOE nuclear facilities."* The Rule further defines nuclear facility to include non-reactor facility and non-reactor facility means *"...those facilities, activities, or operations that involve, or will involve, radioactive and/or fissionable materials in such form and quantity that a nuclear or nuclear explosive hazard potentially exists to workers, the public, or the environment..."*. This inclusion of radioactive facilities is further clarified in EGS 99-01, *Enforcement of 10 CFR Part 830.120 (Quality Assurance Rule) for Facilities Below Hazard Category III*, dated 07/01/99.

SQA—WORK ACTIVITY 2 *Software Risk Assessment*

This is the third article in a series of articles that addresses how the software quality assurance 10 work activities in 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 DOE O 414.1C.

Work Activity 2, Software Risk Management, provides a disciplined environment for proactive decision making to continuously assess what can go wrong, determine what risks are important to address, and implement actions to address those risks.¹

Risk assessment, risk control and risk resolution are the fundamental activities required for project success. Risk assessment addresses identification of the potential risks, analysis of those risks, and prioritizing the risks to ensure that the necessary resources will be available to mitigate the risks. Risk control addresses tracking and resolution of the risks. Risk resolution includes risk avoidance, mitigation, or transference.

Identification, tracking, and management of the risks throughout all phases of the project's lifecycle should include special emphasis on tracking the risks associated with costs, resources, schedules, and technical aspects of the project. Several risk identification techniques are described and detailed in standards and literature.^{2,3}

Examples of potential software risks for the safety software application might include—

- incomplete or volatile software requirements;
- specification of incorrect or overly simplified algorithms or algorithms that will be very difficult to address within safety software;
- hardware constraints that limit the design;
- potential performance issues with the design;
- design changes during coding;
- incomplete and undefined interfaces;
- using unproven computer and software technologies such as programming languages not intended for the target application;
- use of a programming language with only minimal experience using the language;
- unproven testing tools and test methods;
- insufficient time for development, coding, and/or testing;
- undefined or inadequate test acceptance criteria; and
- potential quality concerns with subcontractors or suppliers.

Further guidance beyond that in NQA-1-2000 regarding risk management is provided by IEEE Standard 16085-2004.⁴ SQAS21.01.00-1999, *Software Risk Management: A Practical Guide*, also discusses a risk taxonomy, risk transference, and risk avoidance that may be of interest to the safety software analyst.

For more information contact: debra.sparkman@eh.doe.gov

¹ SQAS21.01.00-1999 (Reference Document), *Software Risk Management: A Practical Guide*, Department of Energy Quality Managers Software Quality Assurance Subcommittee, dated February 2000.

² Christensen, Mark J., and Richard H. Thayer, *The Project Manager's Guide to Software Engineering's Best Practices*, Institute of Electrical and Electronics Engineers Computer Society Press, 2001, pp. 417–447.

³ Society of Automotive Engineers (SAE) JA1003, *Software Reliability Program Implementation Guide*, SAE 2004, Appendix C4.6.

⁴ International Organization for Standardization (ISO)/Institute of Electrical and Electronics Engineers (IEEE) Std 16085, *IEEE Standard for Software Engineering: Software Life Cycle Processes—Risk Management*, IEEE, 2004.

FAQ: *How do the safety software requirements in DOE Order 414.1C differ from those in QC-1?*

The requirements are consistent and complementary. Both require a risk-based graded approach for SQA work activities, the flow down of requirements, and the use of consensus standards. However QC-1 does not specifically identify software safety design. Some work activities specifically identified in DOE O 414.1C are addressed in non-software specific sections of QC-1. An example is training in QC-1 Section 3.2.

“In the Spotlight...” (Continued from page 1)

HQ QAPP;

- Regular interaction with Field QA counterparts, EM-3.2 Site Liaisons, EM-43 and EH-31 on QA issues;
- Coordinating and participating in the review of EM Field Office QAP documents;
- Managing EM directed assessments, audits or review of QA implementation in the Field;
- Annually assessing the implementation of the EM-HQ QAPP;
- Reviewing and approving EM-HQ NQA-1 or 10 CFR 830 project QA plans, procedures or instructions;
- Developing and administering the EM employee QA training program (both general and specialized); and
- Reviewing contractor QAPs where this authority is not delegated to the Field.”

“I am sure other responsibilities will be identified as the QAPP is being implemented.”

Share with us some of your observations from conducting QAP reviews and assessments.

“For the QAP document reviews, I developed criteria based on the QA Order, got assistance from EH with enhancing those criteria, and then used that to review the documents. For the most part, the QA documents received from the field all had similar components with specific areas that needed improvement.”

“In the area of assessments, we have done three that were QA specific where we physically went out to the sites and evaluated the implementation of QAPs. A lot of the assessments that EM-3.2 conducts are part of the feedback and improvement CRAD from the Integrated Safety Management (ISM) guide, which focuses on many QA issues. Next year we are planning on conducting three more assessments that are specifically focused on QA implementation.”

What have been some of the challenges in developing the EM Headquarter’s QAPP? What are some tips you can give to other DOE organizations in preparing their QAPPs?

“One of the major challenges in developing the EM-HQ QAPP is ensuring that the plan gets to the responsible managers for a thorough review. We must consult

with these managers to analyze the plan and communicate clearly the impact it will inevitably have on their organizations.”

“There is also the challenge of understanding how each organization operates. Implementation of the final document will reflect each organization’s responsibilities and capabilities while helping to identify areas that may have been overlooked. This will further improve the EM-HQ QAPP into an executable document.”

“Some tips for other organizations developing a QAPP would be to decide what the organization wants to include in their Plan up front. They need to focus on a topic, gather as much information as they can and grow from there. The topic should accurately reflect the mission and function of the organization and the scope of the QAPP must be attainable. Furthermore, each organization should ultimately rely on the implementation of the plan to determine what’s missing in their QAPP. That is, the process of implementing the QAPP will help an organization discover pieces that may have been overlooked, thus improving the QAPP and making it more complete.”

How is EH supporting you in your efforts to improve QA within EM?

“EH has been extremely helpful with providing assistance in the review of Field QAPs, contractor QAPs, oversight assessments at the Field sites, and interpretation of the QA Order. I believe they can help us in other QA related areas too.”

What are the benefits of implementing the Order 414.1C in your organization?

“The DOE Order 414.C gives structure and meaning to the term QA. Sometimes QA can be seen as a nebulous fuzzy intangible thing that we are expected to implement. The Order provides understanding of what it is we are supposed to be doing. It also gives us an opportunity to better define and document the QA roles we are implementing and determine where we may fall short so that we may improve. With the Order in place we now have something we can measure. QA is all about planning, learning and improving.”

What do you hope to see as the 3 most significant accomplishments of EM in QA for the year 2006?

(Continued on page 6)

“Performing Assessments...” *(Continued from page 1)*

either field investigation or report writing time. The more preparation you do as a lead auditor, the easier it is for your audit team to produce a useful product.

I like to start with a [Lead auditor checklist](#). It identifies the things I have found to be important for a successful audit. Although the items are numbered, I suggest working on the items in an order that works best for you. The checklist should be modified to suit your situation, primarily serving as a reminder of key items that need to be accomplished and their status.

Ideally, the audit notification and plan are issued to the audited organization 30 calendar days before the start of field activity. This helps the lead auditor and the audited organization prepare to conduct an effective and efficient audit. The audit plan should be issued with the formal audit notification. The [assessment plan example](#) (posted on www.eh.doe.gov/qa/) is certainly not as comprehensive as Attachment 1 of DOE G 414.1-2A, (www.directives.doe.gov/pdfs.doe/doetext/neword/414/g414-2a.pdf) but it does contain the key information. You may not always have all the information in time to issue the plan 30 days before field investigation begins. TBDs (to be determined) work fine, and in fact serve as good reminders of yet-to-be completed actions. As a lead auditor, the self imposed 30 days prompts me to assemble my audit team and get on with the other audit preparation in a doable time frame.

Getting your audit team what they need to succeed is one of the primary jobs of the Audit Team Lead (ATL). At the first team meeting, (after the introductions) I go over the audited organization work scope, audit type, requirements basis (i.e. NQA-1-2000), any areas of emphasis, any travel logistics and my contact information. This is usually a good time to establish audit area assignments. My preference is to let the auditors self select the areas they want to cover, with the ATL having the final decision to make adjustments.

At this point the auditors can contact each other to trade audit areas. Jointly emailing what I call the [Audit Staffing, POCs and Completion Status Summary Sheet](#) works well for this. It is very easy for auditors to overload themselves, especially the good ones. To minimize this I have developed an [Audit Work Load](#) spreadsheet that calculates the percentage of NQA-1-2000 requirements assigned to individual auditors. I use the

results of this spread sheet as part of the final ATL assignment adjustments.

After auditor area assignments are finalized, I email the summary sheet to the audited organization point of contact, asking them to insert the audited area organization points of contact with their contact information. I then email it to the audit team. This contact information sharing is essential in setting up appointments and getting appropriate audited organization documents to the auditors before field investigation. It also gives the auditors and their audited organization points of contact the information they need to begin their informal audit preparations.

Before the second team meeting, I send out audit checklists and any other forms the auditors will use during the audit. Checklists are essential to auditor preparation, thorough field investigation and good use of interviewee time. The EH website has some good checklist [examples](#).

At the second team meeting, I like having the audited organization point of contact participate. This can take the place of a pre-audit visit. By listening to and being part of this discussion they can get a better understanding of how the audit will be conducted and often have suggestions on how we can best work together. In the meeting I go over the audit time line, which contains the audit report, meeting times, and expectations. We then go over the checklists and forms that will be used during the audit. I conclude this meeting by asking the auditors to request from their audited organization points of contact documents that will be examined during the audit. I also request that the auditors set up their interviews using the contact information contained on the summary sheet. Setting up the appointments ahead of time is critical to completing the field investigation with minimal impact to the audited organization. The [audit interview and activity schedule](#) is one way of recording this schedule information.

I like to hold the last team meeting about a week before the field investigation begins. By then I will have distributed a copy of the audit report shell to the team. The report shell is the audit report in as complete a form as possible including the format, audit title, number, scope, auditors, content of appendices, etc. This will give the audit team a chance to see what the report will look like, how they need to complete their part, and any

(Continued on page 6)

“Performing Assessments...” (Continued from page 5)

questions they have about the report. This meeting also gives the team a final chance to fill in any information gaps and make any last minute adjustments. By this time you and your audit team should be fully prepared to begin the audit field investigation.

The next installment in this series will discuss some very useful tools for developing managing and communicating issues encountered during audit field investigations.

Credit for developing the presented information goes to the National Spent Nuclear Fuel QA program staff. Ken Scheffter with Project Enhancement Corporation, Karen Brown with Parallax, Inc., Tom Lewallen with Global Technologies Inc. and Don Armour with Battelle Energy Alliance also contributed to this article. For further information contact: Robert.Blyth@nuclear.energy.gov

This article along with the accompanying worksheets may also be found on the DOE EH QA website at: eh.doe.gov/qa/newsletters/How_To_Series1.pdf

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“In The Spotlight...” (Continued from page 4)

“These are the things I expect from the EM QAPP:

1) Leading by example. The EM Program Secretarial Office has embraced the development and implementation of a QA plan at HQ. We have designed our plan with an aggressive but achievable approach that allows us to learn where we need to improve. In addition to monitoring the implementation of our QAPP, I will also be looking at other organizations’ QAPPs and noting useful techniques to further improve the EM-HQ QAPP.

2) Putting lessons learned into effect to continue to improve our QA program at HQ as well as in the Field. This is one of our goals. We can accomplish this by sharing experiences and applying the lessons learned during implementation of the QAPP, setting clear expectations for the Field, and again, leading by example.

3) Helping to solidify a QA mindset and improve it via organization-wide training. We need to educate the entire organization so that everyone has the same idea of what QA is and how it affects the organization. Furthermore, bringing together the concept of ISM and QA and integrating it in all of our work is our primary goal. Our QAPP attempts to, with words, show where the principles and functions of ISM overlap and unify with criterion of QA. I have great hope that implementing our QAPP will facilitate the evidence that integration of QA and safety exists at EM HQ.”

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FAQ: *Our site currently does not use NQA-1-2000. Will this be a big change for our programs?*

DOE O 414.1C invokes a generally accepted nuclear industry standard, NQA-1-2000 or its equivalent. NQA-1-2000 was selected to minimize the impact on nuclear facilities while ensuring acceptable SQA work activities are implemented. The SQA 10 work activities in the DOE O 414.1C and the associated detail in NQA-1-2000 are consistent with other industry standards, such as IEEE software engineering series, ISO, IEC, NASA and ANS. A comparison between the existing site standards and NQA-1-2000 will identify any gaps. The schedule for closing the gaps should be determined by the site and its DOE QAP approval authority. EH support is available to assist in the gap analysis and QAP reviews.

ANNOUNCEMENTS, UPDATES, AND ACTIVITIES

Error in SCALE 5 Impacts Unit Cells

Notification of SCALE 5 Software Error: An error has been identified in SCALE 5 that may impact certain type of unit cells, specifically asymmetric and symmetric slab cells (ASYMSLABCELL and SYMMSLABCELL). Users are encouraged to follow the checklist posted on the [EH website](#) to determine if the error applies to their problems and if the potential impact is non-trivial. The MIPLIB programming will be corrected in SCALE 5.1 which is scheduled for release in March 2006.

Respirator Safety Bulletin

The purpose of this bulletin is to highlight recent respirator failures in the DOE complex. These incidents underscore the importance of maintaining a comprehensive and effective respirator protection program. Respiratory protection is a vital tool for safe work in hazardous and contaminated atmospheres, and respirators are widely employed in accomplishing the DOE mission. The Respiratory Protection Incident is posted on the web: www.eh.doe.gov/paa/safety_bulletins/2005-14.pdf

For information on the
Respirator Filter Recall Safety Alert visit
www.eh.doe.gov/paa/alerts.html

QA Fundamentals Tutorial Update

An updated version of QA training materials is now available online at: www.eh.doe.gov/qa/QATngEH3pec102405.ppt. Readers are encouraged to review the material and modify it as necessary to fit their specific needs for use in providing basic training on the requirements of the DOE O 414.1C and 10 CFR 830.

FAQ: *The SQA section of the order references the 'DEAR ISMS clause.' Can you specify exactly to which DEAR clause you are referring?*

The DEAR ISMS clause 48 CFR 970.5223-1.

Standard Updates

ASME NQA-1 - The Fall meeting of the ASME Nuclear Quality Assurance (NQA) Committee was held during the week of October 10, 2005. Significant progress was made toward achievement of the Committee's top Strategic Plan objective of obtaining United States Nuclear Regulatory Commission (NRC) agreement that a more current edition of the NQA-1 Standard provides an adequate basis for complying with the pertinent quality assurance requirements of Appendix B to 10 CFR Part 50 for commercial nuclear facilities.

As the result of recent consolidations of nuclear utilities, there has been a movement to update multiple unit utility QA programs based on the requirements of NQA-1-1994. There are currently about 40 power plants either committed or considering updating their QA programs to NQA-1-1994. Although the NRC has been supportive of the change to use of the '94 edition, it has been reluctant to endorse a more current edition of NQA-1. The NRC's reluctance to use later editions of NQA-1 began with the '97 edition that was revised to be more performance based.

With the recent expressions of interest by commercial electric utilities in developing new generation facilities, the Administration's support for nuclear power generation, and the ASME Boiler and Pressure Vessel Standards Committee Subcommittee on Nuclear Power (Section III) desire to reference a more current revision of NQA-1, the NRC committee representatives prepared a detailed list of comments for consideration by the NQA Committee. Resolution of these comments will facilitate the NRC process to endorse a more current version of NQA-1.

Upon receipt of the comments last June, an NQA Committee Task Group was formed to expedite development of proposed resolutions for the most significant group of NRC comments. The Task Group results were provided to the full Committee at the Fall 2005 meeting to review, improve, and prepare any ballots needed to revise the NQA-1 Standard. Based on the results of the extensive review accomplished during the meeting, it appears that changes to address the first group of comments will be ready for ballot by the NQA Main Committee late this year. The process will be continued so that proposed

(Continued on page 8)

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EDITORIAL NOTE:

*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*

Happy Holidays!

We're on the Web!

See us at:

www.eh.doe.gov/QA

www.eh.doe.gov/SQA

UPCOMING MEETINGS & WORKSHOPS

14th Annual International Conference on ISO 9000/ Lean & Six Sigma Conference

Event Dates: March 5-8, 2006

- **Golf Tournament:** March 5, 2006
- **ISO 9000:** March 6-7, 2006
- **Lean & Six Sigma:** March 7-8, 2006

Where: Flamingo Hotel, Las Vegas, NV

Info: www.iso9000conference.com / (412) 782-3383

Suspect/Counterfeit Items Training

When: March 7-9, 2006 @ Savannah River

When: March 16, 2006 @ WIPP

Info: Mark Petts 301-903-2414

Nuclear Quality Assurance Committee Meeting

When: March 27- 29, 2006

Where: Phoenix, AZ

Info: <http://cstools.asme.org/csconnect/CommitteePages.cfm?Committee=O10500000&Action=5566>

2006 DOE Price-Anderson Coordinators Training Workshop

When: April 4-6, 2006

Where: Holiday Inn, Gaithersburg, MD

Contact Info: Sue Petersen@eh.doe.gov or
Office of Price-Anderson Enforcement
(301)-903-0100

www.eh.doe.gov/enforce/workshop2006

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