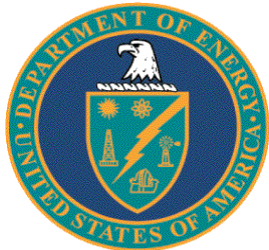


# QUALITY ASSURANCE EXCHANGE

Volume 1, Issue 1  
July 2005

US Department of Energy,  
Office of Quality Assurance Programs (EH-31)



## INSIDE THIS ISSUE:

*In The Spotlight:* **1**  
*Interview with Robert Loesch, Acting Director of Office of QAP*

*A "Continuous Improvement" Success Story* **2**

*From the Field: Summary of Observations EM Field Office QAP Reviews* **2**

*Industry News: ASME NQA-1-2004* **4**

## SPECIAL POINTS OF INTEREST:

- *The latest on Standards and Committees*
- *DOE directives updates*
- *DBFSB briefing*
- *Upcoming meetings and workshops*

## IN THE SPOTLIGHT: INTERVIEW WITH ROBERT LOESCH, ACTING DIRECTOR OF OFFICE OF QUALITY ASSURANCE PROGRAMS

Robert Loesch, DOELAP Administrator, has recently been appointed as Acting Director of the DOE Office of Quality Assurance Programs (DOE/EH-31). In a brief interview with Mr. Loesch, he discussed the major challenge facing the Office of Quality Assurance Programs and the role EH plays in supporting the field and line organizations.

**Q:** *What is the key challenge in Quality Assurance for the Office of Quality Assurance Programs?*

**A:** "Inconsistency. One of the key challenges is the inconsistency of how Quality Assurance is implemented across the complex. Some sites have excellent QA programs while others could use improvement. What would be beneficial would be to identify which sites implement QA effectively and which ones need improvement.

For instance, I recently attended a NNSA workshop at the Savannah River Site. Savannah River is recognized by others as having excellent QA program implementa-

tion. The next logical question is how do we capitalize on that?

The issue is trying to figure out how we can take advantage of good implementations in the field and transfer that knowledge and experience to the other sites. One avenue is through mentoring. Sites that have successfully integrated QA and ISM could mentor a site that needs improvement. Since mentoring is one of the review criteria for VPP Star sites, sites could take advantage of this type of activity – sort of a win-win situation for the field. Hopefully, this newsletter will serve as a vehicle to exchange ideas and best practices between the sites.

We also have the EFCOG QA subgroup, which I support, facilitating the dissemination of information among and between the various site offices and contractors. The subgroup conducts focused studies and reviews and provides feedback to the DOE community. A recent example is the Weld Quality Alert issued by EFCOG.

While this sounds great on paper, the fact is  
*(Continued on page 2)*

## QA REQUIREMENT – ASSESSMENT

From time to time, this newsletter will select one of the requirements in the QA Order and elaborate on key parameters in meeting the requirement(s) and the resultant benefits. This issue will address the requirements related to assessment.

DOE Order 414.1C and 10 CFR 830 Subpart A reflect the concept that all work is a process that can be planned, performed, assessed and improved. The basic requirements are broken into three categories: management, performance, and assessment. Of

these, assessment is the one that provides an evaluation of how well the system is working and feedback on how it can be improved. Assessment is the essential element of continuous improvement.

The Order and the Rule each contain two criteria that address assessments.

**Criterion 9 – Assessment/Management Assessment.**

Ensure that managers assess their manage-  
*(Continued on page 5)*

## A “CONTINUOUS IMPROVEMENT” SUCCESS STORY

by Gustave (Bud) Danielson, EH; Tony Kluk, EM;  
Geoffrey Beausoleil, ID

We are often reminded of the need to work together across organizational lines in order to accomplish our continuous improvement goals. However, we are not often made aware of successful examples. Here is a summary of a success story that is appropriate to share and serves as a great example of how several organizations are improving Quality Assurance (QA) and Integrated Safety Management Systems (ISMS).....together! A complete copy of the “*Continuous Improvement Success Story*” is available on the QA web site at [eh.doe.gov/qa/](http://eh.doe.gov/qa/).

### Developing the Plan

In January 2005, the Office of Environmental Management (EM) teamed with the Office of Environment, Safety and Health (EH), Nuclear Energy (NE), Science, and Technology – Idaho Operations (NE-ID) to conduct a Headquarters assessment of QA and ISMS programs.

The Team first developed the Assessment Plan, starting with applicable QA objectives from DOE P 450.4, DOE O 414.1B and applicable ISMS objectives from DOE P 450.4 and DOE G 450.4-1A.

(Continued on page 3)

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

that every site is a little different in how it operates and applies safety and QA in general. Thus a QA Program that works for one site may not be directly applicable to another site. We have some work to do in this area.”

**Q: What types of support and assistance does EH provide to the field and to the line organizations?**

**A:** “EH works with EM, NE, NA, and SC to provide support on QA assessments, implementation questions, policy clarification, and support for weapon quality assurance surveillances.

So far this year, we have assisted in planning and conducting assessments at Idaho and Oak Ridge, and will

also be assisting Y-12 and Brookhaven. We have assisted EM in developing their headquarters EM QAP and with their review of some of their site office QAPs. NE has asked for our support in their approval process for the new Idaho Operations Office QA Program. We regularly consult with QA management and staff at nearly all of the DOE sites in support of their oversight and implementation issues or questions.

EH will continue to assist the line organizations in developing and reviewing QAPs upon request. We expect to contribute a major part of our resources to assist the Department in implementing the new nuclear safety software requirements recently approved in DOE O 414.1C. We are always available to participate in assessments and assist the line organizations with implementation issues and quality problem resolutions.”

## FROM THE FIELD: SUMMARY OF OBSERVATIONS EM FIELD OFFICE QAP REVIEWS

by Colette Broussard, EM 3.2

EM recently completed a review of Field office QAPs. The review was conducted using review criteria developed by EM in accordance with DOE O 414.1B. The following represents observations based on the overall aggregate assessment of the QAPs. These observations are intended to note possible areas of improvement. Based on this assessment, the QAPs generally exhibited:

1. Lack of clearly defined lines of authority and responsibility.
2. Inadequacy in addressing the requirements for CAMP, S/CI, and Graded Approach.
3. Lack of uniformity in content and form:

- a. Statement of purpose (several did not include such a statement)
- b. Content (Areas to be covered by the QAPs)
- c. Level of detail
  - i. What (what is done to meet the requirements under each criterion.)
  - ii. How (link to procedures)
  - iii. Who (clear delineation of the position that is responsible)
4. Lack of clear and uniform understanding of the requirements. e.g., use of implementation standards, reporting relationships between the field and HQ, implementation of graded approach.
5. Lack of description of flow down of requirements to the prime contractor and subcontractors.

(Continued on page 4)

**“Success Story”** ... (Continued from page 2)

Next the team developed detailed lines of inquiry in each of the QA and ISMS assessment areas. The assessment was planned as a limited-scope assessment looking at ISMS, Suspect/Counterfeit Items (S/CI) prevention process implementation, Corrective Action Management Process (CAMP), Software QA, and several other QA topical areas. A second assessment by NE is planned for late 2005 or early 2006 with a broader scope to include all ten QA criteria and ISMS as applied to the entire NE-ID organization.

**Performing the QA/ISMS Assessment**

When NE-ID received the assessment plan prior to the assessment, they conducted their Self-Assessment in all the topical areas. This was an excellent practice, and one highly recommend for other sites. As a result, NE-ID identified many findings and observed a number of weaknesses that they were able to begin addressing before the Team arrived. The Team found the lines of inquiry to be helpful in performing the assessment.

The Team used Criteria Review and Approach Documents (CRADs), previous DOE assessment reports, and other reference documents to conduct the assessment. The results of the January 2005 limited-scope assessment were documented in the March 14, 2005 report, *Quality Assurance/Integrated Safety Management Assessment Final Report*.

**Improving Your Assessment Plan - Conclusions**

After the final assessment report was issued, the Team incorporated the “lessons learned” into the Assessment Plan. The lines of inquiry were updated to include additional questions and expanding other questions based on

NE-ID subject matter expert suggestions. The assessment plan was also made more “generic” or “fill-in-the-blank” for in case of usage by other organizations.

The process of developing this NE-ID assessment plan, conducting the assessment, and then using the lessons learned to improve the plan so that others can benefit from it is a good example of the Quality Assurance principles of “continuous improvement” and “feedback.” The improvement process is ongoing and further success depends on using the tools and further refining them.

**Key Benefits and Suggestions  
to Improving Your Assessment Plan:**

- Availability of a complete “fill-in-the-blank” QA/ISMS assessment plan you can use immediately and tailor to your organizational needs.
- Continuous improvements benefit from sharing lessons learned.
- Choose your assessment team in a way that integrates the major organizations with vested interest in improving QA/ISMS performance; consider having observers participate.
- Involve the organization to be assessed early in the assessment planning stages.
- Consider implementing multi-stage assessments and/or assessing certain QA/ISMS areas at different times.
- Focus your assessment on the higher-risk projects or activities and use the lines of inquiry in the “generic” assessment plan to increase efficiency.
- Suggest that the organization to be assessed consider conducting a Self-Assessment on the areas prior to the arrival of the assessment team, initiate corrective actions, and provide the assessment team a list of known deficiencies.
- Follow the professional example of NE-ID by being responsive to any and all requests of the assessment team.

## DOE DIRECTIVE UPDATES

**Completed:**

The Office of Quality Assurance Programs (EH-31) has completed updating the DOE QA Order and two associated guides: DOE O 414.1C – *Quality Assurance*, DOE G 414.1-2A - *Quality Assurance Management System Guide*, and 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*. These directives are expected to be issued in July. Sign up for auto notice at [www.directives.doe.gov](http://www.directives.doe.gov).

**Planned:**

EH-31 will be in a revision of DOE G 414.1-1A -*Management Assessment and Independent Assessment Guide for use with 10 CFR, Part 830, Subpart A, and DOE O 414.1A Quality Assurance; DOE P 450.4, Safety Management System Policy, and DOE P 450.5, Line EH&H Oversight Policy*. EFCOG will be providing subject matter expertise to support this effort. The revised guide will address changes in the standards (ISO 19011, NQA-1-2004) and industry experience and will also incorporate EFCOG Assessment Guide developed by Price-Anderson working group. The work will also be coordinated with the revision 2004-1 oversight manual. A small writing team will include members from DOE, its contractors from organizations and EFCOG working under the directions of Bud Danielson, EH-31.

**“From the Field “...**

(Continued from page 2)

A possible key reason for the field office QAPs’ lack of uniformity and adequate detail is not having pre-existing customer expectations. One way to address this may be clearer and earlier communication with the field offices to create uniform and clear understanding of HQ expectations in these QAPs. This includes clarifications on the level of detail needed to effectively meet the requirements in DOE O 414.1B or any subsequent order change.

Based on the actual results of the reviews, a coarse grading approach was developed to assess the major areas of deficiencies. Four levels/grades were identified: a) deficient, b) significant improvement may be needed, c) could use some improvement, and d) adequately addressed. The review results were used to assess each field office’s QAP using this coarse grading approach.

For more information, contact Colette Broussard, [colette.broussard@em.doe.gov](mailto:colette.broussard@em.doe.gov).

| QA Requirement                        | Field Site Offices |       |   |     |        |     |     |     |
|---------------------------------------|--------------------|-------|---|-----|--------|-----|-----|-----|
|                                       | A                  | B     | C | D   | E      | F   | G   | H   |
| <b>Grading Using Color Codes</b>      |                    |       |   |     |        |     |     |     |
| FRA Reference                         | [Color-coded grid] |       |   |     |        |     |     |     |
| Organization                          | [Color-coded grid] |       |   |     |        |     |     |     |
| Consensus Standards Reference         | [Color-coded grid] |       |   |     |        |     |     |     |
| Safety Policies and QA Req. Reference | [Color-coded grid] |       |   |     |        |     |     |     |
| <b>DOE O 414.1B Criteria</b>          |                    |       |   |     |        |     |     |     |
| Program                               | [Color-coded grid] |       |   |     |        |     |     |     |
| Training and Qualification            | [Color-coded grid] |       |   |     |        |     |     |     |
| Quality Improvement                   | [Color-coded grid] |       |   |     |        |     |     |     |
| Documents and Records                 | [Color-coded grid] |       |   |     |        |     |     |     |
| Work Processes                        | [Color-coded grid] |       |   |     |        |     |     |     |
| Design                                | N/                 | N/A   |   | N/A |        | N/A |     | N/A |
| Procurement                           | [Color-coded grid] |       |   |     |        |     |     |     |
| Inspections and Acceptance            | [Color-coded grid] |       |   |     |        |     |     |     |
| Management Assessment                 | [Color-coded grid] |       |   |     |        |     |     |     |
| Independent Assessment                | [Color-coded grid] |       |   |     |        |     |     |     |
| S/CI Prevention Process               | [Color-coded grid] |       |   |     |        |     |     |     |
| Use of CAMP                           | [Color-coded grid] |       |   |     |        |     |     |     |
| Tracking QAP Development              | N/                 | N/N/A |   | N/  | N/AN/A | N/A | N/A | N/A |
| Requirement Flow Down                 | [Color-coded grid] |       |   |     |        |     |     |     |
| Software QA                           | [Color-coded grid] |       |   |     |        |     |     |     |
| Graded Approach                       | [Color-coded grid] |       |   |     |        |     |     |     |
| References to Drivers                 | [Color-coded grid] |       |   |     |        |     |     |     |

**KEY:**  
 Adequately Addressed  
 Could Use Some Improvement  
 Significant Improvement May be Needed  
 Deficient

This QAP review was conducted in late 2004. Since then, the site offices have diligently revised their QAPs addressing the comments provided based on the above. It has been reported that many concerns have been removed and most of the QAPs have been or are in the process of being approved.

It should be noted that the adjacent observations looked at the QAPs as written and do not reflect an assessment of the quality of the operations at the field offices. A more complete assessment of the QA program would in general include three elements: the paper (QAP, procedures), the people (qualification of personnel), and performance (implementation). This review addressed only the paper and was limited to the QAP. The field offices may have clearly defined processes and procedures for the work they do; however, the QAP may not provide adequate reference to these documents. Furthermore, the degree of implementation of these processes and procedures at the various field offices is not known. Therefore, this review and its results should be viewed only as one part of the overall assessment that would include the above mentioned elements.



## RECENTLY PUBLISHED ASME NQA-1-2004

### INDUSTRY NEWS: QUALITY ASSURANCE REQUIREMENTS for NUCLEAR FACILITY APPLICATIONS

ASME NQA-1-2004, *Quality Assurance Requirements for Nuclear Facility Application* is ready to support the design and construction, operation and decommissioning of new nuclear facilities. NQA-1-2004, an American National Standard, is the culmination of over 25 years of work by the ASME NQA Committee and is the nation’s only current nuclear quality assurance consensus standard covering all types of nuclear facilities. In a manner that is compliant with O 414.1C and 10 CFR 830, DOE O 414.1C requires the use of standards to develop and implement the QAP and indicates NQA-1 as the appropriate standard for nuclear activity. The Committee meets twice a year to ensure that the Standard supports the needs of today’s nuclear industry’s future challenges. The main 35 member NQA Committee is composed of volunteers from the industry, nuclear utilities, DOE, subcommittees and various regulatory organizations.

In addition to fine tuning the basic quality requirements and introductions to improve their clarity, the quality requirements have been revised to address new technology and regulatory subjects, such as the use of computer programs, electronic media and information, and commercial grade items. The new edition contains application guides that include a comparison with ISO 9001-2000, DOE Order 414.1 and 10 CFR 830, Subpart A, as well as a guide for managing electronic information. Additional applications guides are being readied for publication in the Standard’s 2005 Addenda that will be distributed to all holders of the 2004 edition.

To obtain your copy go to [ASME.org/catalog](http://ASME.org/catalog). For information on joining the Committee, contact Steve Rossi, Secretary, [steve.rossi@asme.org](mailto:steve.rossi@asme.org) or John Adkins, Chair, [jgadkins@southernco.com](mailto:jgadkins@southernco.com).

***NQA-1-2004, an American National Standard, is the culmination of over 25 years of work by the ASME NQA Committee and is the nation’s only current nuclear quality assurance consensus standard covering all types and life cycle phases of nuclear facilities.***



**“QA Requirement”...** (Continued from page 1)

ment processes and identify and correct problems that hinder the organization from achieving its objectives.

**Criterion 10 – Assessment/Independent Assessment.**

- (a) Plan and conduct independent assessments to measure item and service quality, the adequacy of work performance, and to promote improvement.
- (b) Establish sufficient authority and freedom from line management for independent assessment teams.
- (c) Ensure that persons conducting independent assessments are technically qualified and knowledgeable in the areas to be assessed.

The purpose of an assessment is to identify current conditions for a particular aspect of an organization or its work, identify the intended or desired conditions, and to identify any necessary corrective action. The Order and Rule require both management assessments and independent assessments. **Management assessments** are intended to identify the management aspects of performance and make improvements. **Independent assessments** are intended to improve product and service performance and process effectiveness.

Assessments may also address different activity levels within an organization, namely **processes**, **systems** or **programs**. A **process** is a collection of actions that produce an intermediate outcome and these assessments involve examination of work controls and their implementation. A **system** consists of two or more processes that yield a completed product or service and these assessments are performed to ensure human and material resources are being properly used. A **program** consists of multiple interdependent systems with a number of interfaces to provide the desired product or service. This level of assessment is critical for protecting workers, the public and the environment.

Third-party assessments also provide valuable feedback for improving performance. Third-party assessors typically assess for performance to or conformance with national or international standards Regulatory bodies, such as the NRC or the EPA, measure compliance with regulatory requirements, standards, and related commitments. Third-party assessors have at least one common interest: determining whether an organization has established and implemented an effective assessment process.

Assessment methods can address **compliance**, **effectiveness** or **performance**, and a good assessment will use elements of all three. **Compliance assessment** verifies compliance with requirements through the implementation of procedures. Contractual and regulatory requirements imposed on the organization are determined, flow down of those requirements to implementing documents such as procedures

is verified, and the implementation of the procedures is verified in turn.

**Effectiveness assessment** goes beyond compliance determinations to establish whether compliance has resulted in effective implementation of the intent of top requirements. The assessor is expected to determine if noncompliances with procedures could result in a failure to satisfy upper tier requirements.

**Performance based assessments** first address the adequacy of the process that produced a product or service, and then address the product itself. Performance based assessments place great emphasis on considering all factors affecting the acceptability of a product. Such factors might include, for example, how product specifications were established, what worker skills are required, what worker training is provided, and how process improvements are developed and implemented. Performance based assessment provides highly useful information to management, but it requires a higher level of competence on the assessment team.

Managers should be involved in the assessment process to ensure that assessment results contribute to improved performance. Assessments should provide timely feedback to managers on the effectiveness of management and work processes. Equally important, managers must take timely actions to resolve problems identified by assessments. An effective assessment program builds confidence that organizations can meet customer expectations. Assessments also provide objective evidence of those areas where improvement is needed to achieve organizational goals.

### **DOE Briefs the DBFSB on Quality Assurance**

Periodically, EH, NNSA, and EM brief the Defense Nuclear Facilities Safety Board (DNFSB) on QA related issues. The most recent briefing was conducted on June 1, 2005 at the DNFSB offices in Washington D.C. Similar briefings have also been conducted for Software Quality Assurance (SQA). Starting with the next briefing anticipated to occur in September, 2005, the QA and SQA briefings will be combined.

The presentation slides used by EH in these briefings are available on line at [www.eh.doe.gov/qa](http://www.eh.doe.gov/qa)

For additional information on DNFSB briefings, please contact Robert Loesch at 301-903-4443, [robert.loesch@eh.doe.gov](mailto:robert.loesch@eh.doe.gov)

US Department of Energy,  
Office of Quality Assurance  
Programs (EH-31)  
Washington, D.C.

**Contact:**

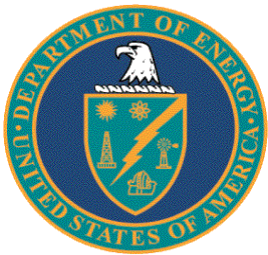
Bud Danielson

**Phone:**

(301)-903-2954

**E-mail:**

[bud.danielson@eh.doe.gov](mailto:bud.danielson@eh.doe.gov)



**We're on the Web!**

See us at:

[www.eh.doe.gov/QA](http://www.eh.doe.gov/QA)

[www.eh.doe.gov/SQA](http://www.eh.doe.gov/SQA)

## UPCOMING MEETINGS & WORKSHOPS

### ***DOE O 414.1C Issued***

Mark your calendars for ***July 25 from 2p – 4p EDT*** to attend the **general information video/teleconference meeting**. More details will be announced closer to the meeting date.

***For additional information, please go to:*** [www.eh.doe.gov/sqa](http://www.eh.doe.gov/sqa)  
or contact Debra Sparkman, [debra.sparkman@eh.doe.gov](mailto:debra.sparkman@eh.doe.gov)

### ***7th NNSA Nuclear Facility Quality Assurance Workshop***

***Date:*** August 9-10, 2005

***Location:*** Sandia National Laboratory, TA IV facilities.

***Expected Outcomes:*** drafts of NNSA Safety Software QA Good Practices Handbook, Guidance on Integration of QA and ISM, Flow down of QA/ISM Requirements from NNSA to M&O Contractors, Subcontractors and Vendors, and updates to the Roadmap for QA Excellence path forward and milestones.

***Participants:*** staff from NNSA Headquarters, Service Center, M&O Contractors, EH, EM and DNFSB.

***Contact:*** Nancy Day at 301-903-9408, or [Nancy.Day@nnsa.doe.gov](mailto:Nancy.Day@nnsa.doe.gov)

***The agenda will be posted on the NNSA QA Website  
(<http://hq.na.gov/dpqa>) by July 15.***

#### **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:** [bud.danielson@eh.doe.gov](mailto:bud.danielson@eh.doe.gov)