QUALITY ASSURANCE EXCHANGE

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U.S. Department of Energy
Office of Corporate Safety Analysis

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Office of Health, Safety and Security

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EM INITIATES QA EVALUATION PLAN

In response to Secretary Bodman's memorandum ***"Improving Quality Assurance"*** (April 2006), and in an effort to improve quality assurance issues within line item construction and operational projects, the Office of Environmental Management (EM) has developed a QA Initiative Evaluation Plan. The purpose of the EM QA Initiative Evaluation Plan is to conduct a series of QA evaluations of EM work with the primary focus to identify project QA requirements and evaluate the extent to which these requirements are being implemented against the work being performed and planned.

The results of this effort will:

- Identify where EM does not have the necessary QA infrastructure and resources to meet mission needs,
- Identify the regulatory framework and business needs that influence EM quality program requirements,
- Provide the basis for considering an EM-wide quality assurance program specific requirement,
- Provide the basis for the development of mechanisms to address quality issues early in a projects' life cycle,
- Promote the sharing of lessons learned specific to QA implementation issues, and
- Facilitate a cultural change, at all levels of EM management, that takes a proactive approach to the self-identification and addressing of quality related issues.

The Office of Management and Operations (EM-60) will execute the EM QA Evaluation Plan schedule, conducting six project evaluations by the end of this fiscal year; the first of which is to start this month.

A future QA Exchange newsletter will feature EM-60 in a full interview on the EM QA Evaluation Plan. For more information on the EM QA Initiative, please contact Bob Murray at Robert.Murray@em.doe.gov

WTS SHARES ISSUES MANAGEMENT PROGRAM

Identifying and correcting problems at an effective level at a DOE nuclear facility is absolutely essential. Ineffective approaches may lead to unsafe working conditions, high cost, and tarnished performance records.

Washington TRU Solutions LLC (WTS) is the managing and operating (M&O) contractor for the Department of Energy/Carlsbad Field Office (DOE/CBFO) at the Waste Isolation Pilot Plant (WIPP). The Plant is designed to permanently dispose of transuranic (TRU) radioactive waste left from the research and production of nuclear weapons. Located in Southeastern New Mexico, plant facilities include disposal rooms excavated in an ancient, stable salt formation 2,150 feet underground. TRU waste consists of clothing, tools, rags, and other disposable items contaminated with trace amounts of radioactive elements, including plutonium.

The DOE requires contractors to implement an effective Integrated Safety Management System (ISMS) for the facilities they operate in accordance with DOE Policy 450.4, ***"Safety Management System Policy."*** The five ISMS core functions describe the specific work activities that must be accomplished, including "Provide Feedback and Continuous Improvement."

(continued on page 3)

"How To" Series on Performing Assessments:

Preparing to be Audited

*This is the fifth 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 or auditee.*

Preparation Before an Audit

It is just as important for the organization that is being audited to be prepared as it is for the auditor. Like an auditor, the organization must perform pre-audit activities to ensure an efficient and productive audit. The following list provides some best practices on preparing to be audited.

1. Be prepared; get a copy of the audit checklists if possible, or at least review the audit plan. Test yourself and have objective evidence documents located. Some individuals even build objective evidence files for the auditors for each checklist.
2. Perform a pre-audit surveillance of known audit areas at least one month ahead of scheduled audit, ideally using the lines of inquiry that will be used in the upcoming the audit. Asking for the lines of inquiry never hurts.
3. Provide in-house training for those individuals who will interface with auditors. Demonstrate what quality means to the project and provide your staff with the audit objectives, checklists if possible, and audit conduct.
4. Ensure the audited organization's Quality Engineer has adequate time to support the project.
5. Provide the auditor with a point of contact list including names, phone numbers, etc. of the people involved with the audit.
6. Provide a brief overview of your activities and processes at the entrance meeting. This level of effort will depend on the type and customer of the audit.
7. Provide a facilitator for the audit. If a large audit, provide each auditor with prepared documents and scheduled interviews.
8. Have badging and other logistics worked out before auditors arrive and appoint a greeter to be available upon arrival.
9. Provide adequate facilities for the auditors; there is nothing worse than a mad auditor.
10. Have appropriate level of management at both the entry and exit meeting. This step is often missed and the level will change depending on the type and customer.
11. Have your implementing documents readily available.
12. Have a support team of personnel responsible for different functions during the audit.
13. Have a rapid response person / group to identify any audit finding quickly and work hard to close problems during the audit.
14. Review problems found and use them as lessons learned. They may be applicable to other areas.

The Art of Being Audited

There is an art to being audited. Knowing how to respond and cooperate with auditors is key in having a pleasant and successful audit. The following are general, common sense tips on how to behave during an audit interview.

1. Be friendly and open. Answer questions concisely, objectively, and honestly.
2. Listen carefully to what the auditor is telling you. If you don't understand, ask for clarification.
3. If you do not know the answer to a question, say so and indicate that you will get the answer – or pass the question on to your Task Manager or the QA Specialist. Do not try to finagle your way through.
4. Demonstrate you know your stuff. Even if you make a mistake or your process has anomalies, an auditor is impressed with individuals who are proud of their work and know the process.
5. Do not debate or argue with an auditor. If you think an auditor has come to a wrong conclusion, let the QA Specialist or Task Manager debate these issues during the daily close-out meetings.

Make Preparation an Ongoing Event

Being prepared for an audit should be an ongoing event. It is necessary to maintain records, documents, and equipment on a regular basis. Knowing your responsibilities as a participant in an audit will help to eliminate confusion, misinformation, and last minute panic prior to an audit. The following are some highly recommended steps to follow on a regular basis.

1. Follow your rules, procedures, inspection plans, and data acquisition methods, and check for revisions.
2. Ensure equipment works properly prior to use.
3. Ensure calibrations are within required dates.
4. Record data according to procedures.
5. Follow requirements and fill out logs.
6. Fill out required laboratory notebooks and logs correctly.
7. Have a good surveillance plan in place that covers all elements used to implement quality. Complete these surveillances throughout the year.
8. Alert the Task Manager or QA Specialist when any work-impacted problem such as an equipment malfunction, a calibration issue, a problem with procedures or data recording, any safety or health related event, or an unexpected work result.
9. Use your "Stop Work Authority." If you ever are in doubt or suspect, stop and ask questions.

Credit for developing this article goes to
Bob Blyth, NE; Gary D. Roberts, BEA;
Ron Peterson, CWI; Mark Vance, ORNL (DOE)

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"WTS Shares…." *(continued from page 1)*

The Feedback and Improvement function completes the ISMS loop and is intended to identify and correct issues, activities, or deficiencies which result in unsafe or undesired work conditions. This function also provides managers and workers with information to improve the quality and safety of subsequent similar work.

WTS is committed to achieving the highest standards of integrated safety and quality management systems, developed around a culture of continuous improvement. Cultivating that commitment, WTS has designed and implemented a new process integral to the feedback and improvement function, the Issues Management Program/Processing of WIPP Forms or the WIPP Form program.

The WIPP Form program implements a robust process to identify issues that require correction, improvement, or management attention at the lowest, effective organizational level.

Program Description

The WIPP Form program, developed to replace a classically modeled Corrective Action Request (CAR) program, is a formal process designed to capture, evaluate, and track the resolution of issues, deficiencies, and associated actions.

The pre-existing CAR program was limited to correcting conditions adverse to quality as are typically found in an operating environment. The CAR program was not designed to capture a broad spectrum of issues; appeared to be "owned" and driven by the Quality Assurance Department; and was not producing the desired long-term corrective action resolutions or improvements.

The WIPP Form program implements a robust process to identify issues that require correction, improvement, or management attention at the lowest, effective organizational level. The scope of the program has been increased to address issues of both high and low significance. Assessment findings and safety issues are also submitted through this process. Any employee may submit a WIPP Form for any deficiency, discrepancy, safety issue, or concern. Further, WIPP personnel are charged with the responsibility of identifying issues and submitting them on a WIPP Form. Please note that although any issue may be submitted via the WIPP Form process, it does not replace the established Employee Concerns program administered by WTS Human Resources.

The WIPP Form program incorporates "best practices" from similar programs at commercial nuclear power facilities across the Nation. Process design included moving control and ownership of the program to the WTS General Manager's office, and promoting representation from management within the company, thus minimizing the perception of the Quality Assurance organization as the sole process owner/driver. The WIPP Form Screening Committee is chaired by a manager appointed by senior management, and is composed of representatives or management of organizations critical to site operations.

Although not required, WIPP Forms are typically reviewed by the originator's manager prior to submittal to the WIPP Form Coordinator. Line management review is not designed or implemented as a screening tool, rather it provides an opportunity for line management to be aware of issues that are being formally presented for consideration. Once the WIPP Form enters the process, the WIPP Form Screening Committee becomes the "hub" of WIPP Form activity, assessing the identified condition(s); ensuring the notification and involvement of all appropriate organizations; reviewing any subsequent Corrective Action Plans; and monitoring proposed corrective actions through closure. Completing the cycle, the WIPP Form Coordinator provides feedback to the originator. This multi-level process fosters communication and awareness of issues, and enhances development of long-term, effective resolutions.

In summary, elements of the WIPP Form process include a multi-level communication loop; a Screening Committee consisting of management level personnel; assignment of management responsibility for corrective action; assignment of additional reviewers (other affected managers, etc.), as necessary, with one assigned the lead role; Committee review of corrective action plans; and maintenance of the completed WIPP Forms with associated evidence of corrective action as records.

Benefits of the WIPP Form Process

Implementation of the WIPP Form process has produced three primary benefits: (1) an input process, available to all employees, providing an opportunity to identify and address issues at the key, first level of the organization, leading to more robust preplanning of work, and follow-up measures to prevent serious injury or damage to equipment; (2) a "no fault" attitude encouraging employees to report issues and identify barriers to achieving safety and environmental standards; and (3) usage of one form to document issues of both low and high significance (including suggestions for improvement), and to address a broad spectrum of issues including, but not limited to, health and safety, quality, employee suggestions, and personnel concerns. The SIPP Form program streamlines the issues resolution process for the employee, administrator, and management.

The WIPP Form program incorporates "best practices" from similar programs at commercial nuclear power facilities across the Nation.

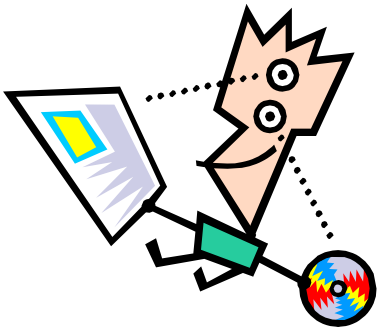
Written and submitted by Jon Hoff and Cathy Nesser, WIPP, WTS QA. For more information on the WIPP Form program, please contact Cathy.Nesser@wipp.ws

SQA WORK ACTIVITY #5 Software Requirements Identification and Management

(*This article is the fifth in a series addressing how the safety 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.)*

Safety system requirements provide the foundation for the safety functions that will be implemented with software. Those system requirements are translated into software requirements that include:

- Functions of the software, including the boundaries of software operation, and how the software is to behave under unanticipated or abnormal events, i.e., failure in a safe mode;
- Specific safety functions that will be performed by the software;
- Performance requirements for the software;
- Security that will be implemented via software, including user access control;
- Interfaces of the software to the system and other systems;
- Design constraints; and
- Installation considerations.



Software requirements should be:

- Complete - requirements define, in total, the functions that the software will perform;
- Correct - requirements match to the intended use of the software;
- Consistent - requirements offer no conflicts with other software or system requirements;
- Clear - requirements are understandable with no ambiguity and do not require interpretation;
- Verifiable - by review and testing, objective evidence can conclude that the requirements are implemented; and
- Feasible - the requirements can be implemented with current technology within the constraints imposed upon the software.

Software requirements must be documented. The software requirements may be documented in system level requirements documents, software requirements specifications, procurement contracts, and/or other acquired software agreements. The form of documentation is driven by the type of safety system software. Custom developed software most likely will contain a larger number of software requirements than configurable, acquired, utility calculation, or commercial design and analysis tool software, and thus, a separate more formal document may be applicable. The requirements for safety system software in control systems may be documented in system documents and drawings.

Documented software requirements are managed to minimize conflicting requirements, to maintain accuracy for validation activities, and to ensure that software placed into operations functions properly. If managed effectively, software requirements are traceable throughout the software life-cycle.

Submitted by Toni Austin, Mgr, IS&T Systems Engineering, Bechtel

FAQ

Our site's SQA program is based on 10 CFR 830, ASME NQA-1-2000, QC-1, RW 0333P, and DOE Orders. Our SQA / QA program and implementing procedures cover all software. Can we continue to use our grading levels if they are different from those suggested in the Guide?

DOE Order 414.1C requires grading levels to be established, documented, and approved in the QAP. This Order does not specify the number of grading levels or their criteria. Once the site's QAP complies with DOE O 414.1C and is approved by DOE, the grading levels can be used for safety software.

COMMUNICATION IS KEY WHEN AUDITING SUPPLIERS

In today's nuclear industry marketplace such as DOE's Office of Civilian Radioactive Waste Management's (OCRWM) Yucca Mountain Project, multi-million dollar orders are not the norm. The services needed may just be for calibration, spare parts, material testing or other quality related services. Unfortunately, you don't have the power to require wide-sweeping changes to the suppliers' program or methods. However, there is a supplier audit process that will provide some control. This article will focus on auditing large and small service supplier facilities.

The first step in the supplier audit process is to communicate with the user organization to determine the scope of services and what quality and technical requirements apply. The quality auditor must understand the requirements prior to communicating with the supplier. Part of this communication is to ensure that the user organization has been in contact with the supplier and the supplier is aware of the potentially numerous quality and technical requirements and the value of the potential contract.

Next, you need to contact the supplier to obtain applicable quality assurance documents, e.g., manuals or procedures, and inform the supplier that an audit will be required to complete the qualification process. This is where communication becomes important as the supplier will want to know why it is being audited for such a small order. The key to open and clear communication with supplier personnel is to remain professional and remember who you are representing. (e.g., the U.S. government or contractor organizations).

Once the audit dates are set with the supplier, you will need to get there. Now comes the fun or painful part, depending on numerous obstacles beyond your control, travel. Again, communication with the supplier and other audit team or user organization personnel is very important. You need to know where the supplier is and obtain directions from the supplier. Internet maps and rental car maps are a good starting point, but nobody is better prepared to tell you how to get somewhere than someone who is familiar with the area. Be sure and ask which airport and hotels are closest or most convenient. Ensure that your team members or others (OCRWM frequently has observers attend audits) know where to go and what time to arrive. Don't be late. It can take far longer than you think to get there, so make sure you ask.

The next step is performing the audit. Since you need the supplier services and probably aren't a large part of the supplier's business, special considerations should be considered while keeping in mind that the user organization's requirements still must be met. Listed below are some things to remember during the audit process.

- You may have to explain the meaning and intent of the requirements.
- Explain why you are doing an audit instead of just accepting a third-party certificate.
- Keep meetings and discussions at the appropriate level of formality.
- Don't overwhelm the auditee with demands.
- Assure that proper controls are in place, which may not always be reflected in detailed manuals, procedures, etc.
- You will want to try and complete any necessary corrective actions while you are there to avoid time consuming (auditor and auditee) follow-up actions.
- Plan enough time for the audit to ensure completion
- Be interested in what the supplier does and how it is done.
- Ensure your documentation (checklist) is completed.
- You may have little luck in recommending changes.
- The user may have to become involved if requirements cannot be met or need to be changed.
- When you are done, leave; don't linger or make up things to do.

Finally, prepare your report and obtain the necessary approvals. Remember who the audience is (supplier and user) for the report.

Written and submitted by Patrick Auer, QA Consultant, Yucca Mountain Technical Services Group, PEC. For more information please contact Pat Auer at pauer@notes.ymp.gov

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

Safety Software Central Registry Activities

TOOL BOX CODE CORNER

Hotspot Evaluation Concluded

The evaluation of Hotspot Health Physic code, developed by Lawrence Livermore National Laboratory, was completed in March 2007. The evaluation results are documented in DOE/HS-0003: Software Evaluation of Hotspot and DOE Safety Software Toolbox Recommendation. Five work activities (software configuration management, verification and validation, problem reporting and corrective action, training, and model validation/performance) include critical recommendations that if implemented properly will increase the level of compliance for those work activities to acceptable quality levels. Upon successful implementation of these critical recommendations, Hotspot will be included in the DOE safety software Central Registry. This inclusion is expected late 2007.

For more information please contact Debra Sparkman at debra.sparkman@hq.doe.gov.

Activities, Updates, & Announcements

QA on the Defense Board Agenda

On March 16, 2007, the Office of Health, Safety and Security's Office of Corporate Safety Analysis (HS-30), along with representatives from the Office of Environmental Management and the National Nuclear Security Administration, briefed the Defense Nuclear Facilities Safety Board (DNFSB) Members on the status of QA efforts for the Department and each respective Program Secretarial Office. The DNFSB interests included, in part, "QA in design" activities, the QA Effectiveness Survey, and overall impressions on where the Department is finding QA issues. Further briefings to the Board Members are anticipated to show progress with the Department's QA efforts.

DOE QA Guide 414.1-1X Under Revision

The DOE QA Guide 414.1-1X ,***"Management & Independent Assessments,"*** is being revised. Comments received from both DOE HQ and Field, as well as DNFSB staff are being addressed, and the Guide updated accordingly. It is anticipated that the new revision will be out in early May 2007.

DOE-STD-1172-2003 Update

A working group of subject matter experts from Headquarters and the field has been formed to update DOE-STD-1172-2003 to assure consistency with the provisions of DOE O 414.1C and DOE G 414.1-4.

DOE-STD-1172-2003, ***"Safety Software Quality Assurance Functional Area Qualification Standard"*** was developed in response to a commitment in the Department's Implementation Plan for DNFSB Recommendation 2002-1, Quality Assurance for Safety Software at DOE Defense Nuclear Facilities.

Following the release of DOE-STD-1172-2003, DOE O 414.1C, ***"Quality Assurance"*** was revised and DOE G 414.1-4, "***Safety Software Guide"*** for use with 10 CFR 830 "***Subpart A, Quality Assurance Requirement"*** and DOE O 414.1C**,** ***"Quality Assurance***" was issued in June 2005.

The current schedule has the revised standard completed at the end of the year.

For more information, please contact Subir Sen at subir.sen@hq.doe.gov.

FAQ

Facility design software used by a DOE contractor may be graded differently than the same software used by a supplier of design services to the DOE contractor. Why does DOE G 414.1-4 recommend different grading of the work activities?

There is a difference in grading work activities. The reason has to do with how much control the DOE contractor has over selecting the facility design safety software tool. When a DOE contractor uses the software, the contractor has control over the procurement of the safety software design tool, acceptance testing of the tool, and the training of the users of the design tool (and some other things). However, if that same contractor hires a company to perform the design, the DOE contractor is procuring a "service" not a tool. Thus, the contractor may not have control over the tool being selected. Although DOE G 414.1-4 describes a different graded approach in this instance, the flow down of requirements of DOE O 414.1C and 10 CFR 830 must be met.

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EDITORIAL NOTE:

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hss.energy.gov/csa/csp/qa/

Upcoming Meetings & Confernces

ASQ World Conference on Quality and Improvement
When: April 30– May 2
Where: Orlando, FL
Contact: Dale Tuttle 414-272-8575 x7438
For more info: http://wcqi.asq.org

EFCOG ISM Working Group Semi-Annual Meeting
When: April 30-May 4
Where: Atlanta, GA
For more info:
http://efcog.org/wg/ism/events/Spring07Mtg/ISMWGSpring07mtg.htm

EFCOG Environmental Subgroup of the ISM Working Group
When: May 10-11
Where: New Orleans, LA
For more info: http://efcog.org

ANS Annual Meeting
When: June 24-28
Where: Boston, MA
For more info: www.ans.org/meetings/annual/

FAQ

The DOE Order 414.1C is silent on software quality requirements for "non-safety software." What software quality standards are required for "non-safety software?"

DOE O 414.1C and the ten QA Criteria apply to all software. However, the Order does not invoke a specific standard or include SQA requirements for non-safety software. Thus the requirements specific to safety software in the Order do not apply. The safety software requirements are based upon generally accepted and implemented SQA practices in industry and can be applied to non-safety software.

Has your contact information changed?

To continue receiving the Quality Assurance Exchange newsletter and help us maintain the QA Point of Contact database with accurate information, please forward your updated contact information to:
qaexchange@hq.doe.gov