Quality Assurance Exchange

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HSS

Exchanging ideas and sharing experiences to foster continuous improvement in QA implementation within the Department of Energy.

In The Spotlight:
Quality Assurance Order Revised

As part of the Department of Energy's (DOE's) Office of Health, Safety and Security (HSS) Directives reform initiative, DOE issued a revision to DOE Order (O) 414.1C, *Quality Assurance* on April 25, 2011. The DOE Quality Council, DOE Departmental Elements, Site Offices, and contractors participated in the review and update of the Order. DOE O 414.1D does not impose any new requirements, however, its content was streamlined; existing requirements and responsibilities were clarified; and the sections were reorganized to reduce redundancy.

Document Organization:

- Attachment 1, *Primary DOE Organizations to which DOE O 414.1C is Applicable*, was deleted and a link to the list of Departmental Elements is now included. Attachment 1 in DOE O 414.1D is now the Contractors Requirements Document (CRD).
- The 10 quality assurance (QA) criteria are now only presented in Attachment 2, thereby eliminating repetition and redundancy.
- The requirements for the Corrective Action Management Program (CAMP) were removed with the intent to streamline and give the Field more flexibility for implementing corrective action programs.

Additional noteworthy changes in the newly issued DOE O 414.1D are discussed below.

Paragraph 3. Applicability:

- Clarifies that, with the exception of the equivalencies and exemptions provided in the Order, applicable requirements of the CRD also apply to the government-owned government-operated facilities and federally- staffed facilities.
- Provides exemption to activities and facilities subject to regulation by the Nuclear Regulatory Commission from the requirements of the Order to the extent that they overlap or duplicate. Other requirements in the Order may be applied if the responsible Program Office deems appropriate.

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Director's Note

The Department of Energy's (DOE's) Office of Health, Safety and Security (HSS) reorganized in May 2011, and within HSS, the Office of Quality Assurance Policy and Assistance (HS-23) is now the Office of Quality Assurance (HS-33) (see http://www.hss.doe.gov/orgchart.html). The Office of Quality Assurance reports to the newly formed Office of Nuclear Safety (HS-30) whose Director reports to the Chief Health, Safety and Security Officer, Mr. Glenn Podonsky. While the name of my office has changed slightly, our mission and functions remain the same. The entire staff of HS-33 is excited about this change and looks forward to the new interfaces, endeavors, and challenges in the coming years.

Other exciting news is that DOE Order (O) 414.1D, *Quality Assurance,* was approved and issued on April 25. In this issue of the *QA Exchange*, we feature an article to delineate some of the major changes that were incorporated into this latest revision of the Order. Please note that the approval and issuance of the Order could not have been made possible without the hard work and dedication of numerous people all across DOE. I would like to extend a huge "Thank You" to all who participated, including Headquarters, Field and contractor personnel.

Finally, DOE Guide 414.1-2A, *Quality Assurance Management System Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements, and DOE O 414.1C, Quality Assurance,* dated June 17, 2005, is currently being revised to be updated and consolidated into it the relevant guidance from DOE Guide 414.1-3, *Suspect/Counterfeit Items Guide for Use with 10 CFR 830, Subpart A, Quality Assurance Requirements, and DOE O 414.1B, Quality Assurance* (November 3, 2004), and DOE Guide 414.1-5, *Corrective Action Program Guide,* dated March 2, 2006. With the approval of the revision to DOE Guide 414.1-2A, both DOE Guide 414.1-3 and DOE Guide 414.1-5 will be cancelled. The revised DOE Guide 414.1-2A (e.g., DOE Guide 414.1-2B) is expected to be issued in the near future. The RevCom process for this revision ended in May, and the comment resolution is to be completed by mid-July. When canceled, the Guides will be archived for future reference.

I hope that everyone has a great and safe summer! And, remember to submit articles, lessons learned, and QA tidbits to *QA Exchange* to enable continuous sharing within the DOE community. Thanks!

– Colette Broussard, Director, Office of Quality Assurance

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Paragraph 4. Requirements:

- Clarifies that the QA criteria listed in Attachment 2 apply to all software using a graded approach.
- Clarifies that national or international consensus standards may be used in whole or in part, consistent with regulatory requirements and Secretarial Officer direction. When the standards do not fully address the requirements, the gaps must be addressed in the quality assurance plan (QAP).
- Clarifies that the training requirement for federal personnel responsible for QA and software QA oversight of defense nuclear facilities includes qualification in accordance with DOE Standard 1150-2002, *Quality Assurance Functional Area Qualification Standard* and DOE Standard 1172-2011, *Software Quality Assurance Functional Area Qualification Standard*, respectively.
- Clarifies that the flow down of the applicable QA requirements and responsibilities includes all levels of the organization.

Paragraph 5. Responsibilities:

- The QAP approval process has been streamlined and clarified.

Paragraph 6. Definitions:

- Definitions have been added for the following:
  - Corrective Action
  - Critical Decision 1
  - Design Authority
  - Hazard
  - Independent Assessment
  - Management Assessment
  - Non Reactor Nuclear Facility
  - Testing
- Definitions have been enhanced for the following:
  - Validation
  - Verification

Attachment 1 – Contractors Requirements Document (CRD) (Attachment 2 in DOE O 414.1C):

- Added specificity to the CRD for the use of a particular consensus standard for Hazard Category 1, 2, and 3 nuclear facilities to the effect that:
  - Existing facilities, or new facilities and major modifications to existing facilities achieving Critical Decision 1 (CD-1) before April 25, 2011, will continue to use the consensus standard cited in the governing DOE-approved QAP consistent with Secretarial Officer direction;
  - New facilities and major modifications to existing facilities achieving CD-1 after April 25, 2011, will use American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA)-1-2008 with the NQA-1a-2009 addenda (or a later edition), *Quality Assurance Requirements for Nuclear Facility Applications*, Part I and applicable requirements of Part II; and
  - Other consensus standard(s) can be used if it is demonstrated that the quality requirements are equivalent to those of ASME NQA-1-2008 with the NQA-1a-2009 addenda. The QAP must document how this consensus standard is (or a set of consensus standards are) used, as well as how they are equivalent to ASME NQA-1-2008 with the NQA-1a-2009 addenda.
- The CRD notes that the terms "nuclear power plant" or "nuclear reactor" in NQA-1, Part II are considered equivalent to the term "nuclear facility" used in the CRD.
- Clarifies the requirement for the contractor to evaluate the QA program of a subcontractor, vendor, and/or supplier whose activities are not governed by the contractor's DOE-approved QAP.

Attachment 4 - Software Quality Assurance (Attachment 5 in DOE O 414.1C):

- The Purpose paragraph has been revised to clarify that software, other than safety software as defined in the Order, is not subject to requirements in Attachment 4. An example has been provided in a footnote that software used solely for consequence assessment purposes in establishing the technical basis of an emergency program or during an emergency response is not considered safety software.
- Clarifies the requirement that safety software is to be acquired, developed, and implemented using NQA-1-2008 with the NQA-1a-2009 addenda (or a later edition) Part I and Subpart 2.7 or other national or international consensus standards that provide an equivalent level of QA requirements as NQA-1-2008. Additional clarification has been provided to ensure that DOE-approved QAPs applicable to safety software based on requirements from DOE O 414.1C are acceptable. The standards used must be specified by the user and approved by the designated DOE approval authority.
- The information that is required to be maintained for the safety software inventory entries has been clarified. At a minimum, the inventory entries must include the following: software description; software name; version identifier; safety software designation (e.g., safety system software, safety and hazard analysis software and design software, safety management and administrative controls software); grade level designation; specific nuclear facility application used; and, the responsible individual.

The above are highlights of the changes in DOE O 414.1D. There are other minor changes, not discussed in this article. The reader is urged to refer to the actual, complete text for the precise language for the highlighted changes, as well as for any changes that are not captured herein. Updates to some of the Guides related to DOE O 414.1D are in progress and will be issued as the revisions complete the RevCom process.

HSS is currently developing generic QA training material that will discuss the changes in DOE O 414.1D. It is anticipated that the training material will be made available on the HSS QA Web site. HSS is also considering the feasibility of delivering the training in classroom settings or as computer based training via the web. Information with regard to the training material and delivery mechanism will be forthcoming.

For additional information on the updated QA Order, please contact: Colette Broussard at 301-903-5452 or Colette.Broussard@hq.doe.gov.

HSS Safety Share: Heat Exposure

Too Much Heat

Heat disorders generally have to do with a reduction or collapse of the body's ability to shed heat by circulatory changes and sweating, or a chemical (salt) imbalance caused by too much sweating. When heat gain exceeds the level the body can remove, or when the body cannot compensate for fluids and salt lost through perspiration, the temperature of the body's inner core begins to rise and heat-related illness may develop.

Ranging in severity, heat disorders share one common feature: the individual has overexposed or over exercised for his/her age and physical condition in the existing thermal environment. Sunburn, with its ultraviolet radiation burns, can significantly retard the skin's ability to shed excess heat.

Studies indicate that, other things being equal, the severity of heat disorders tend to increase with age (e.g., heat cramps in a 17-year-old may be heat exhaustion in someone 40, and heat stroke in a person over 60). Acclimatization has to do with adjusting sweat-salt concentrations, among other things. The idea is to lose enough water to regulate body temperature, with the least possible chemical disturbance.

Preventing Heat-Related Illness

Individuals at risk (e.g., infants and children up to 4 years of age, people 65 years of age or older, people who are overweight, people who overexert during work or exercise, people with alcohol problems, people who are ill or on certain medications, especially tranquilizers and anticholinergics) are particularly susceptible to heat reactions, especially during heat waves in areas where a moderate climate usually prevails.

Heat Wave Safety Tips

Slow down. Strenuous activities should be reduced, eliminated, or rescheduled to the coolest time of the day. Individuals at risk should stay in the coolest available place, not necessarily indoors.

Dress for summer. Lightweight light-colored clothing reflects heat and sunlight and helps your body maintain normal temperatures.

Put less fuel on your inner fires. Foods (like proteins) that increase metabolic heat production also increase water loss; therefore, it is advisable to consume less when in the heat.

Drink plenty of water or other non-alcohol fluids. Your body needs water to keep cool. Drink plenty of fluids even if you don't feel thirsty. Persons who (1) have epilepsy or heart, kidney, or liver disease, (2) are on fluid restrictive diets or (3) have a problem with fluid retention should consult a physician before increasing their consumption of fluids.

Do not drink alcoholic beverages.

Do not take salt tablets unless specified by a physician. Persons on salt restrictive diets should consult a physician before increasing their salt intake.

Spend more time in air-conditioned places. Air conditioning in homes and other buildings markedly reduces danger from the heat. If you cannot afford an air conditioner, spending some time each day (during hot weather) in an air conditioned environment affords some protection.

Know These Heat Disorder Symptoms

HEAT DISORDER	SYMPTOMS	FIRST AID
SUNBURN	Redness and pain. In severe cases swelling of skin, blisters, fever, headaches.	Ointments for mild cases if blisters appear and do not break. If breaking occurs, apply dry sterile dressing. Serious, extensive cases should be seen by physician.
HEAT CRAMPS	Painful spasms usually in muscles of legs and abdomen possible. Heavy sweating.	Firm pressure on cramping muscles, or gentle massage to relieve spasm. Give sips of water. If nausea occurs, discontinue use.
HEAT EXHAUSTION	Heavy sweating, weakness, skin cold, pale and clammy. Pulse thready. Normal temperature possible. Fainting and vomiting.	Get victim out of sun. Lay down and loosen clothing. Apply cool, wet cloths. Fan or move victim to air conditioned room. Sips of water. If nausea occurs, discontinue use. If vomiting continues, seek immediate medical attention.
HEATSTROKE (or sunstroke)	High body temperature (106° F or higher). Hot dry skin. Rapid and strong pulse. Possible unconsciousness.	***HEAT STROKE IS A SEVERE MEDICAL EMERGENCY. SUMMON EMERGENCY MEDICAL ASSISTANCE OR GET THE VICTIM TO A HOSPITAL IMMEDIATELY. DELAY CAN BE FATAL.*** Move the victim to a cooler environment. Reduce body temperature with cold bath or sponging. Use extreme caution. Remove clothing, use fans and air conditioners. If temperature rises again, repeat process. Do not give fluids.

This information was obtained from publication, *HEAT WAVE: A Major Summer Killer,* produced as a cooperative effort of U.S. Department of National Oceanic Atmospheric Administration's National Weather Service, the Federal Emergency Management Agency, and the American Red Cross. NOAA/PA 85001 (June 8, 2007).

This National Weather Service material is public domain and is not subject to copyright protection.

For more information, go to: http://www.nws.noaa.gov/om/brochures/heatwave.pdf

The Suspect/Counterfeit Items Battle Continues

You may have heard the term "Suspect/Counterfeit Items" or "S/CIs." A number of initiatives across the Department of Energy (DOE) complex have focused on searching for, identifying, and removing these falsely represented products. (References: 10 CFR 830.120; DOE Order 414.1D, *Quality Assurance*; and DOE Guide 414.1-3, *Suspect/Counterfeit Items Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements*). S/CIs have been a known problem to industry and the government since the early 1980s. Initially, the concern was on fasteners, and over time has been expanded to include items not only used in construction applications, but by all of us in our daily lives. Worldwide counterfeiting is involved, just to name a few, in fashion clothing, jewelry, music, movies, antique furniture, computer components, cell phones, batteries, cat food, auto parts, aircraft parts, and medicines, in addition to parts used in a nuclear safety system.

Counterfeit items can make it into all levels of supply chains. Be vigilant in checking any items you receive and use.
Photo: Courtesy of the Department of Energy

When counterfeit parts are used, there is no traceability of quality or integrity; and when a part fails, there is no warranty to back it up – no liability is incurred. More importantly, counterfeit parts in a system can injure or kill when components and systems fail as a result of the use of counterfeit materials. The worst confirmed airplane accident due to counterfeit parts occurred in 1989 on a Convair 580 turboprop charter plane carrying 55 people from Oslo, Norway to Hamburg, Germany. At 22,000 feet over the North Sea, the tail section of the craft began vibrating violently and tore loose. The plane splattered over three miles of sea and everyone aboard died. Norwegian investigators painstakingly dredged up 90 percent of the 36-year-old plane and found the cause: bogus bolts, bushings, and brackets. The origin of the counterfeit parts was never determined. (Lubbock Avalanche-Journal, 1996)

The Office of Inspector General (OIG) has brought legal action against parties that have intentionally defrauded the U.S. Government, but the problem continues to grow. Despite measures to detect and eliminate counterfeits, the worldwide counterfeiting industry had expanded to a $200 billion a year business by the year 2000. Accurately gauging the size of the counterfeit market is impossible, but the World Customs Organization estimated the business was worth more than $500 billion in 2005, representing 7% of world trade.

The worldwide counterfeiting business is worth more than $500 billion a year according to the World Customs Organization.

Developing anti-counterfeit strategies is not like dealing with E.coli, which has a biologically programmed method of operation. Counterfeiting is run by humans who are intelligent, resilient, persistent, creative, adaptable, and very motivated. At DOE sites, processes must continuously react to counterfeit items, due to the many channels through which these items can enter a facility. These channels include the purchase of individual items, purchase of large assemblies that contain S/CIs, and equipment used or installed by subcontractors. S/CIs may pose immediate and potential threats to the safety of DOE and contractor workers, the public, and the environment. Failure of a safety or mission critical system due to an S/CI could also have security implications at DOE facilities.

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What can you do to prevent counterfeit items in your personal life?

Not much. But there are some things you can do to greatly reduce them. The basic tips listed below can help purchasers and end-users identify counterfeit parts prior to installation, preventing significant maintenance costs or far worse consequences.

- To the extent possible, only purchase parts from legitimate, well-known and reputable dealers. Be wary of online sales and unknown sales outlets.
- Pay careful attention to the packaging. If it is unusually flimsy, discolored, or in a different layout than the product you usually buy, or if the usual insert or instructions are missing, the part may be counterfeit.
- Pay careful attention to the parts themselves. If you experience unusual installation difficulties, or the paint job on the part is sloppy or discolored, the part may be a knock-off.
- Pay close attention to parts bought in bulk and parts that need to be replaced often. These are typically the types of parts targeted by counterfeiters, because they are more profitable than smaller-volume parts that do not get replaced as frequently.

The main thing to consider is the product's supply chain, especially in the area of pharmaceuticals. Be wary of buying medicines over the internet. The large name drug suppliers are your best bet in getting what you pay for. Another red flag is price. Remember the old saying, "If the deal sounds too good to be true, it probably isn't"? Well, that saying is more pertinent today than ever before in this worldwide counterfeit market.

Programs must be developed and maintained to help train employees to identify suspect items and provide a process that encourages and promotes procurement, engineering, operations, maintenance, and inspection personnel to identify and eliminate substandard parts and materials. Removal of these parts and materials is the first step in the process, and a system of prevention must be implemented from the top down. It involves the designer (who specifies the item), the buyer (who procures the item), the supplier (who supplies the item), the receiving inspector (who examines the item), and the end user (who installs and operates the item) communicating and working together to identify and resolve S/CI problems.

A U.S. Goverment-wide working group has been formed to establish federal policy on S/CI issues.

The U.S. Food and Drug Administration, U.S. Customs and Border Protection, U.S. Immigration and Customs Enforcement, the Departments of Justice, State, and Commerce, and the Agency for International Development have joined together to form the Counterfeit Pharmaceutical Inter-agency Working Group. A similar group has recently been formed to establish a federal policy on the S/CI problem. In March 2011, the White House Intellectual Property Enforcement Coordinator established a U.S. Government-wide anti-counterfeiting working group to prevent the U.S. Government from procuring counterfeit products. The objective of this partnership is to develop a framework for a consistent government-wide approach for reducing the U.S. Government's vulnerability to counterfeits that is flexible enough to accommodate the wide variety of missions across federal agencies. This working group is tasked with studying and identifying any gaps in legal authority, regulation, policy and guidance that might prevent or interfer with an optimal U.S. Government procurement approach. This working group is co-chaired by the Department of Defense and the National Aeronautics and Space Administration (NASA), and consists of members from DOE, the General Council, OIG, and other federal agencies. To achieve the overall goal, the group has determined six objectives.

1. Establish procedures for program managers to identify items at risk for counterfeiting or that require authentication of legitimacy. These procedures will, to the greatest extent practicable, utilize industry standards.
2. Examine whether regulations are needed to require suppliers to take stronger anti-counterfeiting measures.
3. Confirm production authority by the original manufacturer of at-risk products and require confirmation through product and packaging traceability, reporting and marking processes used by prime contractors and their suppliers.
4. Examine government/industry evaluation capabilities and determine whether improvement is needed.
5. Establish an anti-counterfeiting training and outreach strategy for the federal workforce.
6. Examine whether additional measures are needed to protect the rights and interests of the U.S., recoup costs and prosecute offenders.

This group is expected to make recommendations to the U.S. President in October 2011.

This article was submitted and written by Steve Chalk, DOE Richland Operations Office. For more information, contact Steve Chalk at 509-372-8589 or Steven.Chalk@rl.doe.gov.

Did You Know?

Substandard materials are known within DOE as suspect/counterfeit items (S/CI). They pose immediate and potential threats to the safety of DOE and contractor workers, the public, and the environment. Failure of a safety system due to an S/CI could also have security implications at DOE facilities. Over the years, S/CIs have entered the procurement system(s) at DOE sites. Left unidentified and uncorrected these items do present potential risks. A wide variety of counterfeit items have been identified and documented that include:

- Fasteners (bolts and brackets);
- Ratchet straps/tie-down straps;
- Refurbished molded-case circuit breakers;
- Transformers, fuses, resisters, and switch gear;
- Metal struts;
- Pipe components, fittings, flanges, and valves; and
- Material and testing certification.

Examples of locations in which installed S/CI have been discovered include:

- Cranes, elevators, and fork lifts: critical load paths;
- Vehicles: engines, brakes, or steering mechanisms;
- Aircraft: engines and attachments, wings, tails, and landing gear; and
- Facilities: valves, compressors, and vessels used to contain radioactive fluids, high-temperature or high-pressure steam or fluids, or other hazardous material or safety systems support safe operation or shutdown of a facility or process.

This information was obtained from DOE, Office of Health, Safety and Security training document: *Suspect/Counterfeit Items Awareness Training* (June 2007, Revision 6).

EFCOG Activities

Quality Assurance Subgroup Initiatives

The Energy Facility Contracting Group (EFCOG) strives to promote excellence in all aspects of the operation, management, and integration of Department of Energy (DOE) facilities in a safe, environmentally sound, efficient and cost-effective manner through the ongoing exchange of information on lessons learned. EFCOG consists of various Working Groups and Subgroups to carry out the tasks assigned by the Board of Directors. The Quality Assurance Subgroup concentrates on tasks related to current quality assurance news, issues, and events. Their current initiatives, which are undertaken by specifically focused task teams, are described below.

- **The Supply Chain Task Team** is currently working with the Office of Environmental Management (EM) to develop a common list of evaluated suppliers that could be available to DOE EM Contractors. This list would identify suppliers that have been audited and have quality programs that satisfy Nuclear Quality Assurance (NQA)-1 Standard. The audits, conducted by teams of individuals from various EM sites, are lead by a NQA-1 certified Lead Auditor with a checklist focusing on the scope of work that a particular vendor has been contracted for, or may be requested to perform. This task is being conducted simultaneously with existing audits of commodity vendors, using developed checklists and revised procedures which support other EFCOG initiatives.

- **The Software Quality Task Team** is focused on computer model validation and commercial dedication of software.

  - ***The computer model validation task*** includes the review of current industry standards and the U.S. General Accountability Office Report 11-143, *Nuclear Waste: DOE Needs a Comprehensive Strategy and Guidance on Computer Models that Support Environmental Cleanup Decisions,* and proposes guidance which will enhance contractor understanding of what constitutes an effective program for computer model validation.
  - ***The commercial grade dedication task*** includes the review of the draft EM guidance document titled, *Guidance for Commercial Grade Dedication,* as well as current industry initiatives, and proposes enhancements focused on improving the understanding of this process to the contractor community.

- **The Quality Assurance Policies & Program Requirements Task Team** is focused on the development of a standard set of quality metrics.

- **Quality Engineering Task Team** is focused on defining the roles, responsibilities, and functions of the Quality Engineer. This includes a description of the functions the Quality Engineer performs throughout each project's phase, i.e., design, procurement, construction, start-up, etc.

- **The Quality Control (QC)/Inspection Task Team** continues to set work priorities based upon the complex-wide survey they conducted last fall. This survey identified those QC issues that the sites believe are most important and need to be addressed. They will focus on developing guidance to determine the role of QC inspection and test personnel during the implementation stages of a typical DOE contract to discover how they impact the successful implementation of DOE Order 414.1D, *Quality Assurance.* They also intend to develop a white paper identifying the best practices, lessons learned, and alerts focused on how to disseminate the results of inspection and tests. Lastly, they continue to work and provide input to the EFCOG Work Management Subgroup on how to apply a graded approach to QC inspection criteria, work packages, and criteria, review, and approach documents (CRAD) development.

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Highlights of Joint EM-EFCOG Quality Assurance Summit

The Office of Environmental Management (EM) in conjunction with the Energy Facility Contractors Group (EFCOG) held a one-day Quality Assurance (QA) Summit on February 17, 2011. The QA Summit, hosted by Department of Energy (DOE) Oak Ridge Office, brought together over 70 individuals representing a diverse cross section of DOE entities and private sector organizations involved in the design, construction, and commissioning of EM's high profile one-of-a kind nuclear facilities. The main purpose of the QA Summit was to create

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a forum to enable candid discussion and sharing of QA operating experiences, performance and supplier issues, lessons learned, and best practices with the ultimate goal of leveraging insights to improve the overall quality, readiness, and cost effectiveness of major EM projects.

The QA Summit presentation by Dae Chung, Principal Deputy Assistant Secretary for EM, pointed out several successes and accomplishments that have been achieved in recent months to support the improvement of QA across the EM complex. For example:

- EM has instituted a consistent corporate QA Program which has been implemented by all of the field sites;
- EM has implemented standard contract language associated with QA;
- EM has addressed issues specifically related to quality requirements flow-down, graded approach, commercial grade dedication and suspect/counterfeit items; and
- EM has sponsored outreach events for nuclear suppliers and vendors to improve our supplier base.

Although several accomplishments have been demonstrated, areas for continuous improvement are a key focus for the QA disciplines, both Federal and contractor. The bottom line is that "we will succeed only through team work and continuous improvement."

The range of topics discussed at the QA Summit covered a wide spectrum of practices that govern the depth and breadth of QA integration throughout project lifecycle, from inception to its eventual commissioning. Each major EM project is unique in design, underlying technology, and project phase; however, the EM projects do share common experiences with respect to the challenges of QA implementation. The QA Summit served as a key forum to share these experiences and enhance the teamwork and continuous improvement as discussed by Mr. Chung.

The March 10, 2011, EM newsletter featured an article providing a preliminary analysis of the QA Summit conclusions including an initial list of practices to help prevent or minimize QA-related setbacks. This update serves to provide additional detail based on the final analysis of the information provided at the QA Summit. A complete set of the slide presentations, summary of discussions, summary of lessons learned/insights, and a listing of participants can be viewed online by going to the EM Quality Assurance Corporate Board Web site at http://www.em.doe.gov/Pages/qualityassurance.aspx. The analysis on the Web site also includes recommended strategies for follow-up implementation and application by the majority of EM sites and projects. The following provides additional details on the key insights and lessons learned that were discussed during the QA Summit.

- ***Meaningful operational awareness and performance monitoring.*** The key lesson is the need for continued vigilance and organizational focus on QA performance. Naval Reactors has demonstrated an excellent approach by emphasizing supplier ownership of quality. This approach has been demonstrated by working with the suppliers to identify three key issues with respect to quality that need to be addressed. The suppliers work to resolve each issue throughout the performance period to achieve continuous improvement. Once a resolution is achieved, another key issue is selected to ensure the supplier is always addressing at least three issues with respect to quality. The resolution of these issues is then considered in the contractor and/or supplier performance evaluations. This approach does require technical capability in the supply chain hierarchy to effectively self-identify and address critical issues. The success demonstrated by Naval Reactors has provided evidence that this approach is very effective at ensuring continuously improving quality systems and products. While the details of the approach can be altered, the idea of ensuring supplier ownership of quality serves to provide quality products that meet the expectations of the nuclear industry. Recommended strategies for EM include utilization of the EM QA Corporate Board focus areas to consider development or a strategy for implementation of this concept.

- ***Effective implementation of the Commercial Grade Dedication requirements and expectations.*** As construction of new non-reactor nuclear facilities by EM increases, new methods are needed to ensure parts and services can be procured that will have a reasonable assurance of meeting their safety function. Issues have been identified where Commercial Grade Dedication (CGD) activities performed by qualified suppliers had not consistently provided reasonable assurance that items would perform their intended function. Root causes included the failure to confirm that CGD requirements and expectations are clearly understood by the suppliers and sub-suppliers; and the failure to execute rigorous supplier and sub-supplier qualification requirements at initial qualification surveys and subsequent assessments. EM has previously noted CGD as an issue and has been working to resolve the concerns within EM. The recommended strategies include a continuation of the approach currently undertaken by EM to address CGD. Specifically, continuation of CGD training at the sites with a focus expanding to include software in addition to hardware. Furthermore, a CGD guide for EM facilities is in development to enhance the understanding of EM expectations when nuclear qualified suppliers are not available. Both of these areas are being worked by the EM QA Corporate Board and final deliverables will be posted on its Web site.

- ***Planning and execution of readiness activities.*** Several key lessons were derived from those facilities which have recently undergone Operation Readiness Review (ORR) activities. Specific insights include a need for: clear understanding of the readiness expectations at all levels; clear role of senior management in its approach to readiness; and establishment of a Line Management Review Board to ensure consistent expectations for readiness level by functional area. Recommended strategies for EM include: enhanced use of the Standard Review Plan (SRP) Review Modules associated with the readiness activities; and strengthening of in-house processes to communicate readiness to all employees including subcontractors and vendors. The SRP Modules are a joint effort between EM and the Chief of Nuclear Safety and are also available on the EM QA Corporate Board Web site. *(Continued on page 8)*

- ***Business intelligent approach to supplier evaluation and oversight.*** Key lessons related to contract development and acceptance of the finished product were also noted. These lessons include: a need to ensure sufficient clarity, specificity, and consistency in procurement documents to establish a common understanding of the expectations; a need for a formal documented evaluation and selection process based on timely and informed awareness of suppliers' ability to provide the best value; i.e., high degree of confidence that products delivered will be on-time, on-budget, and meeting all quality-related specifications and characteristics. Recommended strategies for EM include: enhanced use of the EM SRP Review Module on Acquisition Strategy, which defines the core performance objectives and criteria; investigation of the potential for developing an EM acquisition best practices strategy guide to deal with never-built-before or procured items and services.

The recommended strategies discussed were designed to leverage the lessons learned with the following objectives in mind:

- Be consistent with existing EM corporate QA requirements and expectations;
- Can be readily implemented as part of current/planned work scope activities; and
- Do not create unfunded mandates for the sites/projects.

The complete analysis of key insights/lessons learned shared during the EM QA Summit can be accessed at http://www.em.doe.gov/Pages/qualityassurance.aspx under the EM QA Corporate Board Meetings, February 2011.

If you have any questions or need additional information, please contact Robert Murray, Director, Office of Standards and Quality Assurance, EM-23, robert.murray@em.doe.gov.

For further reference to the information provided in this article, please visit the EM QA Corporate Board Web site at: http://www.em.doe.gov/Pages/qualityassurance.aspx.

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Quality Assurance Activities

Safety Software Quality Assurance

Safety Software Quality Assurance Functional Area Qualification Standard is Revised

In March 2011, a revision to Department of Energy (DOE) Standard 1172, *Safety Software Quality Assurance Functional Area Qualification Standard,* was approved by Karen Boardman, Chairperson Federal Technical Capability Panel, and posted on the Office of Health, Safety and Security Technical Standards Web site, www.hss.doe.gov/nuclearsafety/ns/techstds.

The Standard establishes common functional area competency requirements for DOE personnel who provide assistance, direction, guidance, oversight, or evaluation of safety software that includes:

- Safety system software;
- Safety and hazard analysis software and design software; and
- Safety management and administrative controls software as defined in DOE Order 414.1D, *Quality Assurance*.

For further information, please contact Subir Sen at 301-903-6571 or Subir.Sen@hq.doe.gov.

New Technical Standard Issued: Design of Safety Significant Safety Instrumented Systems Used at DOE Nonreactor Nuclear Facilities

In April 2011, Department of Energy (DOE) Standard 1195, *Design of Safety Significant Safety Instrumented Systems Used at DOE Nonreactor Nuclear Facilities,* was issued and posted on the Office of Health, Safety and Security Technical Standards Web site at http://www.hss.doe.gov/nuclearsafety/ns/techstds. The standard was developed by a working group with representatives from headquarters, site offices, and their contractors, and staff from Defense Nuclear Facilities Safety Board. The working group was charged with defining the important safety and reliability issues concerning hardware, software, and human-machine interfaces that arise from the introduction of digital instrumentation and controls in safety applications in DOE nuclear facilities. This was a challenge since there are no suitable consensus standards in the industry that could be applied to DOE nuclear facilities. The working group produced this new risk informed and performance based standard, which is the first DOE Technical Standard to address instrumentation and control system design using the latest technology available in the industry. A two-day training course on the new standard is being developed.

For further information, please contact Pranab Guha at 301-903-7089 or Pranab.Guha@hq.doe.gov.

Mark Your Calendar

Upcoming Workshops and Conferences

AUGUST 2011

Nuclear Lead Auditor Training Course

Where: Atlanta, GA
When: August 23-26

SEPTEMBER 2011

DOE Integrated Safety Management Champions Workshop 2011

Where: Kennewick, WA
When: September 12-15

SQA Special Symposia: "Moving Past Compliance Oversight to True Quality Management"

Where: Grand Hyatt Atlanta, GA
When: September 21

OCTOBER 2011

Nuclear Quality Assurance - Fall 2011 Meeting

Where: St. Petersburg, FL
When: October 18-20

2011 American Nuclear Society Winter Meeting and Nuclear Technology Expo: "The Status of Global Nuclear Deployment"

Where: Omni Shoreham Hotel, Washington, DC
When: October 30 - November 3

NOVEMBER 2011

3rd Global Quality Assurance Conference: "Toward Next Generation"

Where: Kyoto, Japan
When: November 13-16

Office of Quality Assurance

Mission:

The Office of Quality Assurance establishes and maintains the quality assurance policies, requirements and guidance for the Department of Energy and serves as the Department's corporate resource to ensure that products and services meet or exceed the Department's quality objectives.

The Office provides assistance to Departmental elements and contractors in the interpretation and implementation of the Department of Energy quality assurance requirements and in the resolution of quality assurance-related issues.

Visit us on the Web:

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