QUALITY ASSURANCE EXCHANGE

HSS
Office of Health, Safety and Security

QA Quote of the Day

"...quality assurance is merely the function of having the right work performed the right way by the right people the first time."

HSS FOCUS ON QUALITY ASSURANCE

It permeates every aspect of our work from the shortest memorandum to the most complex nuclear operation, and yet it is often misunderstood, undervalued, and overlooked as an integral component of line management. "It" is Quality Assurance — in principle and in application – and "it" is at the heart of every successful corporation, institution, and Federal agency.

The Department of Energy's commitment to quality assurance is contained in the DOE Order 414.1C, Quality Assurance, which describes five principles that form a blueprint for a quality culture. These are 1) the establishment of a QA program as part of a comprehensive management system; 2) the requirement of DOE management to support the implementation of QA; 3) the regular conduct of assessment and subsequent corrective action; 4) a mandate that employees at every level of the Department are responsible for producing quality work; and 5) the recognition that the risks to worker and public safety and

health, as well as the environment, decrease and productivity increases with the appropriate rigor of quality assurance.

The corporate responsibility for ensuring implementation of these five principles rests within the Office of Health, Safety and Security (HSS). HS-20, the Office of Nuclear Safety and Environment, interprets QA requirements and develops policy; HS-30, the Office of Corporate Safety Analysis, manages the QA program for the Department, including the various programs and tools that support QA, e.g., the Corrective Action Management Program, the Suspect/Counterfeit/Defective Items program, and Safety Software Central Registry; HS-40, the Office of Enforcement, ensures QA rule requirements are implemented; HS-60, the Office of Independent Oversight, conducts independent assessments for the continuous improvement of the Field and Headquarters. Ultimately however, every DOE employee, is responsible for day-to-day QA implementation.

USE OF QA CONSENSUS STANDARDS

The Office of Health, Safety and Security, in coordination with the Office of Environmental Management and the QA staff of the Chief of Nuclear Safety for Energy have recently responded to some questions regarding QA requirements and the use of consensus standards. Over the course of the next three issues of the Quality Assurance Exchange newsletter, we will focus on the relationship between

10 CFR 830.120/DOE O 414.1C and the use of Quality Assurance consensus standards.

Question #1: Are QA consensus standards to be formally adopted in the QAP and implemented as requirements or can they be referenced in the QAP and used only from a best practice stand point?

The Secretary of Energy affirmed his commitment to quality assurance through a Department-wide memorandum, issued in April 2006. He mandated that all departmental elements implement a QA program for the programmatic activities for which they are responsible. To that end, he required all departmental elements to report on the status of their QA programs through a Department-wide survey, which was conducted in 2006. Efforts are under way to gather additional data again this year to evaluate the progress made over the past year by those same departmental elements. The Secretary's ultimate goal through these efforts is to achieve consistent implementation of the QA Order requirements across the Department.

In addition to maintaining ownership of DOE-wide quality assurance policy and programs, HSS is also providing direct support to other DOE program and staff offices for their quality assurance initiatives. Examples of this collaboration include assisting the Office of Management in developing its QA guide for project management; aiding the General Counsel in developing and providing QA guidance for the National Environmental Policy Act

process; and, reviewing Quality Assurance Program Plans at Headquarters level.

HSS also maintains a positive and constructive partnership with EFCOG through participation in its QA subgroup. HSS is currently establishing a Federal DOE Quality Council that will build and encourage federal-contractor relationships, improve communications through shared lessons learned, and promote consistent interpretation and implementation of QA requirements.

QA must be integrated into every work function no matter how simple or complex. Quality assurance is not a collateral duty or external layer of management checks. When reduced to its most central idea, quality assurance is merely the function of having the <u>right work</u> <u>performed the right way</u> by the <u>right people</u> the <u>first time</u>. Only then can we fulfill the Secretary's vision of a "best in class" quality culture.

SQA FAQ

"Hazard" has not been defined in DOE O 414.1C, but "Hazard Controls" has been defined. Does the definition of "Hazard Controls" include hazards other than radiological?

Yes. Software used to mitigate a hazard by providing hazard controls in a nuclear facility is considered safety software. Those hazards may not all be radiological. The safety software definition is also bounded by the term *nuclear facility*. Thus the hazard (whether radiological or not) and its controls will be associated with a nuclear facility. This software may fall into <u>all</u> 3 categories of the safety software definition.

"Hazard" is defined in 10 CFR 830 as "a source of danger (i.e., material, energy source, or operation) with the potential to cause illness, injury, or death to a person or damage to a facility or to the environment (without regard to the likelihood or credibility of accident scenarios or consequence mitigation)."

"Hazard controls" is defined in 10 CFR 830 as "measures to eliminate, limit, or mitigate hazards to workers, the public, or the environment, including:
- Physical, design, structural, and engineering features;
- Safety structures, systems, and components;
- Safety management programs;
- Technical safety requirements; and
- Other controls necessary to provide adequate protection from hazards.

WHAT IS THE ANALYTICAL SERVICES PROGRAM (ASP)?

The Analytical Service Program (ASP) is a corporate Headquarters' (HQ) program managed by the Office of Health, Safety and Security, Office of Corporate Safety Programs, HS-31. HQ provides oversight, guidance and direction for its three component elements: the Department of Energy's Consolidated Audit Program (DOECAP), the Mixed Analyte Performance Evaluation Program (MAPEP), and the development of software to support environmental field sampling planning and design.

Supporting the field and program line organizations by assuring quality data and accountability for waste disposal is the focus of the ASP. DOE managers, workers and the public can feel confident that data from commercial analytical laboratories operating under contract to various DOE sites can be used as the basis for making defensible clean-up and site closure decisions. Additionally, the ASP helps to ensure that treatment, storage, and disposal facilities receiving DOE low-level radioactive waste are operating in compliance with established regulatory requirements.

The elimination of redundant audit reviews of analytical laboratories and commercial waste facilities that would otherwise be conducted independently by field elements; the standardization of audit methodologies, policies and procedures; and the sharing of lessons learned throughout the DOE Complex are the primary objectives of the DOE-CAP. The program is implemented through a federal DOECAP manager at the Oak Ridge Operations Office. The annual consolidated audits allows laboratory and waste disposal facilities to improve upon overall performance levels while reducing the number of redundant audits, and assures the DOE field managers that the analytical data is of high quality. An annual cost savings of over $2.4 million is realized in conducting 40 annual consoli-

dated audits. This program is voluntary and consists of a cadre of auditors comprised of mostly contractors and some Feds from across the DOE Complex. Each DOE-CAP auditor has to be approved by a qualification review board which evaluates the candidates proficiency in a particular area of review, participate as an auditor in training, take on-line training and successfully pass the associated on-line examination.

The MAPEP also provides quality assurance of analytical data through conducting semi-annual proficiency testing of radiological, stable inorganic and organic analyses for over 120 laboratories supporting the Department's missions and interests. DOE field and program line organizations are informed of which laboratories are performing well, and which have not yielded adequate performance testing results for certain analyses. MAPEP is implemented through the Radiological and Environmental Sciences Laboratory at the Idaho National Laboratory.

Reducing data uncertainty goes beyond the analytical laboratory. The planning, design and collection of soil, water, vegetation and air samples is another component of the ASP. The field and its regulators provide inputs for software development needs and use the various software statistical calculations to reduce the number of field samples; yet maintain the same level of confidence in the data. The ASP is working with several DOE organizations in the application of software development which reduces field sampling costs, while improving upon the quality of data collection by utilizing the visual sample planning toolkit and by providing training opportunities for field employees,

The ASP is one of the Department's greatest success stories based upon a realization that consolidated audits, performance evaluation and testing, and software development used to collect data is a smarter way of doing business that provides confidence in our decision-making.

For more information on ASP, please contact George.Detsis@hq.doe.gov

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

SQA WORK ACTIVITY #6: SAFETY SOFTWARE DESIGN & IMPLEMENTATION

This article is the sixth 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.

Just as addressing quality in the requirements and design phases pays great dividends later in the software life cycle because of reduced defects and rework, safety must be addressed similarly in the design and implementation phases. Safe design of a system, in which safety software is a subcomponent, uses two primary approaches: (1) applying good engineering practices based upon industry proven methods and (2) guiding design through the results of hazard analysis. Identifying and assessing the hazards is not enough to make a system safe. The information from a hazard analysis needs to be factored into the design. The obvious objective is to ensure that the safety software application functions as intended while not executing any unintended functions.

Applying industry accepted software engineering and software quality engineering practices is generally the first approach to developing high quality safety software systems. These practices can be applied to safety software to improve the quality and add a level of assurance that the software performs its safety functions as intended. DOE O 414.1C requires specific SQA tasks, referred to as work activities, to be performed for safety software. Many national and international consensus standards, such as ASME NQA-1-2000, ANS 10.4, and the IEEE software engineering series (e.g., IEEE 1228-1994, *IEEE standard for software safety plans*) provide detailed guidance for performing the work activities.

During software design and implementation the software is developed, documented, reviewed, and controlled. Appropriate risk management is very vital during the design and implementation phases for safety software applications. Issues such as hardware constraints that limit the design, potential performance issues with the design, a design that is based upon unrealistic or optimistic assumptions, design changes during coding, incomplete and undefined interfaces as well as staff who do not have proper training for the development (e.g., fault tolerant methods) and use of safety software must be addressed within the design. In addition, the software design ele-

ments should identify the operating system, function, interfaces, performance requirements, installation considerations, design inputs, anomaly management and design constraints. The software design should be complete, sufficient and traceable to the software requirements. The design activities and documentation should be adequate to fully describe how the software will interface with other system components and how the software will function internally. Data structure requirements and layouts may be necessary to fully understand the internal operations of the software. Using a graded approach, the software design description may be combined with the documentation of the software requirements or software source code.
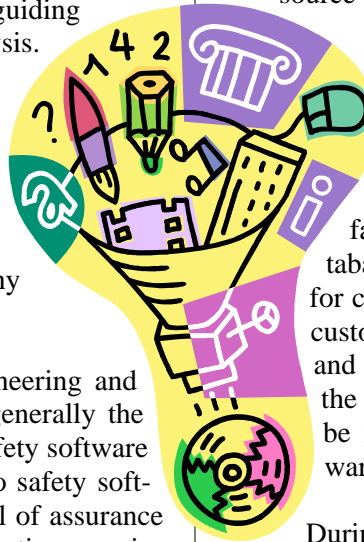
Custom developed software will require more formality in the documentation and review of the design than configurable or utility calculations. Simple process flows, relationships between data elements, interfaces with external components, and basic database table structures may be all that are needed for configurable or utility calculations whereas for custom developed software, complete functional and logical designs of the software components, the input and output data and pseudo code may be required to fully understand the safety software design.

During implementation, static analysis, clean room inspections, and reviews are common techniques to ensure the implementation is robust and remains consistent with the design and does not add complexity or functions which could decrease the safe operation of the software. In addition, the implementation must assure that safety software application functions as intended while not performing any unintended function.

Submitted by Scott D. Matthews, Los Alamos National Laboratory

SQA FAQ

How do the safety software requirements in DOE O 414.1C differ from those in QC-1?

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

Answer #1: DOE O 414.1C and 10 CFR 830 Subpart A both require that the contractor develop and implement a QAP using appropriate national or international consensus standards where practicable and consistent with contractual or regulatory requirements, and identify the standards used. Once a standard is adopted through regulation, code, contract, QAP, or procedure, compliance with the standard is required and is not voluntary.

For a nuclear facility, the contract should require adoption and use of ASME NQA-1, *Quality Assurance Requirements for Nuclear Facility Applications,* for QAP development and implementation. DOE O 414.1C specifies NQA-1 as the appropriate standard for implementing DOE QA requirements for nuclear facility applications. While NQA-1 may also represent a "best practice" based on 30 years of application and as an American National Standard, once adopted in an approved QAP, it becomes a nuclear safety requirement and must be applied using a graded approach as specified in 10 CFR 830.7.

Further, the QAP should specify which parts of NQA-1 are being implemented to meet the ten QA criteria in 10 CFR 830 and DOE O 414.1C and provide justification for any parts of NQA-1 not being fully implemented (e.g., because they are not applicable or were applied using a graded approach).

Question #2: Assuming a consensus standard is adopted, when contractor QAPs are approved by DOE does the QAP supersede requirements in the consensus standards, i.e., contractor is evaluated on the QAP and not on what the consensus standard requires?

Answer #2: The answer is partly dependent on how the contractor adopts the standard in their QAP. A QAP must describe how the DOE QA Criteria are implemented and refers to the NQA-1 requirements that are also used to implement the DOE QA Criteria. In some cases, the QAP or implementing procedures translate the requirements of the standard into terms that describe how the contractor will apply them to the work. In any case, it should be clear in the QAP which parts and edition of the NQA-1 standard are being implemented to meet the ten QA criteria in 10 CFR 830 and DOE O 414.1C.

The adopted standard would not be considered as "superseded" unless specific exceptions to the standard are taken. DOE assesses the contractor based on the approved QAP, adopted standards, implementing documents (procedures, instructions, etc.), regulatory and contractual requirements.

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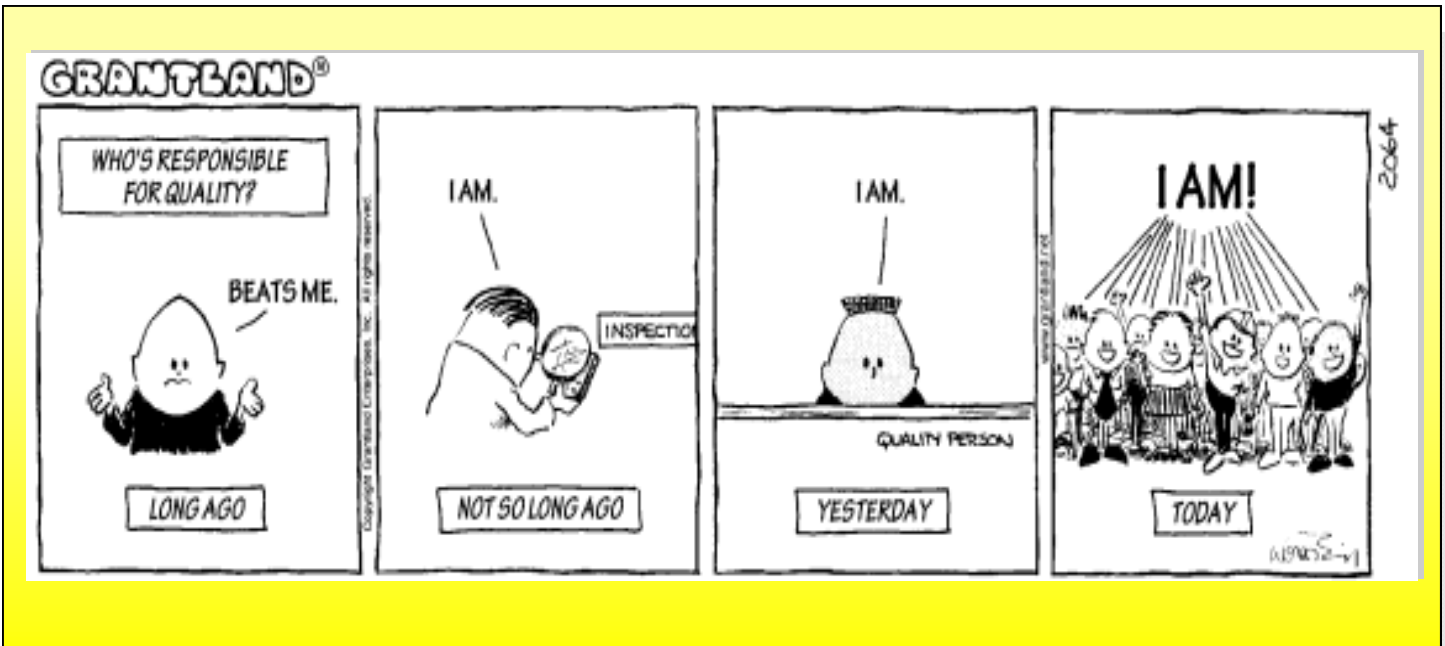
HSS QA ACTIVITY CORNER

IWMS
HSS has issued an Integrated Work Management System (IWMS) Description document that will help to improve organizational performance. Its intent is to integrate the DOE QA program criteria, the Environmental Management System and the Integrated Safety Management System into one overall work management system.

2007 Survey on QA Implementation
DOE is in the process of issuing the 2007 Survey on QA Implementation. Concurrence was obtained from the Under Secretaries and the memo is expected to be signed out by the Deputy Secretary this month. The survey is due back to HSS by the end of October.

Once the data is received by HSS, it will be evaluated and rolled-up in a summary report. HSS expects to issue that report in early 2008.

QA Guidance for DOE O 413.3A
HSS is leading a team of HQ, Field and contractor representatives to develop QA guidance for implementing the DOE Order on Project Management (DOE O 413.3A). This is one of 18 guides being written for DOE O 413.3A. The draft Guide is expected to be undergoing the RevCom process early in 2008.

Revision of DOE G 414.1-1X
(Management and Independent Assessments Guide)
HSS is in the final concurrence phase of the revision to DOE G 414.1-1X. The Guide is anticipated to be released later this month.

EFCOG QA Subgroup
HS-30 has renewed its commitment to sponsor the EFCOG QA Subgroup. As the sponsor, HS-30 will help to ensure Subgroup initiatives are focused and support the Department's needs.

SCDI
The Headquarters sponsored Suspect/Counterfeit/ Defective Items (SCDI) Awareness Training courses have been revised to strengthen presentation of the training objectives and promote consistent content from session to session. The three basic training courses are: a one hour management session, a two hour crafts session, and three hour procurement/engineering session. The management session is now offered as the initial module of the three hour training. Approximately 300 people have been trained to date. Planning is underway to include the SCDI Awareness Training in the National Training Center course offering for FY 2008. For more information on the SCDI Awareness Training and the training schedule, please contact Tom Williams at Thomas.E.Williams@hq.doe.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 to foster continuous improvement in QA implementation.

Readers are strongly encouraged to contribute articles on the implementation of QA requirements, lessons learned, and other QA related topics. We welcome your feedback and suggestions.

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

SQA FAQ

How do the safety software requirements in DOE O 414.1C apply to DOE weapons related work?

Since weapons related work is performed in many of DOE's nuclear facilities, the software that performs a safety function; software that is used to classify, design, or analyze nuclear facilities; or software that performs a hazard control function in support of a nuclear facility falls under the DOE 414.1C safety software requirements. In some instances software for weapons related activities is also used in the hazard analysis of a facility. This software may also be defined as safety software. Naturally the specific instance of use for this software needs to be investigated to properly determine if the software in question is considered safety software. This determination will be performed by the site, the field offices, and the PSO. If determined to be safety software, the software should be included in the site's safety software inventory.

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EDITORIAL NOTE:

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We're on the Web!

See us at:

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

UPCOMING MEETINGS & CONFERENCES

16th Annual Service Quality Conference
When: Oct. 1-2
Where: San Diego
For more info: http://www.asq.org/conferences/service-quality/index.html

QFO Standards Committee
When: Oct. 2
Where: Baltimore
For more info: http://calendar.asme.org/EventDetail.cfm?EventID=5141

NQA Fall 2007 Meeting: NQA Main Committee and Subcommittees Meeting
When: Oct. 8-10
Where: Minneapolis
For more info: http://calendar.asme.org/EventDetail.cfm?EventID=5861

16th Annual Audit Conference
When: Oct. 11-12
Where: Atlanta
For more info: http://www.asq.org/audit/conferences/index.html

International Conference on Software Quality
When: Oct. 16-17
Where: Denver
For more info:
http://www.asq.org/conferences/software-icsq-2007/index.html

34th National Energy and Environmental Conference
When: Nov. 4-7
Where: Providence, RI
For more info: www.asq.org/ee/index/html

National Quality Education Conference
When: Nov. 11-13
Where: St. Louis, Missouri
For more info: http://nqec.asq.org/

ANS/ENS International Winter Meeting and Nuclear Technology Expo
When: Nov. 11-15
Where: Washington, D.C.
For more info:
www.earlbeckwith.com/

Just for Fun!

QA Word Search
find and circle the words listed below

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B  L  N  K  R  N  R  B  J  L  X  O  B  L  O  O  T  C  L  N  R  T  J  D  Z
J  M  D  E  N  R  A  E  L  S  N  O  S  S  E  L  R  T  Q  G  K  N  R  K  Z
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Analytical Services Program	NEPA
Assessment	Oak Ridge
Implementation	Oversight
Central Registry	Quality Assurance
Lessons Learned	Standards
MAPEP	Tool Box

ANSWER SHEET WILL BE POSTED IN NEXT ISSUE