QUALITY ASSURANCE EXCHANGE

HSS
Office of Health, Safety and Security

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DEPARTMENTAL ELEMENTS RESPOND TO "IMPROVING QA"

In his memorandum *"Improving Quality Assurance,"* dated April 26, 2006, the Secretary of Energy stated the Department's priority of implementing an effective Quality Assurance program (QAP) and promulgating a quality culture throughout the DOE complex. The Secretary acknowledged the negative impacts on the DOE mission when quality is not applied consistently to Departmental programs. These impacts include rework, delays, and increased program costs in addition to increased risk to workers, public, and the environment.

The Secretary also requested that Quality Assurance Reporting Guidance be developed to assist in this effort. The guidance was developed by representatives from the former Office of Environment, Safety and Health, Office of Environmental Management, Office of Science, Office of Nuclear Energy, Office of Fossil Energy and the National Nuclear Security Administration.

The Quality Assurance Reporting Guidance provided to Departmental Elements requested responses to questions in the following four quality assurance areas. The areas selected are basic elements of a QAP and provide insight on the implementation of the Department's program and allow for future evaluation of the status of QA across the DOE.

1. **Quality Assurance Program (QAP)/ General Requirements (Criterion 1)**

2. **Flow Down of QA Requirements (Criteria 1 and 7)**

3. **Management, Training & Qualifications (Criterion 2)**

4. **Assessments and Improvements (Criteria 3, 9 and 10)**

The results gathered from the responses received (note: 90% of the Departmental Elements queried responded) indicate that there is evidence that the Department is making great strides in bringing itself into compliance with the DOE O 414.1C, *Quality Assurance*. One of the most notable outcomes of this survey is that it heightened senior management's attention to the Order and prompted several Headquarters (HQ) and field offices to develop written QAPs.

A final report to the Secretary has been written and it provides detailed information on the response to the survey and where the Department stands in adopting a quality assurance culture. This is the first step in assessing the implementation of the Department's QA program. Later in FY-2007 more specific guidance to measure the effectiveness of QA implementation will be provided to Departmental Elements. This will support annual reporting as required by DOE Order 414.1C.

"HOW TO" SERIES ON PERFORMING ASSESSMENTS: POST FIELD INVESTIGATION ACTIVITIES

The previous three articles in this series focused on preparing for and conducting an audit. This article features the post field investigation activities of an audit: the audit report process; technical editing; the factual accuracy review; and how to use a timeline to organize and complete these tasks.

Managing Post Field Investigation Activities
Work will expand to fill the time allotted, audit reports included. Most quality assurance programs specify that an audit report be issued within 30 to 45 days after the exit meeting. When a specific end date is not specified, commit to distributing the audit report within 30 days after the exit meeting.

"How to Series…" (Continued from page 1)

Generating an audit report in this timeframe can be challenging to all members of the audit team. Therefore, configuration management is very important. To help coordinate the audit report tasks and timeline, the audit team leader can develop and distribute a Gantt chart as shown below Chart 1.

Another effective tool for assisting the lead auditor and the technical editor in fulfilling deadlines and keeping track of what is done and what is left to do on the team level, is a modified version of the summary sheet.

Audit Team Technical Editor
One of the most important people on an audit team is one most seldom seen; the technical editor. The technical editor compiles all information gathered by the team and develops it into a clean and comprehensive report.
A suggested lead auditor policy is that once information is sent to the technical editor, unless it is significant, no changes are allowed. Auditors who repeatedly make changes to the same section of the report add unnecessary stress to the technical editor during this phase. All auditors should make sure the information they create is accurate and well done before submittal to the technical editor.

Pre-Report Writing Preparation
Post field investigation activities can be pretty chaotic. Doing as much as possible, as early as possible minimizes the chaos. One very effective technique is to use an audit report shell. A report shell is a very early draft of the report that contains all information known prior to the field investigation, including the major report sections with place holders for the information that will be collected during field investigation. Providing audit team members Form 1s and 2s (found in Appendix 4 of DOE-STD-3006-2000, *Planning and Conduct of Operational Readiness Reviews*) for their assigned areas of investigation is another effective tool for developing the report. Generic exam-

ples of a report shell and prepared Form 1s and Form 2s can be found on the HSS website in Appendix 4: *Writing Guide* of **"DOE Technical Standard 3006-2000."** (click here to view)

Audit Team Reviews
Your team members are probably very competent in their technical field. However, their focus during field investigation is on collecting and analyzing information; not on the details of technical writing. For this reason, it is important that the audit team leader review everything generated by the other audit team members, and vice versa, before submitting information to the technical editor and eventually publishing the report.

The track changes featured in Microsoft Word is a great tool for these reviews. Using track changes makes it very easy to propose, and accept suggested changes. In addition, the comment feature lets people explain, when necessary, why they are suggesting a change or where they believe there is some more work to be done. When there is a difference of opinion about suggested changes, it is very easy for the parties to find and then talk about the material in question.
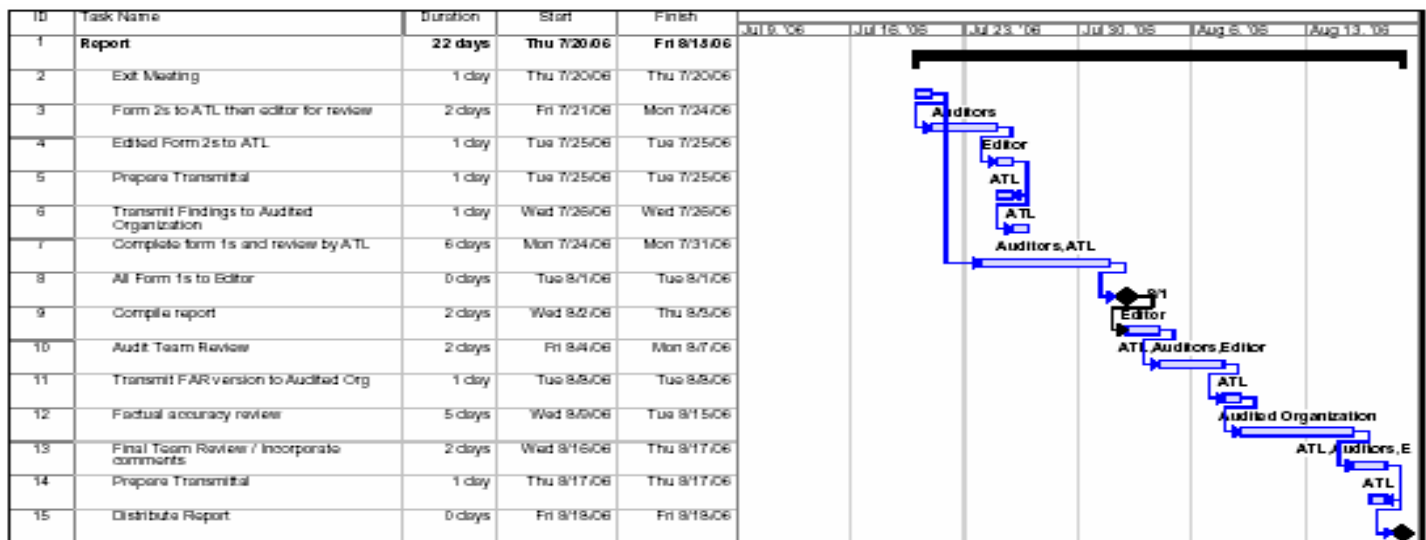
Only after the information has been reviewed and any suggested changes discussed to conclusion, should the report be sent to the technical editor.

Compiling the Report
After receiving the reviewed information from the audit team lead, the technical editor compiles the report using the previously generated audit report shell as the starting point. Once the report is compiled, the technical editor owns the report and any changes made hereafter go through or are made by the technical editor. Like any piece of good technical writing, audit reports go through multiple editing iterations. Adding the date or version number to the file name is a simple way to keep people informed about the version they are working with i.e., "xx audit report 8.12.07.doc" or "team.review2.draft.doc."

Chart 1. Sample Gantt Chart

ID	Task Name	Duration	Start	Finish
1	**Report**	**22 days**	**Thu 7/20/06**	**Fri 8/18/06**
2	Exit Meeting	1 day	Thu 7/20/06	Thu 7/20/06
3	Form 2s to ATL then editor for review	2 days	Fri 7/21/06	Mon 7/24/06
4	Edited Form 2s to ATL	1 day	Tue 7/25/06	Tue 7/25/06
5	Prepare Transmittal	1 day	Tue 7/25/06	Tue 7/25/06
6	Transmit Findings to Audited Organization	1 day	Wed 7/26/06	Wed 7/26/06
7	Complete form 1s and review by ATL	6 days	Mon 7/24/06	Mon 7/31/06
8	All Form 1s to Editor	0 days	Tue 8/1/06	Tue 8/1/06
9	Compile report	2 days	Wed 8/2/06	Thu 8/3/06
10	Audit Team Review	2 days	Fri 8/4/06	Mon 8/7/06
11	Transmit FAR version to Audited Org	1 day	Tue 8/8/06	Tue 8/8/06
12	Factual accuracy review	5 days	Wed 8/9/06	Tue 8/15/06
13	Final Team Review / Incorporate comments	2 days	Wed 8/16/06	Thu 8/17/06
14	Prepare Transmittal	1 day	Thu 8/17/06	Thu 8/17/06
15	Distribute Report	0 days	Fri 8/18/06	Fri 8/18/06

"How to Series…" (Continued from page 2)

After the report is compiled, it is suggested that the lead auditor review it before the technical editor sends it out for a team review. Again, the track changes feature works extremely well for this.

Factual Accuracy Review
Once the audit team is comfortable with the draft report, it is ready for a factual accuracy review by the audited organization. To make comment consolidation easy for the audit team, the audited organization should transmit their comments in a single file.

Although they are not requested to do so, the audited organization will probably point out any remaining typographical errors. Thank them for this. We are all good technical editors, as long as we aren't reviewing our own work, and as human beings generally under information overload, expecting grammar and spell check to work perfectly is not realistic. It is very easy and all too common to make simple, yet glaring mistakes.

Because of the daily management information meetings described in the third article of this series (Quality Assurance Exchange June, volume 2, Issue 2), the bulk of the comments derived from the factual accuracy review should be editorial. When this is not the case, a face-to-face meeting or teleconference call to resolve any differences is a must. When a resolution can't be reached, the audit team and the audited organization will know and understand each other's positions and they can at least agree to disagree. This common understanding is extremely important when developing acceptable corrective actions.

Remember, the editor owns the report, and any negotiated changes resulting from the factual accuracy review are given to the editor for the editor's inclusion and configuration control maintenance.

Obtaining Audit Team Members' Signatures for Report Distribution
When audit teams come from different geographical locations for the field investigation, getting everyone's signature on the audit report can be a problem. A solution is to have the audit team members scan a copy of their signature and send it to the editor. When the audit team member is satisfied with the report, they send the editor an e-mail acknowledging their acceptance, and the editor pastes their signature into the report. To avoid any misuse of these signatures, it is suggested that audit team members use a variant of their legal signature. For example, sign legal documents as Robert and audit reports as Bob. Another suggestion is to use the initials of your first and middle names in your scanned signatures.

The final version of the report should be distributed in PDF format, which allows you to print and scan the signature page as a single image and then insert the signature page into the rest of the report. Or you can save the entire report to a PDF format and use the Acrobat writer "secure, then restrict opening and editing using passwords" feature. If you use this feature, you have to then save the newly created file to activate these restrictions. Either method precludes document readers from copying and pasting the signature images.

Early Finding Transmittal
The essence of auditing is the identification and correction of discrepant conditions. Thus, formally transmitting the findings to the audited organization as soon as possible is essential. This is usually a matter of days after the exit meeting and involves a little extra work for the lead auditor. However, establishing a sense of urgency within the audited organization helps them develop and implement remedies for the discrepant conditions identified.

Proposed Corrective Actions
Implementing a remedy that missed the mark is, at best, embarrassing for the audited organization. To make sure that this doesn't happen, require that the auditor who identified and developed an audit finding approve the corresponding proposed corrective actions prior to their implementation. In addition, establish expected timelines for corrective actions to be implemented and completed. Include this direction in your exit meeting slides and in the report transmittal.

Credit for developing this article goes to Bob Blyth, NE; Karen Brown, Parallax; and Donna Riggs, Oak Ridge (DOE)

For more information contact Bob Blyth at: blythrl@id.doe.gov

The accompanying materials may be found at:

www.hss.energy.gov/CSA/CSP/qa/newsletters

BEST PRACTICES: APPROPRIATE METRICS FACILITATE DATA-DRIVEN INFORMATION TECHNOLOGY DECISIONS

The Six Sigma Program relies on good metrics to provide managers with data needed to make informed decisions that affect the organization. This is particularly true for information technology (IT) operations where data input is constantly changing. Selecting the appropriate metric and applying it to a work process is important, but to make the best use of metrics, one must consistently collect and accurately interpret data to facilitate data-driven IT decisions. This article outlines best practices in choosing the appropriate metric, interpreting the metric output, reporting metric performance, and applying a metric to a work process.

> *"If you can measure it, you can manage it."*
>
> **-** The Six Sigma Program

How do I choose the best metric?

Match the metric to the task under observation. Selecting the metric that produces meaningful data must be preceded by a careful study of what one expects to learn about the process being measured. A properly constructed metric yields sufficient data in a convenient format to facilitate efficient interpretation.

What results do you expect? The results of a metric must be related to a specific question about a work process to enable intelligent decision making. The expectation is that a metric yields data about: cycle times, errors, production rates, labor quantities, equipment downtime, operating costs, etc.

How much labor/cost should it take to administer the metrics? Metrics are costly to setup, implement and maintain. The cost of implementing a metric must be offset by the benefit derived from implementation. For example, tallying the headcount in the IT department does not contribute to effectively managing the department's labor budget. However, measuring the cycle times to complete various tasks and graphing the results enables managers to chart progress against labor management goals.

Rules about metrics. Map out the work process under consideration to ensure a clear understanding of what is being measured. Create a clear correlation between the metric and the question to be answered. For example, to answer the question "what is the average cycle time to complete a laptop rebuild" the metric would measure the beginning to end task of rebuilding laptops. Nothing would be gained by conducting a monthly count of the laptop rebuilds.

Good metric examples

Chart 1. SCR Completion Time Control Chart
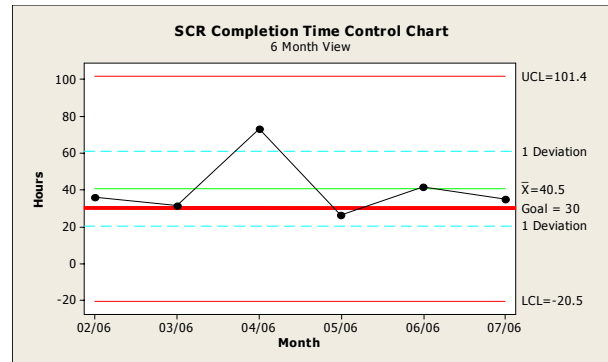
The control chart above (Chart 1.) illustrates the hours spent completing software change requests (SCR) over a six month period. The chart includes upper and lower control limits (UCL, LCL) as well as a stated goal, which is unique for this particular metric.

There are a number of downstream benefits of the above metric. The average completion time can be used in conjunction with the average labor rate to determine the average labor cost per SCR. The deviations from average completion times reveal trends or changes that can be an early warning of evolving problems. Deviations can also demonstrate the effect of moving to a new building, or other non-production related evolutions.

Chart 2. WTS Download Time Metrics
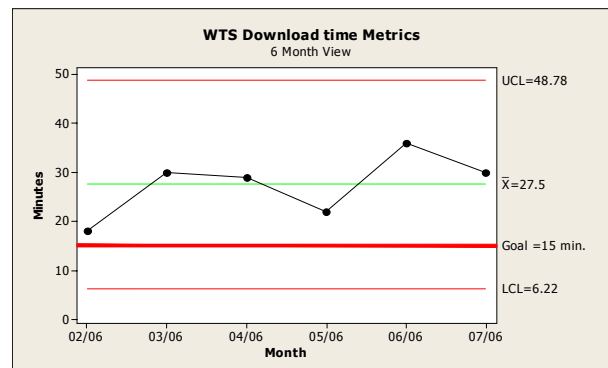
The control chart above (Chart 2.) illustrates the downtime incurred to install waste tracking system (WTS) software modifications (builds) over a six month period. By relating the size and complexity of the builds to downtime, the software manager is able to construct software loads to minimize system downtime.

### *"Best Practices…"*(Continued from page 4)

How to interpret metric output

A consistent summary of technical data is key to interpreting metric data. For the output to be meaningful, it must be consistently analyzed with the same tools and methods at regular intervals. Changing the data analysis method or the metric structure weakens and invalidates the historical data.

A metric should produce data related to a goal. By looking for trends in metric performance data, managers are able to see cause and effect relationships and the impact of decisions or other factors that relate to the work process being measured.

The SDCR Metrics Control Chart (Chart 3.) illustrates the number of software data change requests completed monthly over a six month period. By investigating large deviations from the mean, one can view the impact of: current employee knowledge, the need for additional training, work force adjustment to new procedures, organizational changes, or any number of human behavioral or technical causes.

Chart 3. SDCR Metrics Control Chart
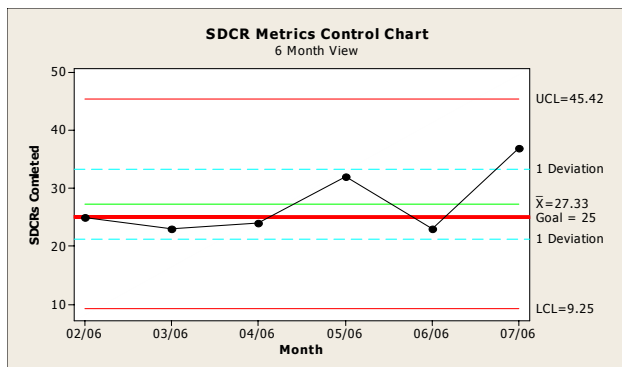
Reporting performance – are we making progress?

Setting up a metric and collecting data is critical to evaluating a process. Making sense and reporting the results is equally critical. There are some guidelines about how a metric should be reported. The report should be simple and easily understood. Where it is possible, only one story per graphic limits misunderstanding of the results being reported. The most helpful graphics are those that illustrate performance in contrast to a goal. Trends should be identified and interpreted with a note to ensure that the essential message of the graphic is not missed.

Control charts are an efficient method of communicating metrics to technical and non-technical audiences. The control chart, featuring the mean, control limits and one or more standard deviations, is normally sufficient to illustrate performance. Often, more than one control chart is necessary to accurately describe a complex process metric.

An important component of a report is the statement of a goal. Readers must be able to readily grasp the meaning of the report and how it relates to the process being evaluated.

Benefits of robust metrics

The most prominent benefit of a metric is performance visibility, which leads to an understanding of process deviations and data-driven decisions. Additionally, accurate performance measurements facilitate problem diagnosis, budgeting, and continuous improvement. Transparency into the operation and performance of work processes not only serves to educate those not directly associated with the processes, but bolsters management confidence that work is being managed. Finally, employee morale tends to be better when their accomplishments and progress have management visibility.

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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

SQA WORK ACTIVITY #4: PROCUREMENT AND SUPPLIER MANAGEMENT

(*This article is the fourth in the series that will address 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.*)

Most software projects will have procurement activities that require interactions with suppliers regardless of the software grade level. Procurement activities may be as basic as the purchase of compilers or other development tools for custom developed software or as complicated as procuring a complete safety system software control system. Thus, there are a variety of approaches for software procurement and supplier management based upon the following:

- the level of control DOE or its contractors have on the quality of the software or software service being procured; and

- the complexity of the software.

Procurement documentation should include the technical[1] and quality[2] requirements for the safety software. Some of the provisions that should be included are:

- specifications for the software features, including requirements for safety, security, functions, and performance;

- process steps used in developing and validating the software, including any documentation to be delivered;

- requirements for supplier notification of defects, new releases, or other issues[3] that impact the operation; and

- mechanisms for the users of the software to report defects and request assistance in operating the software.

These requirements should be assessed for completeness and to ensure the quality of the software being purchased. The four major approaches for this assessment are:

- performing an assessment of the supplier,

- requiring the supplier to provide a self-declaration that the safety software meets the intended quality,

- accepting the safety software based upon key characteristics (e.g., large user base), and

- verifying the supplier has obtained a certification or accreditation of the software product quality or software quality program from a third party (e.g., the International Organization for Standardization, Underwriters Laboratories, and Software Engineering Institute).

It is important to note that while DOE G 414.1-4 grade levels A, B, and C software applications are required to fully meet this work activity, the implementation detail and assessment method of the supplier can vary based on the complexity of the software and its importance to safety.

References:

[1] ASME NQA-1-2000, op. cit., Part I, Requirement 4, Section 202, p. 18.

[2] ASME NQA-1-2000, op. cit., Part I, Requirement 4, Section 100, p.18.

[3] ASME NQA-1-2000, op. cit., Part II, Subpart 2.7, Section 301, p. 105.

FAQ's

Q. If a site is using one of the toolbox codes, is it correct to assume that we can expect error free results?

A. It is difficult, and in most instances impossible, to assure error free results with any software application. Exhaustive testing to ensure error free results is not possible with most software. Many of the tool box codes are moderate to complex in logic, structure and functionality. Since each user of the software and the user's application of the software may exercise a different path through the software that has not been tested, it is impossible to ensure error free results. However, the Central Registry toolbox codes were evaluated based upon SQA criteria consistent with the requirements in DOE O 414.1C. This evaluation identified the gaps in the software quality assurance work activities. Additionally, a guidance report was issued for the use of each tool box code. The intent of the gap analysis and guidance report was to provide a level of confidence in using the tool box codes (within the limitations and guidance noted).

SAFETY SOFTWARE CENTRAL REGISTRY ACTIVITIES

IMBA Added to the Department of Energy Safety Software Central Registry

In August 2006, the Office of Corporate Safety Programs (HS-31) completed an evaluation of Integrated Modules for Bioassay Analysis (IMBA) Expert™ USDOE Edition and IMBA Professional Plus (IPP) for inclusion in the DOE Safety Software Central Registry. As a result of the evaluation, a gap analysis report was generated to document strengths and weaknesses when compared to the safety software quality assurance (SSQA) requirements and criteria in DOE O 414.1C, *Quality Assurance* and DOE G 414.1-4, *Safety Software Guide for Use with 10 CFR 830, Subpart A, Quality Assurance Requirements, and DOE O 414.1C, Quality Assurance.* Based on the completion of this evaluation and approval by the Office of Health, Safety and Security, IMBA Expert™ USDOE Edition version 4.0.28 has been added to the DOE Safety Software Central Registry.

The evaluation of IPP identified three critical recommendations that must be addressed before IPP can be added to the DOE Safety Software Central Registry. The code owner, United Kingdom's Health Protection Agency, is currently addressing the critical recommendations.

HS-31 has also published recommended guidance for the use of IMBA Expert™ USDOE Edition version 4.0.28 and IPP version 4.0.28. The guidance document includes a discussion of the known limitations of IMBA and provides workarounds where possible. Guidance is also given on using certain features of IMBA that can be confusing to the user. The gap analysis and guidance documents can be found at:

www.hss.energy.gov/csa/csp/sqa/central_registry/IMBA/imba.htm

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TOOL BOX CODE CORNER

CFAST Upgrade: The National Institute of Standards and Technology (NIST) is currently working on upgrading CFAST to close the gaps identified during the 2004 evaluation for inclusion of the code into the DOE Safety Software Central Registry. The upgrade will focus improving leak path factor calculations and other model related technical issues. This work will be performed according to DOE Safety Software Quality Assurance (SSQA) requirements which will then serve as the basis for any future code upgrades that NIST may perform. The project is being co-funded by DOE and NRC. The work began the 1st Qtr FY07 with an expected completion during the 3rd Qtr FY07.

HOTSPOT Evaluation: HS-31 has received a request from the Department's Subcommittee on Consequence Assessment and Protective Action (SCAPA) to consider including HOTSPOT into the Safety Software Central Registry. HOTSPOT is routinely used to perform calculations and develop data used in establishing the safety basis for DOE facilities and operations and to support a variety of safety analyses and safety evaluations developed for these facilities. It is also routinely used in the development of Emergency Preparedness Hazard Assessments (EPHAs) to meet DOE O 151.1C requirements. As a result, HOTSPOT meets the criteria to be considered and evaluated as a toolbox code. A team has conducted an evaluation to determine if HOTSPOT complies with SSQA requirements for the Safety Software Central Registry. The evaluation is complete and the gap analysis document is being drafted. The gap analysis is expected to be finalized by the end of January 2007.

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QA POINT OF CONTACT DATABASE UPDATE

DOE HSS Office of Corporate Safety Programs (HS-31) has compiled a point of contact database for both DOE Federal and Contractor employees that have quality assurance (QA) and/or software quality assurance (SQA) functions at DOE Sites and/or Field Offices. The database and its contents will be used by HS-31 to more effectively distribute QA and SQA related communications such as newsletters and announcements of quality related issues important to sites. The purpose of this information is to allow the development of higher quality distribution lists. This database currently has 800+ names. The information contained in this database may not be current due to organizational changes, realignments, etc. Therefore, it will be an on-going task for HS-31 to initiate, maintain, and update contact information in this database.

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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 CONFERENCES & TRAINING
DOE / NUCLEAR-RELATED

ANS Conference on Nuclear Training and Education (CONTE '07)
When: February 4-7, 2007
Where: Hyatt Regency Jacksonville Riverfront, Jacksonville, Florida
For more info: www.ans.org/meetings/docs/2007/conte07-prelim.pdf

OTHER UPCOMING CONFERENCES
OF GENERAL QA INTEREST

Six Sigma Conference
When: February 12-13
Where: Phoenix, Arizona
For more info: www.asq.org/conferences/six-sigma/index.html

2nd Annual Customer-Supplier Division Symposium
When: February 21-23
Where: Phoenix, Arizona
For more info: www.asq.org/conferences/customer-supplier-symposium/index.html

15th Annual International Conference on ISO 9000
When: February 26-27
Where: Lake Buena Vista, Florida
For more info: www.asq.org/conferences/iso-9000/index.html

ASQ 19th Quality Management Conference
When: March 1-2 / Pre-conference courses Feb 26-28
Where: Adams West, Dallas, Texas
For more info: http://secure.asq.org/quality-management-conference-reg-2007.html

USEFUL LINKS AND RESOURCES

The IAEA Department of Nuclear Energy, Division of Nuclear Power publishes the *"Nuclear Power Newsletter"* which features information on training-related projects, planned meetings and workshops, and other articles of interest.
To view the latest issue, go to:
http://www-pub.iaea.org/MTCD/publications/newsletter.asp?id=122

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