



Emergency Management Issues Special Interest Group Annual Meeting

The New DOE/HS Software Quality Assurance Order and Guide

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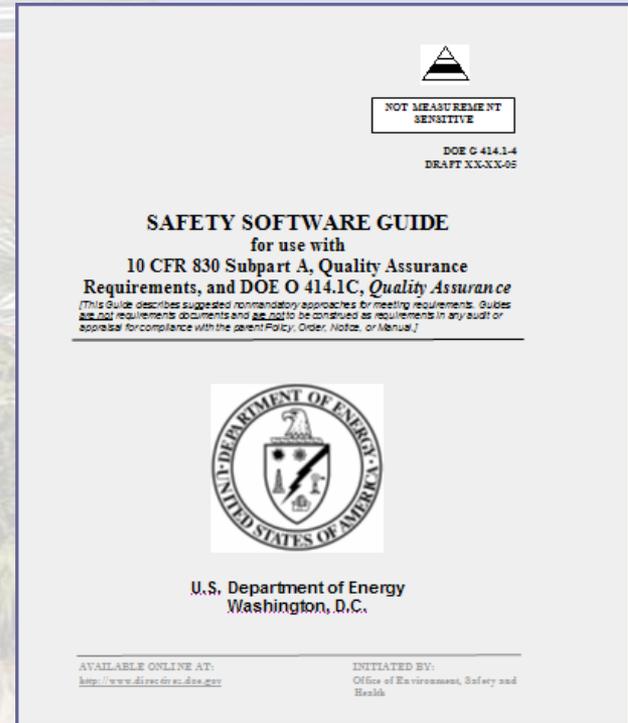
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Background Info

- In 2005 DOE issued an Order and Guide establishing SQA requirements for **safety software**:
 - DOE Order 414.1C
 - DOE Guide 414.1-4



DOE O 414.1D... Issued

DATE: January 21, 2011
TO: DIRECTIVES POINTS OF CONTACT
FROM: KEVIN T. HAGERTY, DIRECTOR
OFFICE OF INFORMATION RESOURCES
SUBJECT: Draft DOE O 414.1D, *Quality Assurance*

The draft directive has been posted on RevCom for review and comment. The purpose is to ensure that Department of Energy (DOE), including National Nuclear Security Administration (NNSA), products and services meet or exceed customers' requirements and expectations. This has been determined by the Deputy Secretary to be a HS priority directive. Therefore, an accelerated Review/Comment period of 21 days has been assigned in RevCom.

INSTRUCTIONS

Headquarters DPCs have until **February 11, 2011**, to submit to the OPI consolidated comments received from subject matter experts and/or field DPCs using the Department's RevCom (<http://www.revcom.doe.gov>).

HQ DPCs

- may set separate deadlines for field offices using the RevCom "Version" link.
- must obtain approval from their secretarial officers or designees before submitting.

U.S. Department of Energy
Washington, D.C.

ORDER

DOE O 414.1D

Approved: xx-xx-2011
Review: xx-xx-2011

SUBJECT: QUALITY ASSURANCE

1. PURPOSE

- To ensure that Department of Energy (DOE), including National Nuclear Security Administration (NNSA), products and services meet or exceed customers' requirements and expectations.
- To achieve quality for all work based upon the following principles:
 - All work is conducted through a single, integrated, and effective management system;
 - Management support for planning, organization, resources, direction, and control is essential to QA;
 - Performance and quality improvement require thorough, rigorous assessment and effective corrective action;
 - All personnel are responsible for achieving and maintaining quality; and
 - Risks and adverse mission impacts associated with work processes are minimized while maximizing reliability and performance of work products.
- To establish additional quality process-specific requirements to be implemented under a Quality Assurance Program (QAP) for the control of suspect/counterfeit items (S/CIs), and safety software as defined in this Order.

2. CANCELLATION. DOE O 414.1C, Quality Assurance, dated 6-17-05.

Cancellation of a directive does not, by itself, modify or otherwise affect any contractual or regulatory obligation to comply with the directive. Contractor Requirements Documents (CRDs) that have been incorporated into a contract remain in effect throughout the term of the contract unless and until the contract or regulatory commitment is modified to either eliminate requirements that are no longer applicable or substitute a new set of requirements.

In late April, 2011
DOE Order 414.1D
was issued, replacing
DOE O 414.1C

Key Observations

- This Quality Assurance Order applies to **all work** conducted by, or for DOE.
- DOE programs must still meet all other QA regulatory requirements (e.g., NRC, EPA)
- The definition of safety software remains essentially unchanged
- All software, not just safety software, must meet 10 basic QA criteria.

Ten Basic QA Criteria

1. Have a Framework for Your SQA Program.

- Establish responsibilities for managing, performing, and assessing work.
- Establish processes for funding, planning & scheduling work.

2. Train Project Personnel

- Train and certify personnel to do their assigned work.
- Provide continuing training.

3. Conduct Quality Improvement Activities

- Implement processes to detect, prevent & correct problems.
- Identify the causes of problems and prevent recurrence.
- Identify items needing improvement.

Ten QA Criteria (cont)

4. Prepare and Maintain Records.

- Prepare and maintain QA-related documents and records.

5. Follow Regulations and Contracts.

- Perform work according to regulatory & contract requirements.

6. Design and Test Software before Implementation.

- Perform design work according to sound engineering/scientific principles and requirements.
- Verify/validate work before implementation.
- Do not have people verify/validate their own design work

7. Define and Implement Procurement Requirements

- Implements procurement requirements.
- Use criteria to evaluate and select prospective suppliers.

Ten QA Criteria (cont)

8. Conduct Acceptance Testing.

- Test software using established acceptance and performance criteria.

9. Identify and Fix QA problems

- Management works to identify and correct organizational SQA problems.

10. Conduct Independent Assessments.

- Plan and conduct independent assessments
- Ensure persons who perform independent assessments are technically qualified
- Ensure assessors are not subject to conflicts of interest

Update QA Program Standards

Examples of national or international consensus standards that may be used in whole or in part...”:

- **ASME NQA 1-2008 with the NQA-1a 2009 addenda, *Quality Assurance Requirements for Nuclear Facility Applications, Part I and applicable requirements of Part II***
- **(b) ASME NQA 1-2000, *Quality Assurance Requirements for Nuclear Facility Applications, Part I and applicable requirements of Part II***
- **(c) ANSI/ISO/ASQ Q9001-2008, *Quality Management System: Requirements***
- **(d) ANSI/ASQ Z 1.13-1999, *Quality Guidelines for Research.***

The Quality Assurance Program (QAP) Guide Enhancements states:

- **Risk** is a fundamental consideration in determining the extent to which controls should be applied at the facility level.
- The type and amount QA controls should be dependent upon function, complexity, consequence of failure, reliability, repeatability of results, and economic considerations.

The Graded Approach in DOE Order 414.1D

QA programs should be commensurate with:

- the relative importance to safety, safeguards, and security;
- the magnitude of any hazard involved;
- the life-cycle stage of a facility or item;
- the programmatic mission of a facility;
- the particular characteristics of a facility or item;
- the relative importance to radiological and nonradiological hazards; and,
- any other relevant factors. (10 CFR 830.3)

An Update to DOE G 414.1-4

- No word on when work will begin to update DOE's Safety Software guide
- The Guide is where the rubber meets the road and the real implications occur for our consequence assessment models.
- As the APGEMS model custodian, I will stay connected with DOE/HS to monitor work on the guide (and hopefully participate in its revision).
- Will report to SCAPA on what is going on...

SCAPA's SQA Guidance Document

DOE SUBCOMMITTEE ON CONSEQUENCE ASSESSMENT AND PROTECTIVE ACTIONS
EMERGENCY MANAGEMENT ISSUES SPECIAL INTEREST GROUP

Software Quality Assurance Guidance for Consequence Assessment Software Designed for Safety-Related and Other Non-Safety Applications

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SCAPA Consequence Assessment Modeling Working Group

04/08/2010

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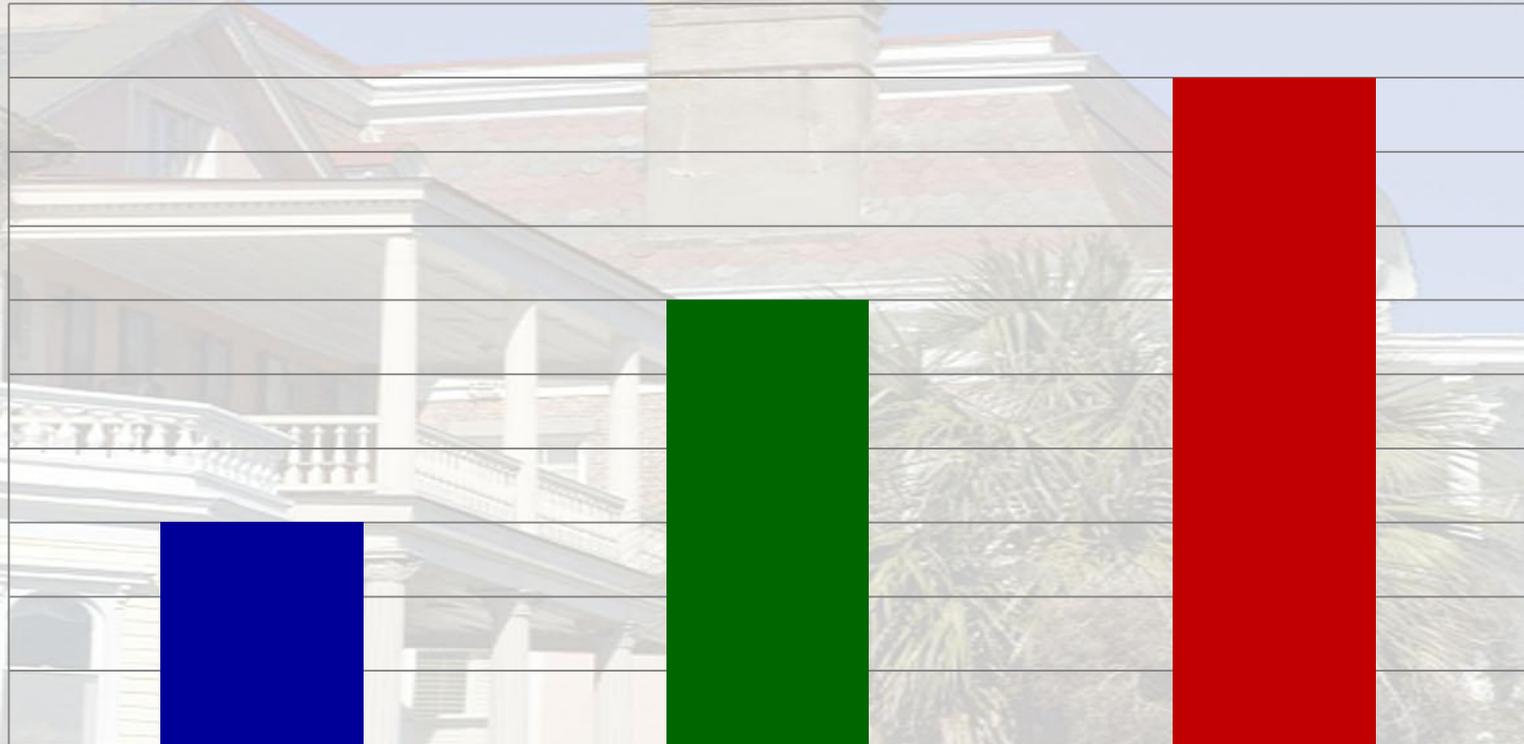
The U.S. Department of Energy Subcommittee on Consequence Assessment and Protective Actions (SCAPA) has developed software quality assurance guidance for consequence assessment software to support applications that do not involve a direct nuclear safety function as outlined in DOE Order 414-1C, but instead provide a safety-related or other non-safety function. This guidance may be applicable to other software products that support emergency preparedness and response applications.

Uses a Graded Approach to the SQA Work Activities for Safety Software

The SQA work activities specified for safety software are:

1. Software Project Management and Quality Planning
2. Software Risk Management
3. Software Configuration Management
4. Procurement and Supplier Management
5. Software Requirements ID and Management
6. Software Design and Implementation
7. Software Safety
8. Verification and Validation
9. Problem Reporting and Corrective Action
10. Training of Personnel.

Relative QA Level



Basic QA
Criteria

SCAPA SQA
Guidance

Safety
Software

Questions? Concerns?

- Please contact:

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