



Department of Energy

Washington, DC 20585

MEMORANDUM FOR INGRID KOLB
DIRECTOR
OFFICE OF MANAGEMENT

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for KEVIN T. HAGERTY
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SUBJECT: Notice of Intent to Revise DOE Order 414.1C, *Quality Assurance*,
June 17, 2005

JM CHRONOLOGY

JM RECEIVED 10/5/10
OUT FOR REVIEW 10/8/10
DRB DISCUSSION 10/21/10

PURPOSE: This memorandum provides justification for revising Department of Energy (DOE) Order (O) 414.1C, *Quality Assurance*.

JUSTIFICATION: As part of DOE's normal review process for Directives, and in an effort to clarify and streamline requirements, DOE (O) 414.1C will be reviewed for appropriate updates and clarification. In addition, consistent with the Department's effort to encourage the use of national consensus standards, the Order will also be updated to endorse the use of the nuclear quality assurance (QA) standard, American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance Standard (NQA-1), *Quality Assurance Requirements for Nuclear Applications*, for certain facilities and ANSI/ISO/ASQ Q 9001-2000, *Quality Management System: Requirements*, for non-nuclear activities.

Background for Existing Directive. The QA requirements in DOE O 414.1C are written to ensure that products and services meet DOE expectations. Assuring quality throughout the DOE complex is needed for reasons of safety, security, mission, and cost savings.

The origins of DOE O 414.1C can be traced to the 1954 Atomic Energy Commission QC-1, Weapons Quality Program. In 1994, DOE issued QA requirements specifically for its nuclear facilities in 10 Code of Federal Regulations (CFR) Part 830, *Nuclear Safety Management* (10 CFR 830). In 1998, DOE converted DOE O 5700.6C, *Quality Assurance*, into DOE O 414.1 to continue to provide QA requirements for nonnuclear facilities and for all DOE Elements. Subsequently, requirements were added to DOE O 414.1C relating to suspect/counterfeit items, corrective action management programs, and safety software quality assurance which also supplement the QA requirements of 10 CFR 830 for nuclear facilities. Consequently, DOE O 414.1C currently applies to work performed by or for the Department, including not only work at nonnuclear facilities but also at nuclear facilities for those additional requirements beyond 10 CFR 830.



Summary of Development Process. The revised directive will be developed using a multi-organizational team, including a writing team and a reviewing team, with representatives from the three Under Secretaries (e.g., from the Headquarters (HQ) Program Office and Field Offices), from HQ Staff and Support Offices, as well as from DOE contractors. Many of the members of this team have been meeting over the past year to revise this Order consistent with the 2008 Project Plan for Safety Directives Revision. As part of that effort, they have reviewed each existing requirement, proposed changes to the requirements, and documented the bases for the changes and for the retained requirements. They will review these proposed changes against the Department of Energy 2010 Safety and Security Reform Plan and update the Order as appropriate. The proposed revision will then be reviewed, in parallel, by an independent multi-organizational management team (i.e., Executive Steering Committee); Defense Nuclear Facilities Safety Board; the DOE Quality Council (consisting of Federal QA subject matter experts and managers from across the DOE complex); and the Office of Health, Safety and Security.

Applicability. The requirements of this Order are applicable to work at DOE with the following exclusions:

- (1) Naval Reactors;
- (2) Bonneville Power Authority;
- (3) Nuclear facilities to the extent the specific requirement duplicates or overlaps the requirements of the Nuclear Regulatory Commission (NRC) [for NRC-regulated activities]; and
- (4) Nuclear facilities to the extent the specific requirement duplicates or overlaps the applicable requirements in 10 CFR 830.

Major Proposed Changes.

- (1) Addition of a requirement in the Contractor Requirements Document (CRD), Attachment 2 of the current Order, to use NQA-1 to implement the QA requirements for hazard category 1, 2, and 3 nuclear facilities. NQA-1-2000 will be required for existing facilities and NQA-1-2008 will be required for "new" nuclear facilities depending upon the project critical decision phase when the new Order is issued. Mandatory use of NQA-1-2008 is necessary to an initiative supported by DOE, Nuclear Regulatory Commission (NRC), Nuclear Energy Institute (NEI) and American Society of Mechanical Engineers (ASME) to bring the entire national nuclear industry into alignment with one QA standard.
- (2) The authority for DOE Secretarial Officers to approve the use of a different but equivalent consensus standard to NQA-1 for these facilities will also be proposed as part of the requirements in the CRD.
- (3) Removal of the Corrective Action Management Program (CAMP) requirements from Attachment 4 in DOE O 414.1C and its placement in one of the directives being currently evaluated by HSS and the Working Group for Revision to Worker Safety Directives (e.g., the Integrated Safety Management Order or the Oversight Order).
- (4) Clarification of the safety software QA requirements in Attachment 5 of the current Order consistent with commitments to the Defense Nuclear Facilities Safety Board (DNFSB) in response to DNFSB Recommendation 2002-1.

- (5) Streamlining and clarifying requirements and responsibilities, and increasing awareness of the current flexibility for contractors of nonnuclear facilities to use a graded approach to tailor implementation of their quality programs including adoption of ISO 9001 for non-nuclear operations. In the process of reviewing the Order the team identified a number of requirements that should be more clearly written to clarify the intent.

Related Changes. A related justification memorandum is in process to revise and update DOE Guide (G) 414-2A, *Quality Assurance Management System Guide for Use with 10 CFR Part 830 Subpart A, Quality Assurance Requirements, and DOE O 414.1C, Quality Assurance*, dated June 17, 2005.

Recommended Development Schedule. See the proposed development schedule below. Additional time is needed to complete the development of this revision to accommodate multiple peer reviews by interested parties that will be conducted before RevCom review. These pre-RevCom reviews are expected to improve the quality of the Order and reduce the number and substance of the RevCom comments.

IMPACT: This revision of the QA Order will need to be coordinated with the revision to the Worker Safety Directives to transfer the CAMP requirements from Attachment 4 in DOE O 414.1C. The actions to the related QA guide (see above "Related Changes") need to occur concurrently with the revision to the QA Order.

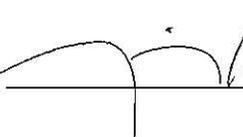
Potential Costs/Savings.

- (1) There will be efficiencies for DOE and US nuclear industry contractors and suppliers to use a single national standard for QA Programs. Currently, DOE, NRC and ASME refer to many different editions of NQA-1. This causes confusion, and multiple methods to maintain Quality Assurance Program plans to different editions, and unnecessary corrective actions to address findings solely based on edition differences.
- (2) Another current negative cost impact is the Commercial Grade Dedication (CGD) process in NQA-1. Again, the entire US nuclear industry participated in a major improvement to the CGD process in NQA-1-2008/9. The new process will help to avoid some of the past deficiencies and reduce associated costs for CGD in DOE. Transition to the new CGD requirements in NQA-1-2008/9 will benefit DOE.
- (3) There could be a minor cost associated with the adoption of the prescribed versions of NQA-1 for those nuclear facilities not currently using that voluntary consensus standard as an implementing standard. However, very few contractors responsible for DOE nuclear facilities are not currently using NQA-1. HSS and PSOs will provide guidance/direction to contractors to ensure resources are not wasted on editorial and administrative changes to address edition changes. Also, the Order and the CRD will contain language that allows the Secretarial Officer to approve use of a consensus standard that provides an equivalent level of quality requirements, including earlier versions of NQA-1.

- (4) There will be some costs associated with additional training requirements for users and overseers of safety software QA, but safety software requirements are only applicable to users of safety software for nuclear facilities as defined in the Order.
- (5) The streamlining and clarification will provide more flexibility to implement the requirements and potentially reduce costs.

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Concur:  Non-concur: _____ Date: 10-21-10

| Timeline: Schedule for Directives Development | Standard (Days) | Proposed (Days) |
|---|-----------------|-----------------|
| Draft Development (Writer) | 60 | 90 |
| Process/Post (MA-90) | 5 | 5 |
| Review and Comment (Interested Parties) | 45 | 45 |
| Comment Resolution (Writer) | 30 | 45 |
| Process/Post in RevCom (MA-90) | 5 | 5 |
| Concurrence (Writer) | 15 | 15 |
| Preparations of Final Draft (Writer) | 5 | 15 |
| Total | 165 | 220 |

Requests extended schedule 10-21-10