

Directive Number and Title:

414.1A, Quality Assurance

Originating Office:

Office of Environment, Safety and Health, Nuclear and Facility Safety Policy

Review Team Members:

Gustave Danielson, EH
JM Drake, SPR
Anne Troy, GC

Background:

When and why was the Order established?

The original DOE-wide QA Order was established in 1981. This Order was developed in response to a report from the Inspector General citing widespread failures in quality attributed to the lack of a corporate DOE QA policy, requirements and guidance. Following Three Mile Island, a panel appointed by the Undersecretary found that top DOE and contractor management paid little attention to quality systems implementation.

In 1991 a major modification of the original Order was made to the Department's first performance-based Order, 5700.6C. The issuance of 5700.6C represented a significant shift in philosophy. Quality had been the responsibility of QA/QC organizations and is now clearly the responsibility of all organizations that contribute to the item or service. Senior management is now accountable for effectiveness of the QA Program. The quality criteria are now expressed in terms of desired outcomes rather than methods for accomplishing the outcomes. The outcome oriented criteria are for use in a quality management system.

Two subsequent revisions were made in 1996 and 1999 (now O 414.1A) addressing Secretarial initiatives such as; the Directives Improvement Project of 1995, Integrated Safety Management (DNFSB 95-2), Corrective Action Management Program (DNFSB 98-1) and most recently revised in 1999. The Order also responds to national/international trends in quality assurance.

The principles, performance-based criteria, and management system framework used in developing the QA Order have since been used in other DOE directives and international standards (e.g., DOE Safety Management System Policy, ISO 9001:2000 Quality Management System, IAEA Quality Assurance Code, and ISO 14001 Environmental Management System).

How was the Order & CRD established?

The 1991 version of the QA Order and Contractor Requirements Document (CRD) were

established through the collaborative efforts of DOE, contractor, and industry line managers and quality experts representing a variety of business sectors (R&D to D&D to Federal oversight). The same method was used for the subsequent revisions. This team evaluated all quality standards, regulations, philosophies, and methods that were current at the time. From those different approaches and their own personal experiences the team first established a set of guiding principles for quality assurance. The principles were then used to define the criteria for a quality management system.

What major modification and recent updates have been made?

The 1991 version, 5700.6C, defined outcomes/results for the contractors to achieve using their own methods approved by DOE. Two subsequent revisions (1996 and 1999) retained the performance based approach while addressing Secretarial initiatives such as; the Directives Improvement Project of 1995, Integrated Safety Management (DNFSB 95-2), Corrective Action Management Program (DNFSB 98-1) and most recently revised in 1999. The current QA Order is the result of 50 years of continuous improvement in quality criteria and management systems.

Overview of Requirements:

What is the orders purpose and how is it accomplished?

The QA Order defines outcome oriented criteria for use in a quality management system. The quality management system includes processes to plan, perform, assess and improve all work to assure it meets requirements. "All work" means any work performed to accomplish the organization's mission as well as safety, security, health, environment, finance, and other supporting activities. The Order allows for flexible graded implementation methods for each of the 10 criteria that are described in a QA Program. Organizations are required to select an appropriate national/international standard to develop and implement the DOE QA Program. Also included are general requirements and responsibilities for issues such as; safety and quality system integration, DOE approval and oversight of contractor QAPs.

Analysis:

Do we still need to apply the Order to contractors?

The need for the QA Order has increased along with the diversity of DOE work, hazards and contractors chosen to implement this work. On a frequent cycle over the last 20 years internal and external oversight organizations repeatedly cite failures in major DOE projects that could have been averted with proper implementation of a Quality Assurance Management System. The QA Order supports Integrated Safety Management (DNFSB 95-2), Corrective Action Management Program (DNFSB 98-1) and DOE Acquisition Regulations. The QA requirements and Order are also consistent with the "Best QA Practices" guidance for Performance Based Contracting promoted by the Department of Commerce.

The QA Order provides DOE Contracting Officers and Program Managers with a flexible and

reliable set of requirements for assuring the work of their contractors. It allows DOE to evaluate and accept a variety of methods and national quality standards proposed by contractors to implement the QA Order.

The DOE and contractor organization comments (8) are summarized in attachment 1 to this report. The current performance-based requirements accommodate all of the comments. No specific improvements were identified that would necessitate a change to the requirements.

If so, are there attentive less bureaucratic approaches?

Most line managers and quality professionals agree that the current 10 quality criteria could not be reduced or restated without destroying the Order's comprehensive approach to a quality management system. To the contrary, it is routine for external and internal oversight organizations to push for increasing the detail and prescriptiveness of the Order as a remedy for contractors who fail to effectively implement the current requirements. All major federal agencies impose some form of QA requirements on their contractors and/or regulated industry. DOE's approach is the least prescriptive.

There are many national consensus standards for quality (e.g., ASME NQA-1-2000, ASQ Q9001:2000, etc). The Order does not duplicate these standards, but does require their use in developing a QAP. Some federal agencies mandate a single standard, but not all agencies use the same standard or even the same version of a single standard. DOE contractors do work under many of these other agency's requirements. This precludes us from mandating one standard for all work.

The Order defines the Department's expectation for a Quality Assurance Program (QAP) in performance-based terms (criteria) that may be satisfied by the prescriptive requirements of national standards. The Order requires that an appropriate national standard(s) be selected to develop and implement the QAP. Each contractor may select the standard that suits their work and hazards.

Are there any other useful changes to the contractor requirements document?
See the Summary Recommendations below.

Summary Recommendations of the Review Team:

Based on a review of the comments received and an analysis of the Order, the team concludes that the Order should be retained with suggested changes noted below. This is based on a recognition that there is a need to maintain these requirements to (a) meet a DOE safety protection or safety management system expectation, (b) preserve the stability and predictability inherent in the DOE Directives System founded on a consensus approach, and (c) preserve established programs that assure the quality of our products and services and are tailored and integrated in contractor safety management systems.

Suggested Changes: Revise the Order as needed in the future to address DOE organizational changes and the final version of the Department's *Quality Assurance Improvement Plan*, Draft Revision 3, January 17, 2002 (currently in development for the Deputy Secretary), team minority view comments, and Office of Procurement and Management Assistance comments. Revise the "Applicability" section to more clearly state that the Order does not apply to activities affecting nuclear safety. In the next revision of the Order, propose deletion of the CRD requirement 1.d. (i.e., contractors "must" consider DOE QA guidance when developing a QAP will become "should consider"). Revise the QA guides to expand information on the graded approach, software quality, DOE oversight, and integrating the quality and safety management system descriptions.

Minority Views

See attachment 2, Minority View by Anne Troy.

Attachment 1 DOE QA Order Review Report

The following summarizes and evaluates comments received on the QA Order.

Only 6 individual organizations (DOE or contractors) and 2 representative bodies have commented on the Order.

- One comment states that the QA Order is performance-based and necessary.
- One comment states that the QA Order is necessary. It further states "some" of the requirements may not be performance-based. The comments did not identify the specific requirements that may have been of concern.
- Four of the comments support retaining the QA Order for non-nuclear activities and retaining the DOE QA Rule, 10 CFR 830 Subpart A, for nuclear facilities and activities. This is the current scope of the QA Order. The requirements of the DOE QA Order and rule are the same, but the difference in scope is clearly defined. The Order explicitly states that the scope is DOE organizations and contractors not subject to DOE's QA rule. The Order further states that it does not apply to work that is subject to QA rules issued by the NRC and EPA. However, the Order "Applicability" section will be further clarified in the next revision.
- Two of the comments suggest the Order duplicates or should be deleted in favor of a national consensus standard. We agree that the Order should not duplicate standards. There are many national consensus standards for quality (e.g., ASME NQA-1-2000, ASQ Q9001:2000, etc). The Order does not duplicate these standards, but does require their use in developing a QAP. However, the Order "Requirement" section 4.a.(6) will be further clarified to specify acceptable national standards in the next revision .

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The QA Order provides the Department's outcome expectations and a framework for such a QA plan/program/management system. The Order also provides a mechanism for DOE line management to review, approve, and monitor/oversee contractor QAPs. Finally, the Order addresses the need for integrating management systems for quality and safety. These types of requirements are not found in QA consensus standards. It is also important to note that the letter initiating this directives review states that contractor performance should be monitored and validated under a QA plan. The DOE Acquisition Regulation requires a QA plan, as well as all of DOE's external customers. The QA Order ensures that all organizations have such a QAP tailored to suit their customer expectations, work and hazards.

Attachment 2
Minority Views

Dissenting Opinion from Anne Troy, Team Facilitator

Summary. This Order is confusing in its scope and subjects contractors to "additional quality requirements and/or specific standards as necessary for certain types of work (e.g., the Office of Defense Programs weapons production standards QC-1) to ensure that it meets their expectations as well as those of the Order." While some of the requirements are statutory or regulatory mandates and DOE is obligated to include them as requirements, this Order heaps up so many that it is hard to figure out the Order's applicability and coverage. This is compounded by the fact that the Order mandates that contractors review guidance documents prior to submission of a Quality Assurance Plan (QAP). The submitted QAP must describe how the graded approach will be applied; yet, other than a definition of what grading means, does not provide the contractor with a feasible method to do grading.

Rebuttal - Neither the field comments from this effort, nor a recent review of the QA Order by the Fernald DOE and contractor organizations, have identified concerns with the general requirements and clarifying notes. They are included in the Order as aids to implementation, increase implementation flexibility, and ensure all work is performed under a documented QA Program. While EH is the OPI for this Order, the requirements and guidance are developed in collaboration with hundreds of DOE, contractor, and professional society members to ensure it addresses all user needs. The Order is issued with concurrence of PSOs, Field Management Council, and General Counsel's Office.

Scope and Coverage. The Order presumes knowledge and understanding of its scope which, upon examination, is unclear. The Team states that the Order only applies to non-nuclear facilities. However, when we look at the scope of the Order, it does not state so explicitly. It is assumed that everyone understands what the Order's scope is; yet, that is not readily apparent based upon the confusion evident in the comments from the field and contractors. Determining the Order's applicability is a process of deductive reasoning: if 10 CFR 830 or if other regulatory QA requirements apply, then this Order does not. Throw in "other requirements as necessary for the work," the Order's requirements and perhaps, guidance, and you have a

Rebuttal - The Team report is revised to recommend clarification of the applicability statements in QA Order paragraph 3. The Order (para. 3.b.) specifically states that DOE line management determines which contracts will include the CRD. The Order (para. 3.c.) acknowledges, but does not impose, the existence of other Federal QA regulations and DOE Cognizant Secretarial Office requirements that may apply to specific types of work performed by DOE contractors. The Order promotes the use of a single integrated QAP to ensure an over arching system is in place that is efficient and cost-effective. Contractors use this approach for their QAPs and define their method of grading QA Criteria implementation in those QAPs.

recipe for frustration. In my opinion, a contractor's most simple course of action is to put together a QAP that addresses any and all QA requirements rather than try grading. Naturally, such a QAP is expensive (to DOE ultimately).

The Order imposes many requirements. A contractor is subject to: (1) the provisions of the Order; (2) other requirements as necessary for the work, e.g., QC-1; and (3) numerous guidance documents. The contractor is forced to review guidance documents violating the "guidance is guidance" rule we live by. The contractor must integrate the QAP with its Integrated Safety Management Plan. The team contends that an integrated QAP isn't hard to produce and, in any case, contractors can grade the myriad of requirements pointing to the definition of grading provided in the Order. However, the Order does not consolidate all quality assurance requirements such as those for transportation and packaging because these requirements do not fall within the environment, safety and health purview of EH.

Grading. The truth of the matter is that no one can "grade" an Order using the definition given in the Order. A definition does not confer upon the contractor any feasible method to perform grading. This is a recognized truth and is one of reasons DOE moved to standards based management (See *Criteria for the Department's Standards Program*, DOE/EH/-0416) in 1994. What we discovered is that one can *tailor* an Order to the work if a robust, formal, and legally defensible process is used. The only tailoring process endorsed by the DOE and the Defense Board is the Necessary and Sufficient Closure Process. EH's failure to promote and permit the use of the Closure Process means that contractors are foreclosed from tailoring the requirements

Rebuttal - In the next revision of the Order, propose deletion of the requirement to review DOE QA guidance. Over many years of experience DOE and its contractors have found that the guides are very helpful. Many past quality problems are attributed to misunderstanding QA and poorly developed QA Programs that could have been prevented by review of the DOE guidance. There is no requirement to use the guidance.

In the next revision of the QA guides propose additional integration guidance. Integration of quality and safety management systems has been required by the Secretary's Policy, P 450.4 for over 5 years. The QA Order has applied to safety and mission performance for more than 12 years. The Integrated Safety Management System Guide and QA Guides include information on integrating quality and safety. The QA guide will be revised to expand this guidance.

Rebuttal: DOE field team members and contractors feel the graded approach is a major strength of this Order. This comment confuses the "tailoring" of Orders or other requirements through an approved process such as Necessary and Sufficient and SRIDs, and the implementation of a selected requirement through "grading" of the requirement to fit the work. Contractors routinely develop QAPs required by this Order by grading criteria in the Order. The Order has no restrictions on applying DOE -approved tailoring processes. This comment also asserts that inappropriate grading leads to "gold plated, excellent protection" programs that DOE cannot afford. Notwithstanding that this statement is without basis, it also confuses the notions of "adequate protection" and "excellence in operations". DOE can only assure adequate protection, but we can promote excellence in operations - an end state that is desirable and saves DOE money.

to its work. The inability to tailor connotes that DOE cannot trust its contractor is figure out the best way to do work safely. Attempts to "grade" the requirements to the work are futile causing thousands of "bring me a rock" scenarios. Because grading is not feasible and tailoring using the Necessary and Sufficient Closure Process not permitted, *adequate* protection becomes gold plated, *excellent* protection. Not surprisingly, excellent protection costs DOE a lot more.

OPAM comments on the E.S. and H Directives

1. Is there any support for the conclusion that DOE's approach to QA is the least prescriptive of any agency? Can it be specified?
Reply - Yes, the NRC, EPA, NASA, and DOD all require compliance with specific rules, standards, and regulatory guides that are typically more detailed and less flexible compared to the performance requirements of the QA criteria. For example, NASA imposes standard ASQ/ISO 9001 for its organizations and contractors and also requires that they be certified by a non-government organization as complying with the standard. The ISO standard may be used to meet the DOE QA Criterion, but goes beyond the DOE Criterion in scope and depth. DOE currently has no formal internal or external management system certification process that validates compliance with all requirements contained in a national quality standard. However, the conclusion was restated without a comparison to other standards in response to suggestions from the Originating Office to shorten the report.

2. States that guidance document will be revised based on comments. What were they? Were they submitted as part of this review? What types of changes? Should this be part of the recommendation?
Reply - Yes, the recommendation states, "Revise the QA guides to expand information on the graded approach, software quality, and integrating the quality and safety management system descriptions." Some of the changes were based in-part on comments (e.g., software) and team comments (e.g., grading). They are all also based ongoing initiatives by the Originating Office to improve the QA Order and guides.

3. Recommendation proposes deletion of the requirement to review DOE QA guidance. Unclear as to what this means.
Reply - Requirement 1.d. of the CRD states, "Contractors must consider the guidance on quality assurance provided by the latest revision of the documents listed below..." This requirement was added to help DOE line organizations receive contractor QAPs that address the requirements on the first submittal for approval. A team member view was expressed that this requirement was unnecessary and could be deleted. The team reached consensus on including this view as a team recommendation.

4. Scope of application? Minority view says it is unclear? Stating that line management will decide applicability may not cut it.
Reply - The team recommendation now agrees with a previous minority view and

suggests that the "Applicability" section of the Order be further clarified with respect to regulated work. Feedback from the Originating Office meeting with GC indicated all minority views from the first revision would be resolved by adding the alternative recommendations. However, the Directives System Policy, Safety Management System Policy, DEAR, and CRDs are all based on the premise that Line Management ultimately decides the contracts that will include Order/CRD requirements and the extent of requirements included. Changes to the QA Order may not alter DOE Policy issued by the Secretary.

5. Should the order recommend that all QA requirements be placed in one order? Orders should be based on subject matter, not office of issuance.
Reply - There is only one DOE QA Order that requires DOE and contractors to establish and implement an overarching QA Program for their work. DOE line management tailors these requirements to suit their projects and associated hazards. In some cases they develop an integrated QA Program for their project that must be implemented by federal and contractor organizations working on the project. These QAPs address the Order and project specific requirements.

After the completion of the preceding portion of the report, the following supplemental views were received for inclusion in the report. These views have not been reviewed or endorsed by the team.

Views of GC-52

Ben McRae, Assistant General Counsel for Civilian Nuclear Programs, joined by Anne Troy, provided the following additional views regarding an alternative approach to that being recommended by the Review Team.

The Performance Based Contracts DOE Order Review was established to re-assess the nature and extent of DOE Order requirements on DOE contractors and determine whether there are opportunities to reduce their impact, consistent with performance based contracting concepts. The overall objective of the Review is to eliminate "how to" type requirements as well as requirements which are determined to be unnecessary, non-value added, inappropriate, or duplicative, and to identify changes that would mitigate the impact of overly bureaucratic procedural requirements, or substitute less costly or more effective approaches or standards.

DOE Order 414.1A is not needed. Subpart A of 10 CFR Part 830 establishes a comprehensive Quality Assurance program that is mandatory for all nuclear facilities. For the most part, DOE Order 414.1A merely repeats the provisions of Subpart A..

At a minimum, the scope of DOE Order 414.1A should be revised to make clear it does not apply

to nuclear facilities. However, it does not seem reasonable that a QA program developed for nuclear facilities should automatically be imposed on non-nuclear facilities through the DEAR clause on Laws, Regulations and DOE Directives (48 CFR Part 970.5204-2). What is needed is a policy statement that would focus on (1) performance objectives for a QA program, (2) the need to tailor QA programs to reflect the work being performed and the associated hazards, taking into account 10 CFR Part 830 for nuclear facilities, and appropriate industry/national/international consensus standards for non-nuclear facilities, and (3) integration into the contractor's safety management system. Accordingly, DOE Order 414.1A should be eliminated and replaced by such a policy statement. In addition to the elimination of this Order, a working group, with representatives from EH, GC and other interested entities, should be convened to review and revise the existing guidance to make it clear and concise and eliminate the potential for de facto regulation.

If the Panel for the Performance Based Contracts DOE Order Review (the Panel)) accepts this recommendation, it should specify a date by which the Order must be eliminated (such as 30 days after the acceptance of the recommendation by the Panel). The Panel's intervention may be necessary to achieve this date.

Views of EH-5

The Office of Safety and Health (EH-5) worked with Ben McRae and Anne Troy to create the alternative approach described in the preceding paragraphs. EH-5 believes there is merit in this alternative approach to streamline requirements, consistent with the hazards in the workplace, into an integrated safety management system. EH-5 believes it will be productive to establish a Working Group to pursue this alternative approach using a deliberative and inclusive process that includes the DNFSB.

View from DOE Departmental Representative to the Defense Nuclear Facilities Safety Board (DOE S-3.1)

The DOE Departmental Representative strongly recommends that the Department consults with the Defense Nuclear Facilities Safety Board (Board) before making any decision to eliminate a "Directive of Interest" to the Board. In recent meetings with Mr. Richard Hopf and Ms. Ellen Livingston, the Board has requested to be notified of any potential decisions to eliminate "Directives of Interest" to the Board. The Board's most recent list of "Directives of Interest," issued on October 16, 2001, includes this directive.

The Board has statutory responsibility to review and evaluate the content of safety-related standards for defense nuclear facilities [42 USC 2286a]. The Department management has long ago established and institutionalized an agreement with the Board for the Board to review and comment on all safety-related directives and changes prior to issuance. The Department's Order and Manual on Directives (O 251.1 and M 251.1-1A) describe the Department's process to ensure the Board has opportunity to review safety-related directives and changes prior to

issuance. A sudden unilateral change in the long-established way the Department does business with the Board on review of safety requirements is likely to cause unnecessary perturbations in the Department's working relationship with the Board.

The Departmental Representative has responsibility to facilitate the Board's review of safety-related directives. If requested, the Departmental Representative will facilitate discussions between applicable Department and Board personnel to discuss potential elimination of this directive. Again, the Departmental Representative strongly recommends that this consultation with the Board needs to occur before a Department decision on elimination is reached.