Department of Energy
Washington, DC 20585

SEP 30 2003

The Honorable John T. Conway
Chairman
Defense Nuclear Facilities Safety Board
625 Indiana Avenue, NW
Washington, D.C. 20004-2901

Dear Mr. Chairman:

This letter is to inform you that Commitment 4.3.1 to the Implementation Plan for Software Quality Assurance (SQA) in response to Defense Nuclear Facilities Safety Board Recommendation 2002-1 has been completed.

Commitment 4.3.1 requires a review to identify industry or Federal agency standards that are appropriate for Department safety software. The report prepared as a result of this review has been provided to your staff and has been posted on the Department's Central Registry web site at http://tis.eh.doe.gov/techstds/toolsframe.html. Questions concerning this commitment may be directed to Chip Lagdon at (301) 903-4218 or me at (301) 903-8008.

Sincerely,

Frank B. Russo
Deputy Assistant Secretary
Office of Corporate Performance Assessment

cc: Beverly A. Cook, EH-1
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Quality Assurance Standards for Safety Software in Department of Energy Nuclear Facilities

Working Paper for Review and Use

U.S. Department of Energy
Office of Environment, Safety and Health

September 30, 2003

FOREWORD

This report is for internal use by Department personnel in support of revising its nuclear safety directives (e.g., Orders and Guides) relative to safety software. This report is not part of the DOE nuclear safety directives and should not be used as such. It has been developed in accordance with a commitment (4.3.1) in the DOE Implementation Plan for DNFSB Recommendation 2002-1.

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Quality Assurance Standards for Safety Software in Department of Energy Nuclear Facilities

1. Introduction and Regulatory Basis

The Department of Energy (DOE) nuclear safety regulation, 10 CFR 830 Subpart A (i.e., the QA rule), establishes quality assurance requirements for activities, including providing items or services, that affect or may affect, nuclear safety of DOE nuclear facilities. The QA rule includes a requirement that voluntary consensus standards be used to develop and implement QA Programs. Safety software is included in the scope of activities covered by the QA rule. Therefore consensus standards must be used for applying QA to safety software activities where practicable and consistent with contractual regulatory requirements. This report describes practicable standards for safety software QA that may be used to satisfy the QA rule.

This report is prepared in response to Commitment 4.3.1 of DOE Implementation Plan for Defense Nuclear Facilities Safety Board Recommendation 2002-1, March 13, 2003. This report is intended for use by the Office of Environment, Safety and Health to make improvements in the Departments directives system to better describe when and how organizations apply standards for safety software quality (Commitment 4.3.2.1). The standards will facilitate directives changes that:

- Grading requirements based on safety, complexity, and project quality requirements;
- Performing safety and performance reviews of software configuration items that will address considerations such as failure analysis and fault tolerance;
- Developing procurement controls for acquisition of computer software and hardware that are provided with vendor developed software and/or firmware;
- Applying QA requirements to the software lifecycle;
- Documenting and tracking customer requirements;
- Performing verification and validation testing; and
- Training of personnel who use software in safety applications.

2. Regulatory and QA Program Compliance

The ultimate responsibility for complying with the QA rule, and for selecting standards for safety software that falls under the scope of the QA rule, rests with the nuclear facility contractor. Nuclear facility contractors with DOE-approved QA Programs must ensure that any changes to their QA Program are made in accordance with the QA rule and any supplemental DOE direction provided through contractual means. This report is for internal use by Department personnel in support of revising its nuclear safety directives (e.g., Orders and Guides). This report is not part of the DOE nuclear safety directives and should not be used as such.

3. QA Program Standards Versus Software Standards

Dozens of consensus standards have been developed that address every aspects of software. In the broadest sense of quality assurance, all of these standards could be interpreted as "QA standards". To develop a useful report, it is necessary to limit discussion of standards to those that directly support compliance with the DOE QA rule and development of a QA Program that includes safety software. There are other documents (e.g., technical reports, agency directives, and industry guides) that may be useful as examples for application of the standards, but they are not developed through an accredited consensus standards process.

4. Standards Use in a QA Program Context

Many of the standards developed address specific phases of software development rather than a QA Program that encompasses software. In some cases the standards do cover a single criterion within the QA Program, such as training. Where this type of standard is used, it must be in the context of the broader QA Program that includes all criteria necessary for effective QA. This report will differentiate between QA Program standards and standards that address a specific criterion.

5. QA Program and Software Quality Standard Requirements

Identification of QA Program standards for safety software must consider the following:

- Compatibility with the DOE QA rule
- Relevance to nuclear facility safety
- Applicability to software developed in-house, purchased, or modified
- Applicable to the entire software lifecycle
- Inclusion of commonly accepted elements for software QA

6. National Standard for Nuclear Facility Quality and Software

The most comprehensive nuclear QA Program standard for application to safety software is the American Society of Mechanical Engineers NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications. This standard includes requirements that are compatible with the DOE QA rule (see Attachment 1) can be integrated/supplemented with other standards, and is directly applicable to safety software. Most importantly, NQA-1-2000 expands upon the basic QA program requirements to specifically address requirements for software quality. Thus placing safety software quality in the context of the overall QA Program. These specific quality requirements are defined in:

- NQA-1 Part I Requirement 3, Section 800, *Design Control*;
- Part II Subpart 2.7, *Quality Assurance Requirements for Computer Software for Nuclear Facility Applications*; and
- Part IV Subpart 4.1, *Guide on Quality Assurance Requirements for Software.*

These three sections of NQA-1-2000 address safety software for the following commonly accepted elements of quality:

- Management

- Design
- Reviews
- Verification
- Testing
- Documentation & records
- Software engineering method
- Problem reporting and corrective action
- Configuration management
- Acquisition/procurement
- Operation
- Maintenance
- Retirement

NQA-1-2000 with Subpart 2.7 is also a practicable choice for implementing the DOE QA rule for safety software because it is:

- Easily supplemented with other IAEA, IEC, IEEE standards (e.g., configuration management)
- Provides independence for developing and verification
- Supports graded implementation
- Widely used among DOE contractor QA Programs
- Accredited as the American National Standard for nuclear application

The table in Attachment 1 describes how NQA-1 2000 aligns with DOE QA criterion and includes other standards that further expand the content of NQA-1 requirements for safety software.

7. International Standards for Quality and Software

7.1. International Atomic Energy Agency (IAEA)

The responsibility for international standards for nuclear safety is assigned to the International Atomic Energy Agency (IAEA). The IAEA has a significant number of standards, guides and requirements for all aspects of nuclear facility safety, including software. The requirements and guidance for nuclear facility quality are addressed in a 1996 Safety Series "Code" No. 50-C-Q, *Quality Assurance for Safety in Nuclear Power Plants and other Nuclear Installations*, and Safety Guides 50-SG-Q1–Q14, respectively. The IAEA Code quality requirements closely parallel the DOE QA rule.

IAEA safety software guidance is detailed in Technical Reports Series No. 397, *Quality Assurance for Software Important to Safety.* This TR provides information and guidance for defining and implementing QA Programs covering the entire life-cycle of software important to safety. The TR was developed using a large amount of available information and standards and offers implementation guidance that is tied to the QA Program requirements found in the IAEA Code. The application guides are useful aids for developing QA Programs for safety software, specifically:

- Appendix I: Illustration of a graded software quality assurance programme;
- Appendix III: Considerations before acquisition of computerized tools;
- Appendix IV: Functions of computer program understanding and reverse engineering tools;
- Appendix V & VI: General training guideline and proposed outlines for training;
- Appendix VII: Characteristics of defect prevention process;
- Appendix VIII: Examples of software development life-cycle models;
- Appendix IX: Recommendations for design input documentation for monitoring, control and safety system software;
- Appendix X: Recommendations for software development plans applicable to monitoring, control and safety system software;
- Appendix XI: Recommendations for standards and procedures handbooks applicable to monitoring, control and safety system software;
- Appendix XII: Recommendations on the content of software requirements specifications for monitoring, control and safety system software;
- Appendix XIII: Recommendations on software design descriptions for monitoring, control and safety system software;
- Appendix XIV: Recommendations on design and development documents for design, engineering and analysis software;
- Appendix XV: Recommendations on application documents for design, engineering and analysis software;
- Appendix XVI: Suggested good coding practices for design, engineering and analysis software;
- Appendix XVII: Recommendations on programming of monitoring, control and safety system software;
- Appendix XVIII: Discussion of verification and validation methods;
- Appendix XIX: Recommendations on verification reports and activities for monitoring, control and safety system software;
- Appendix XX: Recommendations on commissioning monitoring, control and safety system software; Glossary.

This TR, and IAEA Safety Guide (SG) Series No. NS-G-1.1, *Software for Computer Based Systems Important to Safety in Nuclear Power Plants*, provide expanded information that can be fully integrated with the NQA-1-2000 requirements and the DOE QA rule to produce an effective

quality program for safety software. Relevant portions of TR 397 are referenced in Attachment 1 to illustrate their relationship to the DOE QA rule criteria and NQA-1 requirements.

7. 2 International Electrotechnical Commission (IEC)

The IEC is responsible for several software standards in the nuclear power plant arena. These standards are referenced in the IAEA TR 397. Those standards include IEC 880 Software for Computers in the Safety Systems of Nuclear Power Stations, IEC 987 Programmed Digital Computers Important to Safety for Nuclear Power Stations, and IEC 1226 Nuclear Power Plants – Instrumentation and Control Systems Important for Safety – classification.

7.3 International Organization for Standardization (ISO)

The International Organization for Standardization (ISO) is responsible for ISO 9001-2000, *Quality management systems – requirements.* The ISO 9001 standard is designed for use internally or as a contractual requirement for generic quality systems. ISO 9001 does not specifically address computer software. More importantly, ISO is not chartered to develop standards for nuclear safety applications (this is the domain of the IAEA) and consequently lacks sufficient focus (and rigor) to address DOE nuclear facility hazards. Commercial industries that face high hazards and high mission/political risk similar to DOE (e.g., aerospace, telecom, chemical) have each issued supplemental requirements to improve on ISO 9001 for application to their industry.

Although ISO has a guide for applying a previous version of ISO 9001 (1994) to software (ISO 9000-3, *ISO Quality management and quality assurance standards - Part 3: Guidelines for the application of ISO 9001:1994 to the development, supply, installation and maintenance of computer software)*, this guide is not focused on nuclear safety.

Given that: (1) the ISO standards are not developed for nuclear facility applications, (2) the IAEA is the internationally chartered standards body for that subject, and (3) the IAEA offers safety software quality standards compatible to DOE and NQA-1, ISO should not be considered a practicable choice for standards in this subject area.

8. Example Application Guides, Federal Agency Requirements & Procedures

8.1 Department of Defense (DoD)

The DOD software project requirement is Directive 5000.61 and related guidance. These documents address; software development, verification, validation, accreditation, maintenance, review, and management. They also refer to national and industry standards. For example, independent review is addressed in *Verification, Validation and Accreditation (VV&A) Recommended Practices Guide.* The Guide also describes methods for assuring software using a graded approach depend on whether the software was:

(1) previously accredited based on verification and validation data which is available;
(2) previously accredited based on historical use;
(3) not previously accredited, but some verification and validation data available; and
(4) not previously accredited, with little or no verification and validation available.

8.2 National Aeronautics and Space Administration (NASA)

The NASA software document is the Software Assurance Standard, NASA-STD-2201-93. The NASA standard includes processes to establish and implement requirements and procedures as well as evaluating software products against requirements standards and procedures.

8.3 Environmental Protection Agency (EPA)

The EPA uses at least two standards for software in environmental safety projects. EPA regulates the DOE Waste Isolation Pilot Project (WIPP) using 40 CFR 194. This rule and the WIPP QA Program requirements influence many other waste generation sites across the DOE complex. The regulation adopts ASME NQA-1, 1997 and Subpart 2.7. EPA also contracts for cleanup of certain Superfund sites. For these projects EPA has used the national standard *Quality Systems for Environmental Data and Technology Programs - Requirements with Guidance for Use*, ANSI/ASQC E4-1994. The E4 standard is currently undergoing revision and includes requirements for software quality that parallel NQA-1-2000. This standard also parallels the DOE QA rule criterion.

8.4 DOE Program Requirements and Procedures

The Department and its contractors have a variety of program requirement documents and implementing procedures for safety software in use for nuclear facilities. However, the Yucca Mountain Project's Quality Assurance Requirements Document (QARD) DOE/RW-0333P has been evaluated by an external regulatory body and found acceptable. The QARD and software quality supplements describe a rigorous graded approach to safety software suitable for review by other DOE organizations for use in developing their QA Programs for safety software.

9. Practicable Standards FOR DOE QA Rule Implementation

9.1 QA Rule & Standards Alignment

The tables in Attachment 1 describe how NQA-1 2000 aligns with DOE QA criterion. It also includes other standards that further expand the content of NQA-1 requirements for safety software to address appropriate elements for safety software quality.

9.2 Standards Listing

Attachment 2 contains a listing of standards that may be applied to safety software to assure quality.

10. References

ASME American Society of Mechanical Engineers NQA-1-2000, Foreword to Quality Assurance Requirements for Nuclear Facility Applications (2000).

Code of Federal Regulations (CFR). 10 CFR 830, Nuclear Safety Management Rule. DOE

CFR 10 CFR 63, Disposal of High-Level Radioactive Wastes In A Geologic Repository at Yucca Mountain, Nevada U.S. Nuclear Regulatory Commission

DNFSB Defense Nuclear Facilities Safety Board, (2000). *Quality Assurance for Safety-Related Software at Department of Energy Defense Nuclear Facilities*, Technical Report DNFSB/TECH-25, (January 2000).

DNFSB Defense Nuclear Facilities Safety Board, (2001). *Engineering Quality into Safety Systems*, Technical Report DNFSB/TECH-31, (March 2001).

DNFSB Defense Nuclear Facilities Safety Board, (2002). *Recommendation 2002-1, Quality Assurance for Safety-Related Software* , (September 2002).

DOE, U.S. Department of Energy (2000b). *Quality Assurance for Safety-Related Software at Department of Energy Defense Nuclear Facilities*, DOE Response to TECH-25, Letter and Report, (October 2000).

DOE, U.S. Department of Energy (2003). *Implementation Plan for Defense Nuclear Facilities Safety Board Recommendation 2002-1: Quality Assurance for Safety Software at Department of Energy Nuclear Facilities*, Report, (February 28, 2003).

ATTACHMENT 1

Guidance on the Use of NQA-1-2000 and Supporting Standards for Compliance with Department of Energy Quality Assurance Requirements 10 CFR 830 Subpart A and DOE O 414.1 and Application to Safety Software

100 PURPOSE

This guidance may be used by organizations intending to adopt NQA-1 as a national consensus Standard for development and implementation of a Quality Assurance Program (QAP) that meets the Department of Energy (DOE) Quality Assurance (QA) requirements and includes safety software within its scope. This guide describes how NQA-1-2000 addresses the DOE QA requirements and identifies DOE QA requirements that are not addressed by NQA-1. Selected standards from other standards bodies are included where they add emphasis or detail for safety software quality.

200 INTRODUCTION

The Department of Energy (DOE) QA requirements for activities that affect or may affect, quality, nuclear safety or other site specified criteria are established by rule, 10 CFR Part 830 Subpart A, dated January 10, 2001(i.e., Rule). DOE also has equivalent requirements for all other federal and contractor activities in QA Order, O 414.1A, dated September 29, 1999(i.e., Order). The DOE QA requirements and guides are available for review at: http://tis.eh.doe.gov/nsps/quality.html.

The DOE's objective of the QA Rule and Order is for organizations to establish effective integrated management systems (i.e., QAPs) for the performance of DOE nuclear related work. The objective is accomplished through performance oriented quality assurance criteria, coupled with appropriate technical standards to manage, perform and assess work activities. The DOE Rule requires the use of voluntary consensus standards in the development and implementation of the QAP. The NQA-1 Standard is a national voluntary Standard and should be considered for providing the essential implementing methods for a DOE QAP including details for effective and reliable supporting processes and procedures, as presented in this Subpart.

300 DOE RULE AND ORDER GENERAL ADMINISTRATIVE QAP REQUIREMENTS

The DOE Rule and Order include both administrative and regulatory quality requirements. Those administrative requirements relating to QAP approval authority, change control authority, and compliance should not be relevant to the scope of NQA-1. Other administrative quality related requirements that are relevant are addressed in Table 300.

400 DOE RULE AND ORDER QA CRITERIA

The DOE Rule and Order include ten QA Criteria that are used to develop and implement a QAP. Table 400 identifies each of the ten DOE Rule and Order QA Criterion and how they are

addressed by the NQA-1, Part I requirements. Differences in the documents and topics that should be addressed independently of the NQA-1 criteria to meet the DOE criteria are described. In some cases, the NQA-1 Part II *QA Requirements for Nuclear Facility Applications* and Part IV Non-mandatory Guidance in NQA-1 is also appropriate to address the DOE requirements and describe ***how*** the QA criteria will be implemented. Table 400 also includes selected standards from other standards bodies (IEEE and IAEA) where they add emphasis or detail for safety software quality.

TABLE 300 10 CFR 830 Subpart A, dated January 10, 2001 §830.121 Quality Assurance Program DOE O 414.1A dated September 29, 2001	
DOE GENERAL REQUIREMENTS (Summarized)	NQA-1 Requirements
Graded Approach (830.7) Where appropriate, a contractor must use a graded approach to implement the requirements of this Part, document the basis of the graded approach used, and submit that documentation to DOE.	**Part I, Introduction, Requirement 1 and Requirement 2** provides for a graded approach to achieving quality by focusing on activities affecting quality and the application of requirements in a manner consistent with the relative importance of the item or activity. The cited text does allow for a graded approach, however a DOE QAP will need to describe how the graded approach is applied and documented to meet the DOE requirement. **Requirement 3, 801.4** provides grading relative to software. **Part II, Appendix 2A-2** Nonmandatory Guidance on Quality Assurance Programs includes guidance on this topic. **Part IV, 4.1, 101** **IAEA Technical Report (TR) Series 397, Appendix 1**

TABLE 300 10 CFR 830 Subpart A, dated January 10, 2001 §830.121 Quality Assurance Program DOE O 414.1A dated September 29, 2001	
DOE GENERAL REQUIREMENTS (Summarized)	NQA-1 Requirements
QAP Development & Implementation The QAP must describe how the DOE QA criteria are satisfied.	The NQA-1 requirements partially meet the DOE requirement. **Requirement 2** requires that a documented QAP be planned, implemented and maintained; and requires the QAP provide for the planning and accomplishment of activities affecting quality. **Requirement 5** requires that "Activities affecting quality and services shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings that include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed results have been satisfactorily attained." A DOE QAP will need to describe how the DOE criteria are satisfied.
Integrated Management Systems The QA Program must integrate the QA criteria with the Safety Management System (SMS), or describe how the QA criteria apply to the SMS.	The NQA-1 requirements do not address the DOE requirement. A DOE QAP will need to address integration to meet the DOE criterion.

TABLE 300 10 CFR 830 Subpart A, dated January 10, 2001 §830.121 Quality Assurance Program DOE O 414.1A dated September 29, 2001	
DOE GENERAL REQUIREMENTS (Summarized)	NQA-1 Requirements
Ensuring Subcontractor & Supplier Quality The QAP must describe how the contractor responsible for the nuclear facility ensures that subcontractors and suppliers satisfy the QA criteria.	**Requirements 1, 2 and 4, 7 and 18** The NQA-1 requirements meet the DOE requirement by the establishment of quality interfaces between organizations, by the inclusion of applicable QA requirements in procurement documents, supplier evaluation activities and audits of suppliers. A DOE QAP will need to describe how subcontractors/suppliers satisfy the DOE criteria.

TABLE 400 10 CFR 830 Subpart A, dated January 10, 2001 §830.122 Quality Assurance Criteria

TABLE 400 10 CFR 830 Subpart A, dated January 10, 2001 §830.122 Quality Assurance Criteria		
DOE Quality Assurance Criteria	NQA-1 Requirements	Comments, Software Requirements & Other Standards
Criterion 1 - Management/Program	**NQA Requirements 1 and 2** The NQA-1 requirements meet the DOE Criterion, as noted.	**Part IV, 4.1, 400** **IEEE 730-2002** **IAEA TR 397, 2.2** **IAEA Nuclear Safety Guide (NS-G) NS-G-1.1, 4.11**
(1) Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing work.	The NQA-1 requirements satisfy this element of the DOE Criterion.	None
(2)Establish management processes including, planning, scheduling, and providing resources for the work.	NQA Requirement 1, 201 General and Requirement 2, 100 Basic meet the DOE Criterion. NQA-1 requires senior management to establish overall expectations for effective implementation of the quality assurance program and is responsible for obtaining the desired end result. This implies that adequate resources are provided to obtain desired results.	A DOE QAP will need to describe the management process for providing resources.
Criterion 2 - Management/Personnel Training and Qualification	**NQA Requirement 2** The NQA-1 requirements meet the DOE Criterion.	

TABLE 400 10 CFR 830 Subpart A, dated January 10, 2001 §830.122 Quality Assurance Criteria		
(1) Train and qualify personnel to be capable of performing their assigned work. (2) Provide continuing training to personnel to maintain their job proficiency.	The NQA-1 requirements satisfy these elements of the DOE Criterion.	**DOE Draft Computer Software Functional Area Qualification Standard, TRNG 0040** **IAEA TR 397, 2.4** **IAEA NS-G-1.1, 4.9&10**
Criterion 3 - Management/Quality Improvement	**NQA Requirements 2, 15, and 16** The NQA-1 requirements partially meet the DOE Criterion.	**Part II, 2.7, 204** **Part IV, 4.1, 204** **IAEA TR 397, 2.5** A DOE QA Program will need to extend the requirements of NQA-1 to ALL conditions adverse to quality not just significant conditions adverse to Quality.
(1) Establish and implement processes to detect and prevent quality problems.	The NQA-1 requirements partially meet the DOE Criterion. NQA-1 provides a system of establishing quality requirements and monitoring compliance to prevent nonconforming conditions from causing quality problems. This is accomplished through various controls, inspections and test. Requirement 16 includes criteria to prevent recurrence of identified problems.	
(2) Identify, control, and correct items, services, and processes that do not meet established requirements.	The NQA-1 requirements satisfy this element of the DOE Criterion.	
(3) Identify the causes of problems and work to prevent recurrence as part of correcting the problem.	The NQA-1 requirements partially satisfy this element of the DOE Criterion for "significant" or "generic" nonconformances.	
(4) Review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvements.	The NQA requirements partially address this element of the DOE Criterion for known deficiencies.	

TABLE 400 10 CFR 830 Subpart A, dated January 10, 2001 §830.122 Quality Assurance Criteria		
Criterion 4 - Management/Documents and Records	**NQA Requirements 5, 6 and 17** The NQA-1 requirements meet the DOE Criterion.	
(1) Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design. (2) Specify, prepare, review, approve, and maintain records.	The NQA-1 requirements satisfy these elements of the DOE Criterion.	**Part I, Requirement 3, 801** **Part II, 2.7, 201 & 802** **Part IV, 4.1, 201** **IAEA TR 397, 2.6 & 3.1** **IEEE 730, 829**
Criterion 5 - Performance/Work Processes	**NQA Requirements 5, 8, 9, 12, 13, and 14 and the Part I, Introduction** The NQA-1 requirements meet the DOE Criterion, as noted.	
(1) Perform work consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contract requirements, using approved instructions, procedures, or other appropriate means.	The NQA requirements address "work" as activities affecting quality.	A DOE QA Program will need to address "work" as broadly as the DOE Criterion, since the requirements for "work" are derived from multiple sources in the DOE Rule and Order. **Part I, Requirement 3, 802** **Part II, 2.7, 203 & 404** **Part IV, 4.1, 203 & 405** **IAEA TR 397, 3.1 & 3.2** **IEEE 828-1998 & 1219-1998**
(2) Identify and control items to ensure their proper use.	The NQA-1 requirements satisfy this element of the DOE Criterion.	
(3) Maintain items to prevent their damage, loss, or deterioration.	The NQA-1 requirements satisfy this element of the DOE Criterion.	
(4) Calibrate and maintain equipment used for process monitoring or data collection.	The NQA-1 requirements satisfy this element of the DOE Criterion.	
Criterion 6 - Performance/Design	**NQA Requirement 3** The NQA-1 requirements meet the DOE Criterion.	

TABLE 400 10 CFR 830 Subpart A, dated January 10, 2001 §830.122 Quality Assurance Criteria		
(1) Design items and processes using sound engineering/scientific principles and appropriate standards. (2) Incorporate applicable requirements and design basis in design work and design changes. (3) Identify and control design interfaces. (4) Verify or validate the adequacy of design products using individuals or groups other than those who performed the work. (5) Verify or validate work before approval and implementation of the design.	The NQA-1 requirements satisfy these elements of the DOE Criterion.	**Part II, 2.7, 401 & 402** **Part IV, 4.1, 401 & 402** **ANS-10.4** **IAEA TR 397, 3.2 & 3.4** **IEEE 1012-1998 & 1012a-1998**
Criterion 7 - Performance/Procurement	**NQA Requirements 4 and 7** The NQA-1 requirements meet the DOE Criterion.	
(1) Procure items and services that meet established requirements and perform as specified. (2) Evaluate and select prospective suppliers on the basis of specified criteria. (3) Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.	The NQA-1 requirements satisfy these elements of the DOE Criterion.	**Part II, 2.7, 300** **Part IV, 4.1, 300** **IAEA TR 397, 3.3**
Criterion 8 - Performance/Inspection and Acceptance Testing	**NQA Requirements 8, 10, 11, and 12** The NQA-1 requirements meet the DOE criterion.	

TABLE 400 10 CFR 830 Subpart A, dated January 10, 2001 §830.122 Quality Assurance Criteria		
(1) Inspect and test specified items, services, and processes using established acceptance and performance criteria. (2) Calibrate and maintain equipment used for inspections and tests.	The NQA-1 requirements satisfy these elements of the DOE Criterion.	**Part II, 2.7, 404** **Part IV, 4.1, 404** **ANS-10.4** **IAEA TR 397, 3.4** **IEEE 1008**
Criterion 9 - Assessment/Management Assessment	**NQA Requirement 2 and 18** The NQA-1 requirements partially meet the DOE Criterion, as noted	
Ensure managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.	While NQA-1, Requirement 2, 100 Basic, requires management to regularly assess the adequacy and effective implementation of the quality assurance, the DOE Criterion is broader in scope and intent.	**Part II, 2.7, 202** **Part IV, 4.1, 202** **IAEA TR 397, 4.1** **IEEE 1028-1997** While audits per Req. 18 of NQA provide an input to this requirement, a DOE QAP will need to align with the intent, focus and concepts described in DOE Guide, G 414.1-1A, *Management Assessment and Independent Assessment Requirements of 10 CFR 830.120 and DOE- O-414.1 Quality Assurance*, in order to meet the DOE Criterion.
Criterion 10 - Assessment /Independent Assessment	**NQA Requirements 1, 2, 10, 11, 15, 16, and 18** The NQA-1 requirements meet the DOE Criterion.	

TABLE 400 10 CFR 830 Subpart A, dated January 10, 2001 §830.122 Quality Assurance Criteria		
(1) Plan and conduct independent assessments to measure item and service quality, to measure the adequacy of work performance, and to promote improvement. (2) Establish sufficient authority, and freedom from line management, for the group performing independent assessments. (3) Ensure persons who perform independent assessments are technically qualified and knowledgeable in the areas to be assessed.	DOE defines assessment as a general term that includes a variety of evaluation methods (i.e.; reviewing, evaluating, inspecting, testing, checking, surveillance, auditing or otherwise determining and documenting). As such, several NQA-1 requirements may be necessary to address the various DOE independent assessment methods. These activities when combined with the NQA corrective action requirement have the intent of the DOE Criterion, to "promote improvement".	**IAEA TR 397, 4.2** Assessment as a DOE activity for a DOE QAP will need to align with the intent, focus and concepts described in DOE G-414.1-1A, *Management Assessment and Independent Assessment Requirements of 10 CFR 830.120 and DOE- O-414.1 Quality Assurance.*

Attachment 2.

Standards Applicable to Software Quality

American Nuclear Society

ANSI/ANS-10.4-1987 (R1998), *Guidelines for the Verification and Validation of Scientific and Engineering Computer Programs for the Nuclear Industry,*.

American Society for Quality

ANSI/ASQC E4-1994, *Quality Systems for Environmental Data and Technology Programs - Requirements with Guidance for Use* and latest draft revision

American Society of Mechanical Engineers (ASME)

ASME NQA-3-1989, Quality Assurance Program Requirements for the Collection of Scientific and Technical Information for Site Characterization of High-Level Nuclear Waste Repositories.

ASME NQA-1-1997, Quality Assurance Requirements for Nuclear Facility Applications.

ASME NQA-1a-1999, Addenda to ASME NQA-1-1997 Edition, Quality Assurance Requirements for Nuclear Facility Applications.

ASME NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications.

Center for Chemical Process Safety

CCPS, *Guidelines for Use of Vapor Cloud Dispersion Models, Second Edition, Center for Chemical Process Safety*, American Institute of Chemical Engineers, New York, NY, (1996).

Code of Federal Regulations

10 CFR Part 50, Appendix B, *Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants.*

10 CFR 63 *Disposal of High-Level Radioactive Wastes in a Geologic Repository at Yucca Mountain, Nevada.*

10 CFR Part 70, *Domestic Licensing of Special Nuclear Material.*

10 CFR 830, *Nuclear Safety Management.*

Department of Defense (DoD)

DoD Modeling and Simulation (M&S) Management, Directive 5000.59

Modeling and Simulation (M&S) Verification, Validation, and Accreditation (VV&A), DoD Directive 5000.61

Related guidance document, "Verification, Validation and Accreditation (VV&A) Recommended Practices Guide".

Department of Energy (DOE) (Latest revision)

DOE O 200.1 Information Management

DOE O 414.1A, Quality Assurance

DOE G 200.1-1, Software Engineering Methodology

DOE G 414.1-2, Quality Assurance Management System Guide

DOE-RW-0333P, Quality Assurance Requirements and Description for the Civilian Radioactive Waste Management Program

Institute of Electrical and Electronics Engineers (IEEE)

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