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June 20, 2002

Mr. J. A. Ciocco
NRC Project Manager
U.S. Nuclear Regulatory Commission
Room T7-E51, Mail Stop T7-F3
Washington, DC 20555-0001

RE: ASME Comments on Yucca Mountain Review Plan, NUREG-1804, Revision 2,
Draft Report for Comment; Federal Register Vol. 67 No. 61, Friday March 29, 2002

Dear Mr. Ciocco:

The subject USNRC document has been reviewed by members of the ASME Nuclear Quality Assurance (NQA) Committee that is an ASME administered codes and standards committee under the jurisdiction of the Board on Nuclear Codes and Standards. This is in response to the US Nuclear Regulatory Commission's request for public comment.

On the basis of its specific working interest with the subject matter, the NQA Committee, responsible for the development of the ASME NQA-1 Standard, was selected to have primary responsibility for review of the above document and as such the committee's consensus position on the document is provided.

This review by ASME committee members is not to be construed as an approval or endorsement of the subject document by ASME. Rather, the review was performed and the attached comments are submitted as a constructive public service for the purpose of improving future revisions of the subject document. In the time frame available for review and comment, the opinions and comments generated, by necessity, represent those of the reviewers and the consensus is that of the individual committee rather than that of the ASME.

Template - ADM-013

F-PDS = ADM-03
Att = J. Ciocco (JAR3)
Att = H. Bejanek (HFB)

Mr. J. A. Ciocco
U.S. Nuclear Regulatory Commission
June 20, 2002
Page 2

We respectfully request your consideration of the following comment:

The NQA Committee recommends the references to NQA-1-1983 in NUREG - 1804 be revised to NQA-1-2000, Part I, which is the current edition of the Standard. The NQA Committee further recommends that the quality activity described in the NUREG-1804 be revised to reflect the content of NQA-1-2000, including applicable requirements of Part II, and the non-mandatory guidance of Parts III and IV of NQA-1-2000 be considered for use in evaluating compliance with the requirements of Part I and II.

This request is based on the following key points:

1. The NRC has previously endorsed and/or accepted later editions of NQA-1 for application to 10 CFR Part 50, Part 71 and Part 72 requirements.
2. The NQA-1-2000 Standard contains significant performance based quality enhancements from the earlier editions that allows a graded application of the quality assurance program elements. It also contains a resolution of quality and regulatory issues that have developed in the last 20 years, including controls for the application of the latest technology to quality activities.
3. Use of the NQA-1-2000 edition would reduce the level of regulation required in NUREG -1804.

Background

With respect to the current NRC Review Plan "U.S. NRC Review Plan for High-Level Waste Repository QA Program Descriptions", Revision 2 dated March 1989, the NRC expectation was that DOE commit to NQA-1-1989. (Note: All quality affecting site characterization work was performed to a QA program, which was committed to the NQA-1-1989 edition.)

Accepted Editions of NQA-1

The expansion of the NQA Standard from a document initially for nuclear power plants to nuclear facilities has resulted in extensive use in the nuclear industry. Various facilities and organizations have chosen to comply with selected editions based on the time the facility was constructed or the relevant regulation of that period. This has

Mr. J. A. Ciocco
U.S. Nuclear Regulatory Commission
June 20, 2002
Page 3

resulted in approval or acceptance of various editions of the NQA Standard. The following are some selected applications and acceptance, either directly or indirectly, of later NQA editions by the NRC and DOE:

- In 10 CFR 50.55a it is stated, relative to the ASME Boiler and Pressure Vessel Code, Section III, "When applying editions and addenda later than the 1989 Edition of Section III, the requirements of NQA-1, 'Quality Assurance Requirements for Nuclear Facilities,' 1986 Edition through the 1992 Edition, are acceptable for use provided that the edition and addenda of NQA specified in NCA-4000 is used in conjunction with the administrative, quality, and technical provisions contained in the edition and addenda of Section III being used."
- In NUREG 1718 "Standard Review Plan for the Application for a Mixed Oxide Fuel Fabrication Facility", it is stated that "a commitment that it will implement and maintain its QA Program to comply with the applicable requirements of ASME NQA-1-1994, as revised by the ASME NQA-1a-1995 addenda . . ."
- Although not directly governed by a NRC review plan, the Westinghouse Savannah River Company (WSRC) has implemented a later edition of NQA than proposed for Yucca Mountain. The Westinghouse Savannah River Company Quality Assurance (QA) Program implements the QA Rule (10 CFR 830 Subpart A) and DOE Order O 414.1A. In addition to the Rule and Order, ASME NQA-1-97 is used as the basis for the development of management systems for the management, achievement, and assessment of quality. Special QA Program requirements of DOE/RW-0333P, imposed for selected programs of high-level waste form development through qualification, production, and acceptance (e.g., Defense Waste Processing Facility), are added to, and integrated with, the basic WSRC QA Program requirements for the affected facilities and activities. All of these requirement documents are implemented in accordance with the WSRC Site Standards/Requirements Identification Document (S/RID) which is approved by DOE-SR.
- The quality program being implemented by BWXT Y-12 as a prime contractor to the U.S. Department of Energy (DOE) for BWXT Y-12 organizations in Oak Ridge, TN utilizes ASME NQA-1-2000 as the program basis. The Y-12 Complex has historically embraced the quality concepts and principles identified in ASME NQA-1. The NQA-1-2000 edition is the consensus standard that was chosen as the model for Y-12. The specific NQA-1-2000 Requirements (Part I) correlate to the DOE Order O 414.1A / 10 CFR 830.121 / 10 CFR 830.122, "Quality Assurance Criteria" elements as presented in the quality program.

Mr. J. A. Ciocco
U.S. Nuclear Regulatory Commission
June 20, 2002
Page 4

- The Westinghouse Electric Company's Quality Management System manual for compliance with 10 CFR 50 Appendix B utilizes ASME NQA-1-1994 as the program basis. Westinghouse has received approval from the NRC's Division of Inspection Program Management, Office of Nuclear Reactor Regulation that the manual meets the requirements of 10 CFR 50, Appendix B.
- Exelon Nuclear's Quality Assurance Topical Report for compliance with 10 CFR 50 Appendix B utilizes ASME NQA-1-1989 as the program basis. Exelon has received approval from the NRC's Division of Inspection Program Management, Office of Nuclear Reactor Regulation that the manual meets the requirements of 10 CFR 50, Appendix B.

It should be noted that the NRC accepted programs listed above have also committed to the exceptions taken in Regulatory Guide 1.28, Revision 3 to NQA-1-1983, including Addenda 1a. However, this does not preclude programs from using additional criteria in later editions of the NQA Standard.

Quality Enhancements Included in NQA-1-2000

The NQA Standard has been revised numerous times since 1983 to incorporate the quality experience of the nuclear industry and to apply new technology to basic quality requirements. The revision of the Standard is analogous to the corrective action process that seeks to prevent recurrence of identified issues by changing the initial quality criteria. In addition, revisions have occurred to reflect changes in regulatory requirements. The NQA Committee believes the 2000 edition of the NQA Standard is more consistent with the current QA practices for meeting regulatory requirements. .

A major change to the NQA Standard occurred in the 1990s when the NRC staff, the Nuclear Energy Institute (NEI), and nuclear industry representatives were seeking ways to make quality assurance practices more performance based. There were discussions both inside and outside the NRC suggesting that 10CFR 50 Appendix B might be modified to facilitate a more performance-based approach. In response, the NQA Committee in 1994 initiated an action to develop a more performance-based approach to QA and also to eliminate the redundancies and inconsistencies among the various parts of the document that had developed due to localized paragraph and section revisions. The resultant changes to NQA-1 for this effort were incorporated into the NQA-1-1997. The 1997 edition reflects a shift to a more performance oriented, graded application for the relative importance of the item or activity. Many of the lingering "good practice" details from the N45.2 Standards were relocated to the Part III

Mr. J. A. Ciocco
U.S. Nuclear Regulatory Commission
June 20, 2002
Page 5

Appendices as guidance. A considerable amount of duplication related to repeating the requirement for documentation and procedures was removed, thus producing a document that is easier to use and understand.

The NQA Committee also maintains the NQA Standard to encompass the current status of the nuclear industry. Initiatives to correct issues or to reflect regulatory changes have been incorporated into NQA-1. Some of these major initiatives and changes are summarized as follows:

Configuration Management: During the mid-1980's, the subject of design basis and configuration management were a nuclear utility industry issue. As the nuclear utilities transitioned from construction to operation and maintenance, the issues associated with configuration management became more difficult, especially for the older units. In December 1988, the ASME NQA Committee formed a special Task Group to evaluate the related issues facing the nuclear industry and to determine if changes to the NQA Standard were appropriate. The Task Group included other industry groups addressing configuration management issues and two NRC staff members. The Task Group recommended specific changes to the NQA-1 Standard which addressed definitions related to configuration management and changes to the existing requirements for design and test controls.

Computer Software: In the early 1980s the NQA Committee recognized the personal computer and related software were going to become an integral part of almost every quality process, especially design activities. The authors of the N45.2 did not envision the unique quality assurance issues associated with this new technology. The words "computer" and "software" are not even included in N45.2, the daughter standards, 10 CFR 50 Appendix B, and NQA-1-1983 only briefly mentions them in design requirements. The NQA Committee directed the development of a work practices document to address this issue and published it in NQA-2a-1990, Part 2.7, *Quality Assurance Requirements for Computer Software in Nuclear Facility Application*.

Computer technology continued to rapidly expand, including in the last several years the use of digital technology in all industry sectors, including nuclear. Computers and computer programs have become an integral part of design, manufacturing, and operation of nuclear facilities. Associated improvements in computer program design and implementation has rendered many of the 1980s and early 90s design methods or techniques obsolete.

As the computer industry has continued to mature, the NQA Committee has endeavored to refine the computer program process within the NQA Standard. Specifically, actions were launched to update Part 2.7. This led to the publication of Part II, Subpart 2.7, *Quality Assurance Requirements for Software* in the 1995 Addenda. In

Mr. J. A. Ciocco
U.S. Nuclear Regulatory Commission
June 20, 2002
Page 6

conjunction with these efforts, specific QA requirements, applicable to all computer programs, were incorporated into the 1997 edition Part I restructuring efforts. These requirements are found in Part I, Requirements 3 and 11. The 2000 edition of NQA contains an application guide for software requirements in Part IV, Subpart 4.1, *Application Appendix - Guide on Quality Assurance Requirement for Software*.

Commercial Grade Items: In the late 1980's the nuclear industry was facing two significant issues that ultimately had a common solution. Due to the high cost of nuclear replacement parts, counterfeit parts were beginning to appear in the industry. The high production cost factor combined with a decrease in orders due to a decline in new plant construction was forcing some suppliers to drop their nuclear business product lines. This left the utilities without an option for replacement parts. Through their nuclear utility organization, NUMARC, (later NEI) the utilities turned to the EPRI Nuclear Construction Issues Group (NCIG) for a solution. NCIG developed a document for the dedication of commercial grade items (CGI) that allowed the utilities to verify that an item would perform its design function and was the item ordered from the supplier. This concept was reviewed by the NRC in two Generic letters, plant inspections, and an inspection plan presented at a NRC sponsored workshop in 1993.

The EPRI document is the cornerstone of the CGI concept but it was initially issued as an EPRI utility propriety document and not written as a quality standard. In actions parallel to the EPRI CGI activity, the NQA committee established a Task Group to take the key requirement elements from the CGI process and include them in the Standard. This was accomplished and the 1995 Addenda included changes related to CGI in Requirement 3, Requirement 7, and a new Appendix 7A-2 for detailed guidance on the dedication methods. These CGI requirements and guidance are the only consensus criteria for the CGI process available to the nuclear industry. Subsequent to this effort the NRC revised 10 CFR Part 21 (which is applicable to parts 30, 40, 50, 60, 61, 70, 71, and 72) to include the CGI terminology and concepts. NQA is currently in the process of revising the Standard to reflect the regulation change.

Responsible Design Organization: During the course of work on software control, configuration control, commercial grade items and a review of the analysis of the Hyatt Kansas City walkway failure it became clear to the NQA Committee that the scope of responsibility of the responsible design organization was not confined to Requirement III, Design Control. De facto design changes can result from deficiencies in the translation of design drawings and specifications into manufacturing and/or construction drawings, inadequate acceptance criteria for inspection or test, and improper review and disposition of nonconforming items. An awareness of the responsibility for design control ultimately resulted in an array of significant revisions to NQA 1, Part I for 11 of the 18 requirements and is integrated and articulated in the 1997 NQA edition.

Mr. J. A. Ciocco
U.S. Nuclear Regulatory Commission
June 20, 2002
Page 7

Corrective Action: Requirement 16, Corrective Action, has one of the briefest descriptions in 10 CFR 50 Appendix B for setting forth the principles of corrective action. In just four sentences, the requirement states that conditions adverse to quality be identified and promptly corrected and, for significant conditions adverse to quality, the cause for the condition is determined and actions to preclude recurrence are taken.

In response to the nuclear industry's need for more direction in the implementation of effective corrective action programs, the NQA Main Committee developed a guidance document, Appendix 16A-1, that explains in more detail the five basic elements of the corrective action process. Each basic element (identification and documentation, classification, cause analysis, corrections, follow-up) is explained in detail. The appendix includes a flow chart that clearly shows how the process is intended to fit together. The cause analysis guidance includes suggestions for classification of causes and guidance regarding management involvement is included. With this guidance, NQA-1 has established the framework for implementing a successful corrective action program.

Research and Development: In response to requests for guidance on applying the NQA criteria to nuclear research and development activities, *Subpart 4.2, Guidance on Graded Application of Quality Assurance for Nuclear-Related Research and Development* was added in the 2000 edition of the NQA Standard. The application of the provisions of the NQA Standard to nuclear research and development extends the scope of the Standard to basic research, applied research, and development work. This Subpart would appear to be applicable to this type of Yucca Mountain activity.

Future NQA Editions: The NQA Committee has added criteria related to electronic records that will be published in the 2002 Addendum. In addition the Committee is working in the areas of management assessments, performance based auditing, risk informed graded QA, management of electronic data and a variety of comparisons to other recognized quality criteria, including quality criteria applicable to DOE facilities.

The use of an outdated NQA-1-1983 Standard fails to capture the efforts of the nuclear industry to provide continuous improvement to the quality program basis. This twenty-year gap of quality criteria must be bridged with additional regulation that has been incorporated unnecessarily in the NUREG-1804, Yucca Mountain Review Plan, to compensate for the use of an outdated Standard.

Regulatory Regulation Reduction

As noted above, there are inconsistencies in the editions of NQA-1, which are referenced in regulations and review plans. These inconsistencies will require additional regulatory action to resolve. In addition, use of an outdated edition of NQA-1

Mr. J. A. Ciocco
U.S. Nuclear Regulatory Commission
June 20, 2002
Page 8

will likewise require additional regulatory action to compensate for use of an outdated standard. Use of the latest edition of NQA-1 will eliminate the need for these additional regulatory actions.

NUREG -1804 has added basis regulatory criteria that have been developed by both nuclear industry and the NRC for the last nineteen years in order to apply the "latest" regulatory criteria to Yucca Mountain. Most of this additional work was unnecessary if a current edition of NQA had been used. This additional wording could and should be eliminated from NUREG -1804 by electing to use NQA-1-2000. The following are some of the areas that could be eliminated or greatly reduced by changing the NUREG -1804 to NQA-1-2000:

- Commercial Grade Dedication is defined by 10 CFR Part 21 and the current regulatory terminology and dedication process is not contained in the 83 edition of NQA.
- References to the guidance on electronic records.
- NUREG -1804 contains 5 pages for "Acceptance Criteria 19" for software controls that have been addressed by NQA-1-2000. Near the end of these five pages (4.5 - 39) the NUREG gives some credit to NQA-1-2000 by adding "additional provisions contained in Subpart 2.7 of American Society of Mechanical Engineers NQA-1-2000 " to provide clarification for any details that may have been omitted in the NUREG. Subpart 2.7, *QA Requirements for Computer Software for Nuclear Facility Applications*, is an example of an applicable NQA-1 Part II document that is appropriate for establishing requirements and thus its reference could potentially eliminate the need for the 5 pages of Acceptance Criteria 19.
- NQA currently has Standard revisions in ballot process that would address NUREG Acceptance Criteria 20 and 21. A NUREG update to a future revision of NQA 1 could eliminate these areas.

It is evident that the NRC's deficiency in maintaining a current evaluation of 10 CFR 50 Appendix B criteria in a single document has resulted in the nuclear industry's use of different standards and the use of different editions of the NQA-1 Standard. If the NRC would develop a current single document for the Appendix B criteria, it would prevent the duplication of the NRC's effort to write project specific criteria for basic requirements.

Mr. J. A. Ciocco
U.S. Nuclear Regulatory Commission
June 20, 2002
Page 9

Summary

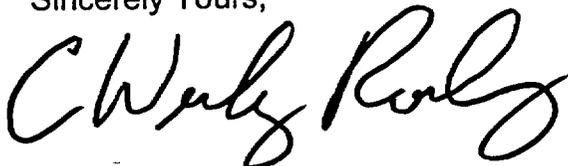
Based on the information presented above (NRC endorsement of several different versions of the ASME NQA-1 Standard for various nuclear facility applications, improvements in the NQA Standard in the last 20 years, and the potential to reduce the volume of regulation), it is recommended that the staff reconsider the expectation that the U.S. Department of Energy (DOE) must commit to NQA-1-1983. The NQA-1 document has gone through considerable improvement since the 1983 edition to incorporate performance based experience. A major opportunity would be missed by not using this last 20 years of cumulative QA experience as the starting point for site-specific regulation. This could also serve as a starting point for utilities to consider NQA-1-2000 for any future nuclear generation.

The Yucca Mountain facility is intended to provide storage for thousands of years. It will be under construction and use beyond the 21st Century and NQA provides the only national industry consensus document that will continue to change to meet industry and regulatory positions. The NQA Committee is dedicated to maintaining a quality standard for the nuclear industry, and requests that the NRC take advantage of the last 20 years of nuclear industry experience by utilizing NQA-1-2000 as the basis for NUREG -1804.

The NQA Committee has NRC staff representation on the Committee and is receptive to working with the NRC staff on issues related to the establishment of requirements that will benefit and protect the American public.

Should there be any questions regarding these comments, please direct them to Gerry M. Eisenberg, ASME Director, Nuclear Codes and Standards at the above address or by phone at 212-591-8510.

Sincerely Yours,



C. Wesley Rowley
Vice President, Nuclear Codes and Standards

Cc: Members, ASME Board on Nuclear Codes and Standards
Members, ASME Nuclear Quality Assurance Committee