



Department of Energy

Washington, DC 20585

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Mr. John Linehan, Chief
Project Management and Quality
Assurance Branch
Division of High-Level
Waste Management
Office of Nuclear Materials
Safety and Security
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Mr. Linehan:

This is in response to the request of Mr. Kennedy of your staff during the meeting of November 18 for a description and justification of the Department of Energy's proposed changes to Appendix H, Revision 1, "Requirements for Computer Software Used to Support a High-Level Nuclear Waste Repository License Application", of the Yucca Mountain Project QA Plan, NNWSI-88-9.

A draft copy of the proposed changes and their justification is enclosed. We look forward to discussing these proposed changes with your staff.

Please feel free to contact Gordan Appel (586-1462) of my staff about any questions.

Sincerely,

Ralph Stein
Associate Director for Systems
Integration and Regulations
Office of Civilian Radioactive
Waste Management

Enclosure (As stated)

cc: L. Barrett, RW-3
S. Zimmerman, Nevada

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November 28, 1988

Description of changes to Appendix H, Revision 1, "Requirements for Computer Software used to Support a High-Level Nuclear Waste Repository License Application", of the Yucca Mountain Project QA Plan, NWWSI/88-9.

Section Description of Change and justification for change

1.0 Page H-1, Objectives, Lines 1-3

Added purpose statement

2.0 Page H-1, Applicability, Lines 2-3

Added "site characterization" to clarify the intent to control the development of software used for site characterization as well as the design, analysis, performance assessment, and operation of the repository.

2.0 Page H-1, Applicability, Lines 6-8

The last sentence was restructured to clarify that the applicability of the requirements of this appendix would be described in plan(s) for software quality assurance. This clarification was also included in paragraph 2.1 of the latest draft of NQA-2, part 2.7 "Quality Assurance Requirements of Computer Software for Nuclear Facility Applications". Mr. Mark Peranich of the NRC is a part of this Nuclear Quality Assurance Standard activity.

4.0 Page H-2, Software Life Cycle, Line 1

Deleted "Individuals or". Change made to clarify that "Organizations implementing software development activities" were responsible to develop controls for the design and development of software.

4.0 Page H-2, Software Life Cycle, Line 3

Added "or acquisition" to clarify that the requirements of this appendix are not limited to software developed by program participants, but are applicable, as appropriate, to all software used on the Yucca Mountain Project regardless of how the software was acquired.

4.0 Page H-2, Software Life Cycle, Line 5

The requirements for verification and validation originally in this section were moved to Section 5.0. The change was needed to eliminate confusion by combining all the requirements for verification and validation into one section. Specific changes to the original text are covered under the discussion of proposed changes to section 5.0.

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Description of changes to Appendix H

Section Description of Change and justification for change

4.0 Page H-2, Software Life Cycle, Lines 9-10

Changed "before succeeding phases can be begin." to "as specified in each organization's Software QA Plan."

The specific requirement for completion and approval of all documentation related to a life cycle phase prior to beginning succeeding phases was deleted. This change was necessary to allow for iterative or parallel development of documentation. The provision for iterative development of software will reduce unnecessary document revisions and redundant reviews of initial requirements by allowing the scientist to evaluate different mathematical models and numerical methods prior to finalizing system requirements. NQA-2, Part 2.7, has also recently been revised to address the same specific issue. To clarify the implementation of the requirement, an additional sentence was added to require that the SQA Plan identify the documentation required to be reviewed and approved for each phase of the software development cycle. Minimum documentation, regardless of the development cycle used, is specified in paragraph 3.2 of Section III, and is unchanged from the original commitment.

4.1.1 Page H-3, Software QA Plan, Lines 3-5

Moved requirement for standards and conventions to separate paragraph and changed "shall" to "should".

The requirement for the SQA Plan to specify the standards, conventions, techniques, or methodologies which guide the development has been reduced to a recommended practice (i.e. should). Much of the software of this project has been previously developed. To require that coding standards or conventions be established for existing software could require unnecessary recoding of that software when enhancements and maintenance activities are performed.

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Section Description of Change and justification for change

4.1.2 Page H-3, Software QA Plan

Changed "Regardless of the life cycle model used, the following requirements shall apply as interpreted and defined by the organizations software QA Plan" to "The following elements shall apply, as appropriate, for the specific lifecycle model defined, interpreted and described in each organizations software QA Plan". Added further clarification as to how the example life-cycle model is to be adapted for program participant use in determining the specific requirements for each organization.

This paragraph was reworded to be consistent with the requirements of Section 2.0, Applicability, and Section 4.0, Software Life Cycle. A change was necessary to clarify, consistent with Section 2.0 and 4.0 requirements, that the SQA Plan(s) would establish the applicable requirements for software development activities, and that those requirements would be graded depending upon the nature and complexity of the software being developed.

4.1.2.1 Page H-3, Requirements Phase, Line 9 (3rd bullet)

Changed "all realizable classes of" to "identified" input data.

This bullet was changed to simplify the intended requirement. The purpose of the requirement specification is to identify the functions, performance characteristics, design constraints and external interfaces of the software to be developed. "Identifying" the input data that drives or affects the development effort is more realistic than specifying, before the design phase, how the software will respond to all realizable classes of input data.

5.0 Page H-5, Software Verification and Validation, Line 11
(last sentence of 2nd paragraph)

Deleted "in the Verification and Validation Report".

The original text was too prescriptive in that it specified the methodology for documenting the verification and validation, rather than simply requiring that the V&V effort be documented. To require a Verification and Validation Report would have required duplicating information already contained in the documentation of verification activities during the development process (see section 5.1) and the NUREG-0856 code assessment documentation committed to in paragraph 3.1.5 of Section III of the Project QA Plan.

5.0 Page H-5, Software Verification and Validation, Paragraphs 3-4

These paragraphs moved here from Section 4.0 to consolidate all requirements for Verification and Validation under one section.

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**5.0 Page H-5, Software Verification and Validation, Line 12
(1st sentence of 3rd paragraph)**

Changed "is" to "should".

There is no regulatory basis for the requirement to perform verification and validation in two stages. This requirement was originally based on an earlier draft requirement of NQA-2, Part 2.7, which has been deleted in the current version. This change is consistent with NUREG-0856 Section D(2) documentation for Code Assessment.

**5.0 Page H-5, Software Verification and Validation, Line 17
(1st sentence of 4th paragraph)**

Change "shall" to "should" to be consistent with change to related requirements of Paragraph 3 above.

**5.0 Page H-5, Software Verification and Validation, Line 19
(last change bar of section 5.0)**

Deleted "The results of this stage shall, however, form the input to a verification and/or validation plan that shall be documented, reviewed, and approved prior to independent tests".

This sentence was deleted because it specified the methodology for documenting the planning of the verification and validation activities. The requirement to develop and approve verification and validation plans or procedures has not changed but incorporated in related sections of this appendix (5.0, 7.0 and 8.4).

5.1 Page H-5, Verification, Line 1

Insert "applicable" to clarify that verification activities will be performed in accordance with the specific life-cycle model established in each organization's software QA Plan. Each Software QA Plan will be reviewed and approved by the Project Office to assure that the requirements established are adequate based on the nature and complexity of the software developed by that organization.

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5.2 Page H-5, Validation, Line 1

Deleted "at the end of the software development cycle"
Added requirements for restricting the use of software that has not been fully validated to Paragraph 3.1.6 of 88-9, Section III.

The wording was revised to eliminate an unrealistic schedule for completing validation activities. It is not feasible to stop all software development or application activities until validation activities are completed as some of the necessary data will not be available until after site characterization activities are completed. In order to assure the necessary level of control of software that has not been fully validated, Paragraph 3.1.6 of Section III to 88-9 was revised to provide restrictions for such use similar to those used in the release of preliminary design drawings.

5.2 Page H-5, Validation, Line 5

Changed "in site" to "in situ" testing to correct typographical error.

5.2 Page H-6, Validation, Line 2

Deleted "including an evaluation of the degree of validity of the model"

The original sentence was revised to simplify the requirements for documenting alternative approaches to validation. The evaluation of the degree of validity of the model is inherent in the overall validation goal of demonstrating "that the model as embodied in the computer software is a correct representation of the process or system for which it is intended" (Section 5.2, 1st sentence). The original wording was based on a draft supplement to NQA-3 that has been subsequently deleted in the balloting of that standard.

6.1 Page H-6, Configuration Identification, Last line

Deleted requirements to establish a labeling system that "Provides the ability to reconstruct the configuration of the software from the requirements phase up to the present time"

The original text for this requirement was based on an early draft of Part 2.7 of NQA-2 which has subsequently been deleted. The intent of the requirement was that a control system be established that would allow for each configuration item and its related life-cycle documentation to be reconstructed. The specific wording, however, appeared to require maintaining developmental versions of the software prior to baselining a configuration item. The original intent of the requirement has been maintained in appendix H and clarified through a change to section 6.2, discussed below.

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Section Description of Change and justification for change

6.2 Page H-6, Configuration Change Control, Lines 1-2 and 5

Deleted "A proposal for" in the 1st sentence
Changed "The proposal shall be formally evaluated" to
"The change should be formally evaluated" in 3rd sentence.

The original text was too prescriptive in that it specified the methodology for documenting and reviewing configuration changes, rather than simply requiring that changes to software configuration be controlled. The requirement for assuring that all changes to software baselines are approved is maintained in the last sentence of 6.2.

6.2 Page H-6, Configuration Change Control, Line 6

Added "...and software configuration items." to clarify that changes to software baselines includes control of each of individual configuration items that the software is comprised of.

6.3 Page H-7, Configuration Status Accounting, Line 1

Changed "configuration control of software" in the original text to "software configuration items" to clarify that the control of a specific version of software includes the individual configuration items that the software is comprised of.

7.0 Page H-7, Documentation, Lines 1-4

Changed "The following is the minimum acceptable documentation of computer software developed or modified for use on the NWSI Project. It follows the phases of the software life cycle." to

"Minimum acceptable lifecycle documentation of computer software developed or modified for use on the Yucca Mountain Project shall be specified in each participants software QA Plan(s). The documentation provided shall describe the following, as applicable."

This paragraph was reworded to be consistent with the requirements of Section 2.0, Applicability, and Section 4.0, Software Life Cycle. A change was necessary to clarify, consistent with Section 2.0 and 4.0 requirements, that the SQA Plan(s) would establish the applicable requirements for in-process documentation of software development activities, and that those requirements would be graded depending upon the nature and complexity of the software being developed. The minimum documentation required, regardless of the life-cycle used, is unchanged from the original Appendix H requirements specified in paragraph 3.2 of Section III of 88/9.

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7.3 Page H-8, Software Implementation Documentation, Lines 4-5

Changed "shall" to "should" in the last sentence.

The original text was overly prescriptive in that the software verification and validation plan(s) were to be completed after implementation. The wording was based on an earlier draft of NQA-2, part 2.7, which deleted the requirement altogether. The change is needed to allow for an iterative or parallel software development and verification process for modules or subroutines.

7.4 Page H-8, Software Verification and Validation Documentation, Lines 3-4

Deleted "at the end of the development cycle".

The wording was revised to eliminate an unrealistic schedule for completing validation activities. It is not feasible to stop all software development or application activities until validation activities are completed as some of the necessary data will not be available until after site characterization activities are completed. In order to assure the necessary level of control of software that has not been fully validated, Paragraph 3.1.6 of Section III to 88-9 was revised to provide restrictions for such use similar to those used in the release of preliminary design drawings.

8.0 Page H-9, Reviews, Line 3

Deleted "prior to proceeding to the next development phase"

The specific requirement for completing all documentation reviews related to a life cycle phase prior to beginning succeeding phases was deleted. This change was necessary to allow for iterative or parallel development of documentation. The provision for iterative development of software will reduce unnecessary document revisions and redundant reviews of initial requirements by allowing the scientist to evaluate different mathematical models and numerical methods prior to finalizing system requirements. NQA-2, Part 2.7, has also recently been revised to address the same specific issue.

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8.1 Page H-9, Software Requirements Review, Line 3

Deleted "and formatted to provide traceability of requirements throughout the development cycle."

The original requirement for formatting the requirements specification "up-front" to provide traceability to documentation in other phases of the development cycle is not feasible, because the content of those other documents will not have been developed when the requirement specification is completed. The wording of this requirement also originally came from an earlier draft of NQA-2, part 2.7, which has subsequently been deleted through the balloting process. The intent of the requirement is met in that the reviews performed in subsequent phases must assure that the requirements are adequately addressed in the design and implementation.

8.3 Page H-9, Software Implementation Review, Line 3

Deleted "and concludes in review and approval of the verification and validation plan." to eliminate requirement for a specific verification and validation plan and to require approval of the plan at the conclusion of implementation (coding the software). See also description of changes to section 5.0, 7.0 and 8.4 and their justification.

8.4 Page H-10, Software Verification and Validation Review, Lines 2-4

Changed "evaluation of the adequacy of completed software verification and validation activities and concludes in review and approval of the Verification and Validation Report." to "evaluation of the adequacy of verification and validation plans or procedures and completed software verification and validation activities. The review results in an approval of verification and validation documentation."

The change was made to eliminate a specific requirement for a single Verification and Validation Report. As discussed under the justification of the related changes to section 5.0, requiring a specific report required a duplication of verification documentation developed during the development of the software and code assessment documentation at the completion of the software development. In addition, the change was made to clarify that all verification and validation documentation would be reviewed and approved. This change allows the program participants to establish a iterative or sequential approach to the development process without establishing the specific methodology to be used. The original wording was based on an earlier draft of NQA-2, part 2.7, which has subsequently been changed to make provision for an iterative development process. The proposed change is consistent with the requirements of NQA-2, part 2.7, which was approved by the NQA Main Committee in October, 1988.

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9.0 Page H-10, Discrepancy Reporting and Corrective Action, Lines 5-6
Added "procedures" after corrective action to clarify requirement.

11.0 Page H-10, Acquired Software, Line 1
Changed "Requirements" to "Procedures" to clarify the mechanism for establishing the needed controls of software transfer.

11.0 Page H-10, Acquired Software, last line on page
Deleted "The software shall be used only for those applications for which the documentation is complete."

The requirement was too prescriptive in that no applications, even preliminary performance assessments needed to evaluate program goals and objectives, could be performed until all verification and validation documentation was complete. The wording was revised to eliminate an unrealistic schedule for completing documentation. Instead the SQA Plan will establish the documentation requirements for acquired software in accordance with the minimum requirements of paragraph 3.2 of 88/9 Section III. In addition, paragraph 3.1.6 of Section III to 88-9 was revised to provide controls for the use of software for which the verification and validation documentation is not completed, consistent to those used in the release of preliminary design drawings.

11.0 Page H-11, Acquired Software, Line 6

Deleted "in the user's manual."

This change was made because the requirements prescribed the methodology for documenting conversion of software, instead of simply requiring that such conversions be documented.

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12.0 Page H-11, Computer Software Applications, Line 3

Added "site-characterization" to clarify the scope of applicability of appendix H requirements to software developed on the Yucca Mountain Project.

12.0 Page H-11, Computer Software Applications, Lines 18-19

Changed "All auxiliary software used shall be included" to "All auxiliary software used should be included"

The intent of the original requirement was to assure that auxiliary software used to pre-process or post-process data files used in technical calculations be identified in the documentation supporting the technical calculation. However, the documentation of any auxiliary software used to support the primary codes is already required in the user's manual documentation of the primary scientific, engineering and mathematical codes. The proposed change will allow for that documentation to be referenced or directly included in the documentation of the technical calculations.