

Licensees with 10 CFR part 50, appendix B, quality assurance programs have committed to using quality assurance standard NQA-1-1983, the latest edition endorsed by NRC in Regulatory Guide 1.28 or committed to the ANSI 45.2 series standards. More recent editions of NQA-1 do not contain sufficient detail to describe how the applicable NRC quality assurance requirements would be satisfied. For example, in NQA-1-1997, many detailed provisions have either been removed from the standard or relocated to a non-mandatory appendix.

However, Section 4.5.1, "Quality Assurance Program," of the draft Yucca Mountain Review Plan provides that "Exceptions and alternatives to these acceptance criteria and the documents and positions contained in Section 4.5.1.5 of the draft Yucca Mountain Review Plan may be adopted by DOE, provided the applicant can otherwise demonstrate compliance with quality assurance program requirements in 10 CFR part 63." Therefore, DOE may propose alternatives to the Yucca Mountain Review Plan quality assurance acceptance criteria, provided adequate justification is submitted to demonstrate that the proposed alternatives adequately describe how the quality assurance requirements of 10 CFR Part 63 will be satisfied.

No changes have been made to the Yucca Mountain Review Plan in response to this comment.

Issue 5: Which nonmandatory requirements of NQA-1-1983 must be followed?

Comment. A commenter stated that the Yucca Mountain Review Plan is not clear on the use of the "non-mandatory guidance" in NQA-1-1983.

Response. Guidance on the use of nonmandatory requirements in NQA-1-1983 is sufficiently clear in the Yucca Mountain Review Plan. Commitment to NQA-1-1983 requirements is subject to exceptions, clarifications, or modifications provided in the Yucca Mountain Review Plan quality assurance acceptance criteria or Paragraph C of "Regulatory Position," of Regulatory Guide 1.28. Any nonmandatory requirements identified in NQA-1-1983 that are not addressed in either the Yucca Mountain Review Plan quality assurance acceptance criteria or Paragraph C of Regulatory Guide 1.28 need not be followed.

No changes have been made to the Yucca Mountain Review Plan in response to this comment.

Issue 6: Which elements of the quality assurance program should be in place at the time of license application submittal?

Comment. A commenter recommended that the Yucca Mountain Review Plan clearly state which elements of DOE's quality assurance program should be in place at the time of license application submittal. The commenter stated an expectation that, as for nuclear power reactor licensing activities, the quality assurance program description would be submitted to NRC separately from the Safety Analysis Report, well before the quality assurance program is fully implemented. Field procedures would be in place, with follow-on commitments to ensure that planned programmatic activities are implemented.

Response. The time frame for implementation of the quality assurance program is sufficiently clear in the Yucca Mountain Review Plan. Section 4.5.1.3, "Acceptance Criteria," states that "The DOE quality assurance program and associated quality assurance program controls and implementing procedures regarding activities performed must be in place before activities begin." These activities include site characterization; acquisition, control, and analysis of samples and data; tests and experiments; scientific studies; facility and equipment design and construction; and performance confirmation.

Section 4.5.1.3 of the draft Yucca Mountain Review Plan has been modified to identify these activities.

Issue 7: Should the step-wise licensing approach be applied to the review of the quality assurance program description?

Comment. A commenter recommended that the step-wise licensing approach be applied to the content and level of detail of the quality assurance program description required for the different phases of repository licensing. Another commenter stated that, typically, a quality assurance program description that encompasses all phases of repository construction, operation, and closure, as required by the Yucca Mountain Review Plan quality assurance acceptance criteria, is prepared in stages (i.e., there are specific elements of the quality assurance program description required to be submitted and reviewed for the design and construction phase/activities, whereas others are required to be submitted and reviewed for the operations phase). This commenter also stated that, although some of the elements of the quality assurance program descriptions are similar among licensing steps, there are different policies, organizations, programs, and

procedures that will be implemented for each step.

Response. A step-wise licensing approach should be applied to the review of the quality assurance program description. Section 4.5.1.3 of the Yucca Mountain Review Plan has been modified to state the following:

The U.S. Department of Energy shall establish a quality assurance program to include all activities up to the time of receipt of high-level radioactive waste for disposal in the geologic repository. These activities include site characterization; acquisition, control, and analysis of samples and data; tests and experiments; scientific studies; facility and equipment design and construction; and performance confirmation. The Yucca Mountain Review Plan will be modified, at the appropriate time, to include facility operation, permanent closure, and decontamination and dismantling of surface facilities. The U.S. Nuclear Regulatory Commission staff should assure that the scope of the Yucca Mountain Review Plan includes those activities described in the U.S. Department of Energy quality assurance program under review. Appropriate conditions should be imposed on quality assurance program and Yucca Mountain Project approvals that reflect the scope of activities described in the quality assurance programs and applications submitted for U.S. Nuclear Regulatory Commission review and approval by the U.S. Department of Energy.

Issue 8: Why are quality assurance program references (Section 4.5.1.5) divided into two groups?

Comment. A commenter stated that the rationale is not clear for division of quality assurance references" between "commitments" and "noncommitments."

Response. Identifying the scope of potentially applicable information will facilitate a licensing review and preparation of a more complete license application. The "commitments" listing of references is mandatory. Commitments are required to be addressed by DOE. The "noncommitments" are not mandatory, but guidance documents that may be used by both DOE and NRC staff reviewers as a source of additional guidance. If noncommitment documents are identified in the license application, NRC staff can refer to these same documents during the review process.

No changes were made to the Yucca Mountain Review Plan in response to this comment.

Issue 9: Is it necessary to have both general and specific acceptance criteria for the review of the quality assurance program description?

Comment. A commenter argued that because there are no "general" quality assurance requirements identified in the applicable NRC regulations, it is inappropriate to have "general" quality