

assurance acceptance criteria, in addition to “specific” quality assurance acceptance criteria, in the Yucca Mountain Review Plan. The commenter requested clarification as to the difference between the general and specific acceptance criteria and provided specific recommendations for revisions.

*Response.* The general acceptance criteria in Section 4.5.1.3 of the draft Yucca Mountain Review Plan provide NRC staff with a broad view of the overall quality assurance requirements and the specific criteria provide the details of the individualized quality assurance requirements. Reiteration of the requirements is useful to promote consistency in NRC staff review.

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

*Issue 10:* Is the Yucca Mountain Review Plan guidance for review of the quality assurance program description appropriate for performance assessment?

*Comment.* A commenter recommended revisions to reflect a quality assurance program geared to performance assessment, rather than only experimental activities and calculations.

*Response.* A preclosure safety analysis and a postclosure performance assessment regulatory requirements are important components in evaluating the Yucca Mountain project. The quality assurance terminology is appropriate and adequate for performance assessment because it has been proven effective in a wide range of applications.

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

*Issue 11:* How much overlap is appropriate between acceptance criteria in Section 4.5.1, “Quality Assurance Program,” and Section 4.2.1.3, “Model Abstraction”?

*Comment.* A commenter stated that the data and model criteria in Acceptance Criterion 21 of Section 4.5.1.3, “Acceptance Criteria” appear to be redundant or inconsistent with the technical requirements in Section 4.2.1.3, “Model Abstraction.”

*Response.* In response to other comments, Acceptance Criterion 21, “Scientific Investigation,” has been consolidated into Acceptance Criterion 3, “Design Control.” This change has not changed the scope of the quality assurance requirements.

*Issue 12:* How should quality assurance software requirements be applied?

*Comment.* Two commenters requested clarification as to which types of

software were subject to quality assurance software requirements. One commenter argued that quality assurance software requirements should apply only to software developed to support a safety or waste isolation function.

*Response.* Section 4.5.1, “Quality Assurance Program,” of the Yucca Mountain Review Plan has been modified to specify that it applies to software developed to support functions important to safety or to waste isolation.

*Issue 13:* Should the discussion of the corrective action program be clarified?

*Comment.* Two commenters recommended that the discussion of the corrective action program be clarified with respect to terminology, procedures, and the role of quality assurance staff in the program.

*Response.* The discussion of the corrective action program in Section 2.5.13 of the draft Yucca Mountain Review Plan is appropriate as written because it is consistent with widely accepted and proven approaches to corrective action in quality assurance programs.

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

*Issue 14:* Is the review of quality control and certification for nuclear waste transportation canisters and casks and their fabrication included in the review of the quality assurance program description?

*Comment.* A commenter asked whether NRC will review the quality control for the manufacturing processes used to produce nuclear waste transportation canisters and casks. The commenter also asked whether NRC will specify conditions or criteria for certification of canisters and whether manufacturing processes, construction, and quality control issues are periodically reviewed by NRC to ensure adherence to approved certification criteria and that canisters are constructed to required specifications.

*Response.* Under 10 CFR part 71, NRC is responsible for certifying the designs of shipping casks that may be used to move commercial nuclear waste by truck or rail to Yucca Mountain. NRC will also review the manufacturing processes used to produce transportation canisters and will periodically inspect the manufacturing processes and construction to ensure that design criteria are adhered to and that transportation canisters are constructed to applicable specifications.

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

*Issue 15:* What is the scope of license applicant qualification information that should be covered in the review of the quality assurance program description?

*Comment.* A commenter recommended that NRC provide for a thorough review of the background, experience, management capability, and track record of the license applicant in the Yucca Mountain Review Plan.

*Response.* DOE, in accordance with 10 CFR 63.21(c)(22), is required to include information about its organizational structure as it pertains to construction and operation of the repository, and the personnel qualifications and training requirements. NRC has a program in place to observe detailed technical and programmatic audits of DOE’s Yucca Mountain project and its contractors. Various aspects of DOE’s quality assurance program, specifically with regard to the Yucca Mountain project, are routinely evaluated by NRC. However, only the license applicant activities specifically related to a Yucca Mountain repository fall under the scope of the regulatory requirements in 10 CFR part 63.

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

*Issue 16:* Should the text be revised to address various consistency, clarification, editorial, and format issues?

*Comment.* A commenter provided several comments on various consistency, clarification, editorial, format, and other miscellaneous issues.

*Response.* Section 4.5.1, “Quality Assurance Program” of the draft Yucca Mountain Review Plan has been modified, as appropriate, to incorporate various editorial changes for consistency, clarification, and format issues related to this comment.

## 9 Structure of the Yucca Mountain Review Plan

### 9.1 Level of Detail

*Issue:* Is the level of detail in the Yucca Mountain Review Plan appropriate to guide the review of a license application?

*Comment.* Commenters noted that the degree of specification in review methods varies substantially throughout the Yucca Mountain Review Plan. In some sections, presumptions are made as to what is important to safety or waste isolation by including discussion of specific design solutions (e.g., backfill). The commenters consider these assumptions to be inconsistent with the risk-informed, performance-based regulations at 10 CFR part 63. The