

practice. NRC staff tailored information from those sources to the unique requirements specifically applicable to a Yucca Mountain repository.

As stated in Section 4.5.1, "Quality Assurance Program," of the draft Yucca Mountain Review Plan, DOE has flexibility in defining methods and controls while still satisfying pertinent regulations, and DOE may adopt exceptions and alternatives to the 18 acceptance criteria in the Yucca Mountain Review Plan, provided DOE can otherwise show it satisfies the requirements in 10 CFR part 63.

No changes have been made to the Yucca Mountain Review Plan as a result of this comment.

*Comment 2.* Two commenters questioned whether quality assurance acceptance Criteria 19–22, that address software, sample control, scientific investigation, and field surveys, respectively, are necessary and whether these areas are already adequately covered by quality assurance acceptance criteria 1–18.

*Response 2.* The Yucca Mountain Review Plan quality assurance acceptance criteria are consistent with the quality assurance criteria of 10 CFR part 50, appendix B, which apply to nuclear power plants and fuel reprocessing plants. Criteria 19–22 clarify certain quality assurance requirements in 10 CFR part 50, appendix B, for application to the Yucca Mountain repository. However, these four acceptance criteria did not expand the scope of applicability for quality assurance.

To maintain consistency between the structure in the Yucca Mountain Review Plan and quality assurance requirements in 10 CFR part 63, subpart G, NRC staff has consolidated specific acceptance criteria 19–22 into specific acceptance criteria 3, 8, and 10 as follows: Acceptance Criterion 19, "Software," and Acceptance Criterion 21, "Scientific Investigation," have been consolidated into Acceptance Criterion 3, "Design Control"; Acceptance Criterion 20, "Sample Control," has been consolidated into Acceptance Criterion 8, "Identification and Control of Materials, Parts, and Components"; and Acceptance Criterion 22, "Field Surveys," has been consolidated into Acceptance Criterion 10, "Inspection."

*Issue 2:* Are Yucca Mountain Review Plan quality assurance acceptance criteria and review methods more prescriptive than appropriate for a risk-informed, performance-based regulatory approach?

*Comment.* A commenter argued that many of the quality assurance acceptance criteria and review methods

prescribe quality assurance program features more narrowly than is consistent with risk-informed, performance-based principles. The commenter stated that this approach limits the license applicant to a program that is not based on common nuclear industry practice and would place an unnecessary burden on the applicant to justify deviation from the specified approach. The commenter further stated that this approach would result in a description of implementation details in the quality assurance program description that may be more appropriate for inclusion in detailed implementing procedures.

The commenter identified a number of specific locations in the Yucca Mountain Review Plan that are related to these comments.

*Response.* The Yucca Mountain Review Plan quality assurance acceptance criteria are appropriate for a risk-informed, performed-based quality assurance program. The Yucca Mountain Review Plan quality assurance acceptance criteria provide guidance on issues associated with the uniqueness of the geologic repository. Exceptions from Yucca Mountain Review Plan approaches are acceptable, so long as the quality assurance requirements in 10 CFR part 63 are satisfied. Exceptions and alternatives to the acceptance criteria contained in the Yucca Mountain Review Plan may be adopted by DOE, provided DOE demonstrates that it can otherwise satisfy the requirements of part 63.

A quality assurance program description written in compliance with 10 CFR part 63, subpart G, is specifically tailored to the proposed high-level waste repository at Yucca Mountain and the Yucca Mountain Review Plan incorporates appropriate NRC quality assurance guidance. The Yucca Mountain Review Plan states that, where appropriate, the quality assurance program description may reference a commitment to comply with certain provisions of documents identified in Section 4.5.1.5 of the draft Yucca Mountain Review Plan and need not repeat the text of the document in the quality assurance program description.

No changes have been made to the Yucca Mountain Review Plan as a result of this comment.

*Issue 3:* Should certain text from quality assurance standards that is included in the Yucca Mountain Review Plan be replaced by references to the corresponding text in those standards?

*Comment.* A commenter stated that many of the more prescriptive acceptance criteria appear to be direct or

modified excerpts from references that could be more simply identified as NRC-endorsed sources, allowing the license applicant to maintain flexibility in developing implementation methods, consistent with risk-informed, performance-based principles. The commenter argued that the Yucca Mountain Review Plan should only reference these sources as acceptable means to implement NRC's quality assurance regulations.

A number of specific locations in the Yucca Mountain Review Plan where these comments apply were identified.

*Response.* Several quality assurance standards referenced in the Yucca Mountain Review Plan were written for a 10 CFR part 50, appendix B-type quality assurance program. Although 10 CFR part 50, appendix B requirements are similar to 10 CFR part 63 quality assurance requirements, unique considerations associated with a geologic high-level waste repository that relies on both natural and engineered barriers pose major differences. Therefore, the Yucca Mountain Review Plan includes text from these quality assurance standards, modified as necessary, in order to provide clear guidance during a license application review. This approach provides guidance on, and background for, the quality assurance elements unique to the geologic repository in one document. Section 4.5.1, "Quality Assurance Program" of the draft Yucca Mountain Review Plan states, "Where appropriate, the quality assurance program description may reference a commitment to comply with certain provisions of a document identified in Section 4.5.1.5 of the draft Yucca Mountain Review Plan and not repeat the text of the document in the quality assurance program."

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

*Issue 4:* Should the Yucca Mountain Review Plan reference more recent quality assurance standards?

*Comment.* Three commenters recommended using a more recent edition of standard NQA–1 rather than NQA–1–1983 and revising the text of the Yucca Mountain Review Plan accordingly. Another commenter suggested incorporating Nuclear Safety Standards from July 2002.

*Response.* NRC endorses standards through the use of regulatory guides. These regulatory guides provide sufficient detail to ensure that programs and activities governed by such standards comply with the applicable regulations.