In their May 11, 2009 “Memorandum and Order (Identifying Participants and Admitted Contentions),” Construction Authorization Boards (CAB) 01, 02 and 03 admitted as a legal issue contention NEV-SAFETY-149, relating to the use of the quality assurance (QA) program in connection with the U.S. Department of Energy’s (DOE or Department) Total System Performance Assessment (TSPA).\(^1\)

In response to the September 30, 2009 Case Management Order #2 (issued by CAB 04), DOE and the State of Nevada agreed that this contention involves the following legal issue:

\(^1\) See U.S. Dep’t of Energy (High-Level Waste Repository), LBP-09-06, 69 NRC __ (slip op. at 138) (May 11, 2009).
Whether, under 10 C.F.R. § 63.114, DOE may rely upon its quality assurance program and procedures as a basis for excluding from consideration in the TSPA, potential deviations from repository design or errors in waste emplacement.2

On October 23, 2009, CAB 04 issued its “Order (Identifying Phase 1 Legal Issues for Briefing)” approving this formulation of the legal issue to be briefed.3

As discussed below, DOE is required by § 63.113(b) to conduct a performance assessment that meets the requirements of § 63.114 and other provisions. The NRC and EPA rules require that only those features, events and processes (FEPs) found to have sufficient consequence and probability of occurrence be included in the performance assessment.4 NRC regulations also require DOE to implement a quality assurance (QA) program and procedures to assure that activities important to waste isolation and important to safety are correctly performed.5 Section 63.114 does not contain any provision that requires DOE to ignore the expected effects of the QA program and procedures in evaluating potential deviations from repository design or errors in waste emplacement. In assessing whether potential deviations from repository design or errors in waste emplacement must be considered in the TSPA, it is legally permissible for DOE to determine that implementation of the QA program and its procedures, including post-placement inspection and monitoring, provides a basis for reasonable

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2 U.S. Department of Energy, State of Nevada and Nuclear Energy Institute Joint Proposal Identifying Phase 1 Legal Issues for Briefing, Attachment 1 at 4 (Oct. 6, 2009). Nevada’s contention references a number of other regulations. DOE and Nevada agreed that, while either party is free to discuss those or other regulations in their brief, the legal issue to be decided focuses exclusively on what is required to comply with 10 C.F.R. § 63.114.


4 See 10 C.F.R. §§ 63.102(j), 63.114; Implementation of a Dose Standard After 10,000 Years, 74 Fed. Reg. 10,811, 10,829 (to be codified at 10 C.F.R. § 63.342); 40 C.F.R. § 197.36.

5 10 C.F.R. Part 63, Subpart G.
assurance that such deviations or errors will not cause a significant change in the results of the TSPA.  

II. Argument

DOE is required by § 63.113(b) to conduct a performance assessment that meets the requirements of §§ 63.114, 63.303, 63.305, 63.312 and 63.342. The NRC and EPA rules require that only those FEPs found to have sufficient consequence and probability of occurrence be included in the performance assessment. There is nothing in § 63.114 or any other NRC regulation that indicates that in determining which FEPs must be included and which can be excluded DOE must ignore the effects of the QA program and procedures.

As defined in 10 C.F.R. § 63.141, QA encompasses all of the planned and systematic actions necessary to provide adequate confidence that the geologic repository and its structures, systems, or components will perform satisfactorily in service. QA requirements apply to all structures, systems, and components important to safety, to design and characterization of barriers important to waste isolation, and to related activities. The QA requirements require DOE to establish measures to assure that applicable regulatory requirements and the design basis, as defined in § 63.2 and as specified in the license application, are correctly translated into the

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6 NEV-SAFETY-149, the source of this legal issue, challenges DOE’s statement of the basis for excluding FEP 1.1.03.01.0A, “Error in Waste Emplacement.” State of Nevada’s Petition to Intervene as a Full Party, dated Dec. 19, 2008 at 783. The challenged statement was not in the License Application, but instead was an error in a supporting technical document. See id.; Answer of the U.S. Department Of Energy to the State of Nevada’s Petition to Intervene, dated January 16, 2009 (DOE Answer to Nevada Petition) at 1381-82. That error had been identified and corrected (changed from “excluded by regulation” to “excluded on the basis of low consequence”) before DOE submitted the License Application. DOE Answer to Nevada Petition at 1381-82; Scientific Analysis/Calculation Error Resolution Document ANL-WIS-MD-000027 ERD 01, dated May 23, 2008, (LSN# DEN001595379) at 2. Consequently, this aspect of Nevada Safety Contention 149 is moot.

7 See 10 C.F.R. §§ 63.102(j), 63.114; 74 Fed. Reg. at 10,829 (to be codified at 10 C.F.R. § 63.342); 40 C.F.R. § 197.36.

8 10 C.F.R. § 63.141.

9 Id. § 63.142(a).
design documents. These measures must assure that appropriate quality standards are specified and included in design documents and that deviations from such standards are controlled.

The repository design presented in the Safety Analysis Report (SAR) Section 1 is the basis for the TSPA. The TSPA is required by subsection 63.114(a)(1) to include information on the design of the engineered barrier system. The technical basis for either inclusion or exclusion of degradation, deterioration or alteration processes of engineered barriers in the required performance assessment is required to be addressed by § 63.114(a)(6). Consequently, the TSPA necessarily must take into account the design of the engineered barrier system, as it is developed in accordance with the applicable QA requirements. In fact, virtually every statement in the SAR about the design, construction and operation of the geologic repository relies in one respect or another upon implementation of the QA program to assure that designs are executed as intended, that construction proceeds according to design, and that operation is consistent with design and construction specifications. Therefore, it is clear that the TSPA could not possibly take into consideration the design details required by 10 C.F.R. § 63.114(a) without relying on the effectiveness of the QA program. Consequently, the Commission must have intended that DOE would take into consideration QA program effectiveness in its screening of FEPs.

Decades of nuclear experience have demonstrated that QA programs are effective in protecting the public health and safety, and the Commission has repeatedly relied upon QA requirements similar to those in 10 C.F.R. Part 63, Subpart G in finding that there was reasonable

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10 ld. § 63.142(d).
11 Id.
12 SAR references in this brief are to SAR revision 1, dated February 19, 2009.
assurance that the activities involving a nuclear facility could be conducted without endangering the health and safety of the public.\textsuperscript{13}

DOE may rely on rigorous QA and quality control requirements governing repository design and emplacement of waste packages to exclude consideration in the TSPA of deviations from design or errors in waste emplacement based on low significance. Under the regulatory requirements for performance confirmation and QA, \textit{any deviation from design must be evaluated for potential impact, and significant deviations detected during the operational period must be corrected}.\textsuperscript{14} Thus, DOE has a reasonable basis for concluding that implementation of the QA program and the performance confirmation program will provide reasonable assurance that if any significant deviations do occur, they will be identified and corrected during the operations phase. Consequently, it is legally permissible under § 63.114 and the other relevant NRC regulations, for DOE to determine that implementation of the QA program and its procedures, including post-placement inspection and monitoring, provides a basis for reasonable assurance that such deviations or errors will not cause a significant change in the results of the TSPA and therefore, that such deviations can be excluded from the performance assessment.

\textsuperscript{13} \textit{See, e.g., Carolina Power & Light Co. (Shearon Harris Nuclear Power Plant), LBP-00-12, 51 NRC 247, 275-78, 282 (2000) (finding where a licensee’s quality assurance plan satisfied the applicable requirements of 10 C.F.R. § 50.55a(a)(3) and Part 50, App. B, that the licensee’s plan was sufficient “to provide an acceptable level of quality and safety”), aff’d CLI-01-11, 53 NRC 370 (2001); see also Disposal of High-Level Radioactive Wastes in a Proposed Geologic Repository at Yucca Mountain, NV, 66 Fed. Reg. 55,731, 55,746 (stating that “Part 63 contains a number of requirements (e.g., qualitative requirements for data and other information, the consideration and treatment of uncertainties, the demonstration of multiple barriers, performance confirmation program, and QA program) designed to increase confidence that the postclosure performance objective is satisfied. The Commission will rely on the performance assessment as well as DOE’s compliance with these other requirements in making a decision . . .); cf. Commonwealth Edison Co. (Braidwood Nuclear Power Station, Units 1 and 2), LBP-87-14, 25 NRC 461, 467 (1987) (stating that the issue under consideration was “whether there was a sufficiently large breakdown in quality assurance procedures that there is no ‘reasonable assurance’ provided that the safety systems at Braidwood will perform their functions and the public health and safety will be protected”)}, aff’d CLI-87-07, 26 NRC 1 (1987).

\textsuperscript{14} 10 C.F.R. § 63.142(q) (Corrective action.).
III. Conclusion

DOE may rely on the expected effectiveness of the QA program and procedures to exclude from consideration in the TSPA potential deviations from repository design or in waste emplacement consistent with the regulatory requirements of 10 C.F.R. § 63.114 and other applicable provisions of the NRC regulations.

Respectfully submitted,

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