

**UNITED STATES OF AMERICA  
NUCLEAR REGULATORY COMMISSION**

**Atomic Safety and Licensing Board**

**Before Administrative Judges:**

<b>ASLBP BOARD</b> 09-892-HLW-CAB04 Thomas S. Moore, Chairman Paul S. Ryerson Richard E. Wardwell
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<b>In the Matter of</b>	)	
	)	
<b>U.S. DEPARTMENT OF ENERGY</b>	)	<b>Docket No. 63-001-HLW</b>
	)	
<b>(High Level Waste Repository)</b>	)	<b>January 21, 2011</b>

**STATE OF NEVADA’S SEPARATE COMMENTS REGARDING THE IMPACT  
OF LBP-10-22 ON NEV-SAFETY-130, 149, 161, and 162**

As indicated in the “U.S. Department of Energy’s Joint Report in Response to CAB Order of December 8, 2010 and to LBP-10-22,” also filed today, Nevada, DOE, and NRC Staff have differing views regarding the effect of the Construction Authorization Board’s (CAB’s) rulings on Phase 1 Legal Issues 7, 8 and 10 on NEV-SAFETY-130, 149, 161 and 162. Nevada’s position in this regard is stated briefly in DOE’s stipulation chart, and is explained more fully below.

**A. EFFECT OF LEGAL ISSUE 7 ON NEV-SAFETY-149: DEVIATIONS IN  
DESIGN AND WASTE EMPLACEMENT**

This contention (paragraph 1, as submitted) provides as follows:

Legal issue: In SAR Subsection 2.2.1.2 at 2.2-17, DOE excludes deviations from repository design or errors in HLW emplacement from events considered in the TSPA (FEP 1.1.03.01.0A) on purely legal grounds that are unexplained and erroneous.

See Nevada Petition to Intervene at pg. 783. As explained below, NEV-SAFETY-149, as originally pled and elaborated upon in Nevada’s Reply to DOE’s Answer to Nevada’s Petition to

Intervene, is admissible as a factual contention challenging the technical sufficiency of DOE's screening analysis of this FEP (deviations from design and errors in waste emplacement).

The history of this contention is important here. As the CAB discussed (LBP-10-22 at 19-20), Nevada originally believed it was DOE's position that these FEPs were screened out as a matter of law. Accordingly, while NEV-SAFETY-149 included a factual component ("This proposition [that deviations from design and errors in waste emplacement may be screened out] is belied by decades of nuclear experience" (Petition to Intervene at pg. 784)), the contention as originally pled was designated as a legal issue contention. When, in its Answer to Nevada's Petition to Intervene, DOE attempted to clarify that these FEPs were not screened out for a legal reason, but instead for "low consequences," Nevada was initially skeptical that this was in fact the case.

This skepticism was well founded because, as far as Nevada could determine, DOE's screening analysis consisted of an entirely qualitative discussion of how DOE's quality assurance program would function to eliminate consequential deviations from design and errors in waste emplacement. There was no quantitative analysis of human error probability and consequences that the NRC's FEP screening criteria appeared to require. *See* Nevada's Reply to DOE's Answer to Nevada's Petition to Intervene at pp. 652-654, and DOE's screening analysis of FEP 1.1.03.01.0A and related FEP 1.1.08.00.0A in "Features, Events, and Processes for the Total System Performance Assessment: Analyses," DEN001584824 at pp. 6-39-6.40 and 6.52-6.61, cited by DOE in its Reply at pp. 1382-1383 (screening analysis attached as Exhibit A hereto). DOE's discussion here appeared to be asserting that implementation of DOE's quality assurance program would, *per se*, necessarily operate to eliminate completely all consequential deviations from design and errors in waste emplacement. Nevada reasonably believed such a "*per se*"

discussion read more like a legal argument than a technical one, notwithstanding DOE's clarification.

Nevertheless, recognizing that DOE may have in fact tried to screen out these FEPs for technical as opposed to legal reasons, Nevada in its Reply elaborated upon the factual component in NEV-SAFETY-149 as submitted.<sup>1</sup> Nevada argued that "nothing in [DOE's] entirely qualitative discussion about how great DOE's QA program will be implemented even remotely supports the proposition that errors in repository design and errors in waste emplacement will occur at a frequency of less than one chance in 10,000 in 10,000 years, or one in one-hundred million per year.... Indeed, the Commission may take official notice that no human reliability program will reduce human errors to less than one in one-hundred million per year." *See* Nevada Reply to DOE's Answer at pp. 653-654.<sup>2</sup>

The CAB's decision on legal issue 7, LBP-10-22 at pp. 19-20, holds that deviations from repository design or errors in waste emplacement caused by human errors must be screened in (or out) as FEPs using the same frequency or consequence criteria that apply to other FEPs, although DOE may take the effects of its quality assurance program into account in evaluating probability or consequences. This ruling is fully in accord with the factual allegations in NEV-SAFETY-149, as originally pled and then as Nevada elaborated upon it in its Reply. In particular, Nevada's factual contentions that DOE's screening analysis "is belied by decades of nuclear experience" (Petition to Intervene at pg. 784), that "nothing in [DOE's] entirely qualitative discussion about how great DOE's QA program will be implemented even remotely

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<sup>1</sup> Material in a petitioner's reply that "legitimately amplifie[s]" the contention set forth in the petition to intervene may be considered in defining the scope of the contention. *PPL Susquehanna LLC (Susquehanna Steam Electric Station, Units 1 and 2)*, LBP-07-04, 65 NRC 281 at 301 (2007); *Pa'ina Hawaii (Material License Application)*, LBP-06-12, 63 NRC 403 at 416 (2006); *Louisiana Energy Services, LP (National Enrichment Facility)*, LBP-04-14, 60 NRC 40 at 58 (2004).

<sup>2</sup> In fact, it did not become clear to Nevada that DOE's "per se" discussion was not a kind of legal argument until the oral argument before the CAB when DOE represented to the CAB that this was the case.

supports the proposition that errors in repository design and errors in waste emplacement will occur at a frequency of less than one chance in 10,000 in 10,000 years, or one in one-hundred million per year” (Nevada Reply to DOE’s Answer at pg. 654), and that “the Commission may take official notice that no human reliability program will reduce human errors to less than one in one-hundred million per year ” (*Id*), taken together, constitute an admissible factual contention challenging the technical sufficiency of DOE’s screening analysis of this FEP.<sup>3</sup>

**B. EFFECT OF LEGAL ISSUE 8 ON NEV-SAFETY-130: DRIP SHIELD EMPLACEMENT PLAN, EQUIPMENT, AND SCHEDULE**

This contention (paragraph 1, as submitted) provides as follows:

SAR Subsection 1.3.4 at 1.3.4-1 identifies two engineered components within the repository drift that are important to waste isolation – the waste package and the drip shield –and the license application relies on installation of drip shields to prevent exceeding the allowable dose to the RMEI. The drip shields are a new technology that has never been designed in detail, prototyped, fabricated, or installed in any actual application in order to develop a basis for predicted performance or to demonstrate that drip shields can be installed and perform as assumed in the TSPA; therefore, the contribution of the drip shields in the predicted performance of the repository should be ignored in the TSPA or, at a minimum, the no drip shield scenario should be considered as an alternative conceptual model and propagated through the assessment.

*See* Nevada Petition to Intervene at pg. 701. This contention was supported by over six pages of detailed technical analyses addressing (among other things) uncertainties and failures in drip shield design and fabrication, uncertainties and failures in the design of the drip shield emplacement equipment, problems with drip shield installation procedures, availability of material resources, and the effects of drift deterioration and collapse on DOE’s ability to install the drip shields (Paragraph 5 of NEV-SAFETY-130, Nevada Petition to Intervene at pp. 703-709). As explained below, NEV-SAFETY-130 is admissible as pled and is unaffected by the CAB’s resolution of Legal Issue 8.

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<sup>3</sup> NEV-SAFETY-149, clarified and elaborated as a factual contention, is necessarily general because both the FEP it addresses and DOE’s screening analysis are equally general. *See* attached Exhibit A.

NEV-SAFETY-130, 161 and 162 all address drip shields. However, unlike NEV-SAFETY-161, NEV SAFETY-130 does not invoke the requirement that there be multiple barriers, or demand an analysis that simply postulates the absence of drip shields in order to assess whether DOE's multi-barrier protection system is wholly dependent on a single barrier. And, unlike NEV-SAFETY-162, NEV SAFETY-130 does not address the safety problems associated with the concept that drip shields will be installed only after all of the wastes have been emplaced.

Instead, NEV-SAFETY-130 offers strong factual support for the proposition that DOE has not shown reasonable assurance that it will, in fact, be able to design and install the drip shields as planned and, for this reason, and this reason only, the contribution of the drip shields to the predicted performance of the repository should be ignored, or, at a minimum, the no drip shield scenario should be considered as an alternative conceptual model and propagated through the assessment.

This has absolutely nothing to do with the CAB's resolution of Issue 8, which only addressed the need for a neutralization analysis in relation to the requirement that there be multiple barriers. The CAB's holding that DOE need not postulate the absence of drip shields in order to assess their contribution to multi-barrier safety does not also constitute a holding that the drip shields must be assumed to exist, just as DOE proposes, notwithstanding any factual evidence to the contrary. By analogy, if DOE had proposed an anti-gravity machine as an engineered barrier, the CAB's holding on Issue 8 would eliminate the need to postulate the absence of the machine in order to determine compliance with the multi-barrier requirement, but it would not eliminate from contention legitimate issues regarding whether such a machine could ever exist.

**C. EFFECT OF LEGAL ISSUE 8 ON NEV- SAFETY-161: CRITICAL ROLE OF DRIP SHIELD**

This contention (paragraph 1, as submitted) provides as follows:

The LA violates the requirement that there be “multiple barriers,” because its safety depends dispositively on a single element of the engineered system- the drip shield.

*See Nevada Petition to Intervene at pg. 857. In LBP-10-22 (at pg. 23), the CAB held that, although there was no legal requirement to perform a drip shield neutralization analysis, there remained the “related factual question of whether DOE has adequately demonstrated that the multi-barrier protection system is not ‘wholly dependent on a single barrier’” (quoting from 74 Fed. Reg. at 10,826 and 66 Fed. Reg. at 55,758). This CAB statement is an accurate paraphrase of NEV-SAFETY-162, and this contention is therefore admissible. The only effect of LBP-10-22 is that NEV-SAFETY-161 must now be litigated as a factual contention, without the benefit of any legal requirement that a neutralization analysis be performed, although Nevada would not object to its being reworded to use the CAB’s quoted language.*

**D. EFFECT OF LEGAL ISSUES 8 AND 10 ON NEV-SAFETY-162: DRIP SHIELD INSTALLATION SCHEDULE**

NEV-SAFETY-162 (paragraph 1, as submitted) provides as follows:

From SAR Subsections 1.1.3.1 and 1.1.3.2, and related subsections, it is clear that DOE plans to install the drip shields about one-hundred years from now, after all of the wastes are emplaced in the in the tunnels and just prior to repository closure, but this cannot be justified as safe because if installation of the drip shields proves to be defective or impossible it will be too late to assure safety by alternative means.

*See Nevada Petition to Intervene at pg. 861. The summary in paragraph 2 (Id) elaborated that it would be too late to assure safety by alternative means short of retrieval.*

As explained below, this contention is admissible as a factual contention questioning whether, in the circumstances of this case, installing the drip shields only after all of the wastes are emplaced is a safe concept.

Here again, the history of the contention is important. In the process of formulating Legal Issue 10, there was some disagreement about whether this legal issue (as formulated by Nevada), which addressed the nature and timing of safety findings required by Part 63, was within the scope of NEV-SAFETY-162. *See* “State of Nevada’s Legal Issue for NEV-SAFETY-162,” filed with the CAB on October 6, 2009, where Nevada explained that a drip shield plan “cannot be justified as safe” if NRC’s safety regulations effectively prohibit it, and whether the regulations contained such a prohibition was the essential question posed by Legal Issue 10. However, while Legal Issue 10 was within the scope of NEV-SAFETY-162, Legal Issue 10 did not replace it. NEV-SAFETY-162 was not designated as a purely or even primarily “legal issue” contention, and now that the legal issue is resolved, the factual question remains whether (as stated) DOE’s drip shield installation plan “cannot be justified as safe.”

Legal Issue 10 arose not because it was equivalent to NEV-SAFETY-162 but because, in its Answer to Nevada’s Petition to Intervene, DOE questioned Nevada’s citation to 10 C.F.R. § 63.31(a)(2) in the discussion of materiality in paragraph 4 of NEV-SAFETY-162. *See* Nevada’s Reply to DOE’s Answer at pp. 694-695. In its Reply, Nevada argued that 10 C.F.R. § 63.31(a)(2) supported the materiality of NEV-SAFETY-162 because the regulation required a finding of reasonable assurance of disposal safety before a construction authorization could be issued, and disposal safety incorporated the finding of construction completion in 10 C.F.R. § 63.41(a)(2). Now that the CAB has found that the construction completion finding in 10 C.F.R. § 63.41(a)(2) cannot be imported into the construction authorization finding in 10 C.F.R. § 63.31(a)(2) (LBP-10-22 at pg. 28), this purely legal aspect of NEV-SAFETY-162 is now resolved against Nevada, but it does not follow from this that DOE’s plan is approved as a matter of law. While this CAB holding perhaps leaves some question about the materiality of NEV-

SAFETY-162 (raised by DOE) unresolved, it does not make the contention inadmissible as a factual contention.

Nevada submits that NEV-SAFETY-162 is material for the simple reason that it alleges that DOE's disposal plan is unsafe as a factual matter, and if this is true the broad construction authorization finding in 10 C.F.R. § 63.31(a)(2) cannot be made, putting the construction completion finding in 10 C.F.R. § 63.41(a)(2) completely aside, as the CAB's decision requires. However, as explained below, other of Nevada's factual contentions will need to be resolved before NEV-SAFETY-162 can be addressed on its merits.

As explained in paragraph 5 of NEV-SAFETY-162 (Nevada Petition to Intervene at pg. 862), other (now admitted) Nevada contentions are relevant to the question whether DOE's plan to install drip shields only after the waste is emplaced is safe. In particular, admitted NEV-SAFETY-130 contains numerous and well-supported factual arguments to the effect that the installation of drip shields will be difficult or impossible, and this has an important bearing on the litigation of NEV-SAFETY-162 because, if NEV-SAFETY-130 is proven correct, there is the strong likelihood that all of the wastes will in fact be emplaced without drip shields. Disposal safety would then depend on retrieving the wastes. However, retrieval cannot be counted upon to assure disposal safety because, even if retrieval is technically possible, the decision to retrieve would entail an analysis and balancing of the short-term safety risks to retrieval workers and the long-term risks to safety and the environment of leaving the wastes in the repository without drip shields, and the outcome of such an analysis cannot be predicted.

Nevada suggests that NEV-SAFETY-162 be ruled admissible as a factual contention, but that the litigation of NEV-SAFETY-162 be postponed until after Nevada's related admitted drip shield contentions (especially but not limited to NEV-SAFETY-130) are resolved. Alternatively,



a CAB decision on admissibility of NEV-SAFETY-162 could be postponed until after Nevada's related admitted drip shield contentions are resolved.

Finally, the CAB's ruling on Legal Issue 8 does not affect NEV-SAFETY-162. The safety significance of NEV-SAFETY-162 is increased to the extent that it becomes less likely that the drip shields will actually be installed as proposed, which is the subject of contentions such as NEV-SAFETY-130. However, NEV-SAFETY-162 does not invoke the requirement that there be multiple barriers - it does not ask one to postulate that the drip shields will be absent in order to assess their contribution to the post-closure performance assessment. Rather, NEV-SAFETY-162 addresses DOE's proposed timing of the installation of the drip shields, and would be mooted if DOE simply agreed to install the drip shields before or during waste emplacement.

For the reasons set forth above, NEV-SAFETY-130, 149, 161 and 162 are admissible contentions.

Respectfully submitted,

*(signed electronically)*

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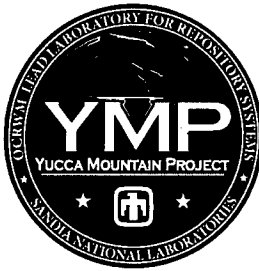
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# Exhibit A



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QA: QA

ANL-WIS-MD-000027 REV 00

March 2008

## **Features, Events, and Processes for the Total System Performance Assessment: Analyses**

Prepared for:  
U.S. Department of Energy  
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Prepared by:  
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Under Contract Number:  
DE-AC04-94AL85000

**FEP: 1.1.03.01.0A**

**FEP NAME:**

Error in Waste Emplacement

**FEP DESCRIPTION:**

Deviations from the design and/or errors in waste emplacement could affect long-term performance of the repository. A specific example of such an error would be erroneously emplacing the waste packages in a saturated or wet zone of the repository. Errors of this type would impact repository performance by affecting waste package corrosion and radionuclide transport.

**SCREENING DECISION:**

Excluded – by regulation

**SCREENING JUSTIFICATION:**

Possible types of waste emplacement errors are emplacement of packages closer to each other than in the design specification, and emplacement of a package so that it straddles a known Quaternary fault with potential for significant displacement. The emplacement of waste packages in a wet zone (i.e., zones of potential seepage) is not an erroneous emplacement, and is expected, and is included in the TSPA (see included FEP 2.1.08.01.0A (Water Influx at the Repository)). Saturated conditions are not expected in the repository (see excluded FEP 2.1.08.09.0A (Saturated Flow in the EBS)).

Inherent in the approach to FEP evaluation is the expectation that the repository be constructed, operated, and closed according to the design used as the basis for FEP screening and in accordance with NRC license requirements. Repository construction, operation, and closure will be subject to a quality assurance program and quality control procedures that will evaluate and disposition any deviations from the design. Of particular relevance, control procedures imposed during the repository operation phase will aim to ensure that any errors in waste emplacement are rectified before repository closure.

Inadequate quality controls on operational issues such as these are discussed in detail in excluded FEP 1.1.08.00.0A (Inadequate Quality Control and Deviations from Design), and are excluded from the performance assessments. As a result of the rigorous quality assurance/quality control requirements governing emplacement of waste packages and inspection and approval of such emplacement, errors in emplacement location resulting in waste packages being placed substantially closer to each other than specified by design, or being placed on a known fault, are not expected. The regulatory requirements for performance confirmation and quality assurance require that any deviation from design be evaluated for potential impact, and that significant deviations which are detected during the operational period be corrected. Erroneous emplacement of waste packages is not expected because of quality controls.

In summary, FEP 1.1.03.01.0A (Error in Waste Emplacement) is excluded from the performance assessments conducted to demonstrate compliance with proposed 10 CFR 63.311 and 63.321 (70 FR 53313 [DIRS 178394]), and with 10 CFR 63.331 [DIRS 180319], on the basis of regulation.

**INPUTS:**

Table 1.1.03.01.0A-1. Direct Inputs

Input	Source	Description
10 CFR 63.2007. Energy: Disposal of High-Level Radioactive Wastes in a Geologic Repository at Yucca Mountain, Nevada. [DIRS 180319]	10 CFR 63.331	Separate standards for protection of groundwater
70 FR 53313. Implementation of a Dose Standard After 10,000 Years. [DIRS 178394]	10 CFR 63.321	Individual protection standard for human intrusion
	10 CFR 63.311	Individual protection standard after permanent closure

## **FEP: 1.1.08.00.0A**

### **FEP NAME:**

Inadequate Quality Control and Deviations from Design

### **FEP DESCRIPTION:**

This FEP addresses issues related to inadequate quality assurance and control procedures and inadequate testing during the design, construction, and operation of the repository. It also includes inadequacy in the manufacture of the waste forms, waste packages, and engineered features. Lack of quality control could result in a poorly designed repository, unmodeled design features, deviations from design, material defects, faulty waste package fabrication, and faulty or non-design standard construction. All of these may lead to reduction in the effectiveness of the engineered barriers.

### **SCREENING DECISION:**

Excluded – low consequence

### **SCREENING JUSTIFICATION:**

As described below, this FEP is excluded from the performance assessments on the basis of low consequence. Implementation of sound administrative and safety controls including a quality assurance program that meets the regulatory requirements of 10 CFR 63.142 [DIRS 180319] provides the foundation for demonstrating that unanalyzed defects in quality control or deviations from design will not have a significant adverse impact on postclosure performance of the repository.

Inherent in the FEPs evaluation approach is the expectation that the repository will be constructed, operated, and closed according to the design used as the basis for the FEP screening and in accordance with NRC license requirements. The postclosure-relevant aspects of the repository design are consistent with included FEP 1.1.07.00.0A (Repository Design). The inclusion of the repository design is accomplished through analyses of individual FEPs that are either excluded or included based on that design. The structures, systems, and components of the repository design that are relevant to the features of the natural barriers and the EBS used in performance assessment are identified in *Postclosure Modeling and Analyses Design Parameters* (BSC 2008 [DIRS 183627]); *Total System Performance Assessment Data Input Package for Requirements Analysis for Transportation Aging and Disposal Canister and Related Waste Package Overpack Physical Attributes Basis for Performance Assessment* (SNL 2007 [DIRS 179394]); *Total System Performance Assessment Data Input Package for Requirements Analysis for DOE SNF/HLW and Naval SNF Waste Package Physical Attributes Basis for Performance Assessment* (SNL 2007 [DIRS 179567]); *Total System Performance Assessment Data Input Package for Requirements Analysis for Engineered Barrier System In-Drift Configuration* (SNL 2007 [DIRS 179354]); and *Total System Performance Assessment Data Input Package for Requirements Analysis for Subsurface Facilities* (SNL 2007 [DIRS 179466]).

If there are significant deviations from the design that result from inadequate quality control, it is possible to affect the analyzed conditions. In recognition of this, regulations establish requirements for the management systems for the construction and operation of the repository to include administrative and procedural safety controls as well as design verification, testing, and performance confirmation. The establishment of adequate administrative and procedural safety controls ensure construction and operations are within analyzed conditions of the postclosure safety analysis and TSPA or that any deviations are analyzed for significance. This is consistent with the approach used to establish bounds for the performance evaluation of any engineering project. It is also necessary because the determination of the degree of the deviation (due to the potential inadequacy of the quality assurance, quality control, or testing) cannot always be evaluated a priori and must ultimately be based on specific deviations on a case-by-case basis.

*Adequate Quality Assurance and Quality Control Procedures*

The DOE Quality Assurance Program is established by regulation. As specified by 10 CFR 63.142 [DIRS 180319], "Quality assurance criteria:"

*(a) Introduction and Applicability.*

DOE is required by § 63.21(c)(20) to include in its safety analysis report a description of the quality assurance program to be applied to all structures, systems, and components important to safety, to design and characterization of barriers important to waste isolation, and to related activities. These activities include: site characterization; acquisition, control, and analyses of samples and data; tests and experiments; scientific studies; facility and equipment design and construction; facility operation; performance confirmation; permanent closure; and decontamination and dismantling of surface facilities.

Of particular relevance is the fact that 10 CFR Part 63 [DIRS 180319] requires the DOE to implement a layered quality assurance program for DOE, major contractor, and vendor activities similar to those for the 10 CFR Part 50 [DIRS 181964] power reactor and utilization facility environment. These programs provide a layered, defense-in-depth approach to activities (control of design, materials, shipping, handling, storage, fabrication, construction, installation, inspection, testing, operations, maintenance, oversight, identification and correction of nonconformances and conditions adverse to quality, etc.) for the applicant/licensee; engineering, procurement, and construction contractors; and vendors of equipment, materials, and services. In regulating other activities and facilities, the NRC has found that these programs are sufficiently self critical and self correcting to permit a conclusion that their implementation provides a reasonable assurance of safety. Since the 10 CFR Part 63 [DIRS 180319] quality assurance requirements are drawn from those established for reactors in 10 CFR Part 50 [DIRS 181964], repository safety analyses place the same reliance on the effectiveness of the quality assurance program as is done in the case of reactors.

In addition, provisions exist to evaluate the acceptability of and uncertainty in data that were not produced in accordance with the quality assurance program. These provisions require DOE to evaluate data required to support its license application. If data related to structures, systems, and components important to safety, to design and characterization of barriers important to waste isolation, and to activities related, thereto, have not been collected in accordance with a quality

assurance program that meets these requirements, the DOE is required to show that such data have been qualified for their intended use. The NRC recognizes that some data supporting a license application for a high-level waste repository may not have been initially collected under the quality assurance program. NUREG-1298 (Altman et al. 1988 [DIRS 103750], *Qualification of Existing Data for High-Level Nuclear Waste Repositories*, provides guidance on the use and qualification of data not initially collected in accordance with the quality assurance program. This guidance has been incorporated into the quality assurance program.

*Adequate Testing During Design, Construction, and Operation of the Repository*

Adequate testing requirements are also established by regulation. 10 CFR 63.74 establishes testing requirements during design, construction, and operation of the repository. In particular:

(a) DOE shall perform, or permit the Commission to perform, those tests the Commission considers appropriate or necessary for the administration of the regulations in this part. This may include tests of—

- (1) Radioactive waste,
- (2) The geologic repository, including portions of the geologic setting and the structures, systems, and components constructed or placed therein,
- (3) Radiation detection and monitoring instruments, and
- (4) Other equipment and devices used in connection with the receipt, handling, or storage of radioactive waste.

(b) The tests required under this section must include a performance confirmation program carried out in accordance with subpart F of this part.

The performance confirmation program is being conducted to evaluate the adequacy of assumptions, data, and analyses that form the bases of the postclosure performance assessment. Key geotechnical and design parameters, including any interactions between natural and engineered systems and components, will be monitored throughout site characterization, construction, emplacement, and operation to identify any significant changes in the conditions assumed in the license application that may affect compliance with the performance objectives specified in 10 CFR 63.113(b) and (c) [DIRS 180319].

*Adequacy in the manufacture and testing of waste forms, waste packages, and engineered features.*

As noted, the quality assurance program is required to be applied to design and characterization of barriers important to waste isolation, and to related activities; this includes the manufacture and testing of waste forms, waste packages, and engineered features. The performance confirmation program specifies requirements for the testing and monitoring waste forms, waste packages, and engineered features in 10 CFR 63.133 and 10 CFR 63.134 [DIRS 180319]. These requirements include:

10 CFR 63.133, Design testing.

(a) During the early or developmental stages of construction, a program for testing of engineered systems and components used in the design, such as, for



example, borehole and shaft seals, backfill, and drip shields, as well as the thermal interaction effects of the waste packages, backfill, drip shields, rock, and unsaturated zone and saturated zone water, must be conducted.

and

10 CFR 63.134, Monitoring and testing waste packages.

(a) A program must be established at the geologic repository operations area for monitoring the condition of the waste packages. Waste packages chosen for the program must be representative of those to be emplaced in the underground facility.

(b) Consistent with safe operation at the geologic repository operations area, the environment of the waste packages selected for the waste package monitoring program must be representative of the environment in which the wastes are to be emplaced.

(c) The waste package monitoring program must include laboratory experiments that focus on the internal condition of the waste packages. To the extent practical, the environment experienced by the emplaced waste packages within the underground facility during the waste package monitoring program must be duplicated in the laboratory experiments.

*Errors in the manufacture and fabrication of waste packages.*

The treatment of waste-package failure as a result of errors (which remain undetected) due to inadequacy in their manufacture and fabrication are addressed in included FEP 2.1.03.08.0A (Early Failure of Waste Packages). Several general types of manufacturing defects are considered as mechanisms that could possibly adversely affect waste package performance, and include weld flaws, improper weld material, improper base metal, improper heat treatment, improper low plasticity burnishing, improper weld-flux material, poor weld-joint design, surface contamination, mislocated welds, missing welds, handling or installation damage, and administrative or operational error (SNL 2007 [DIRS 178765]). These defects are considered in the development of the early waste package failure event probabilities.

The closure lid welding process could also induce stresses in the waste package outer barrier lid, which could contribute to stress corrosion cracking of the waste packages. Induced stresses from the final closure weld process are addressed in included FEP 2.1.03.02.0A (Stress Corrosion Cracking of Waste Packages). This FEP accounts not only for stresses induced by welding the lid, but also lid weld flaws. Therefore, lid weld stresses and lid weld flaws that contributed to stress corrosion cracking of the waste packages are directly accounted for in the performance assessments.

*Errors in the manufacture and fabrication of waste forms and waste package internals.*

The radionuclides in the waste form are generally of a form that are highly insoluble to water and are not expected to mobilize, except for a limited number of radionuclides, thus significantly

reducing the radionuclide release rate. Control parameters related to the waste form capabilities are waste form moisture removal and inerting, loading of waste forms, and handling of waste forms. Deviations from design with respect to loading waste packages is addressed in excluded FEP 2.1.14.15.0A (In-Package Criticality (Intact Configuration)) Waste form manufacture and fabrication errors related to the use of improper absorber materials or waste form misloads are addressed in the excluded criticality FEPs (see for example FEP 2.1.14.15.0A (In-Package Criticality (Intact configuration))). Excluded FEP 2.1.13.01.0A (Radiolysis) evaluates the effects of a design-specified quantity of water being left inside a waste package.

As indicated in included FEP 2.1.02.12.0A (Degradation of Cladding Prior to Disposal), cladding degradation prior to receipt at the repository can occur during reactor operation, spent fuel pool storage, dry storage, transport, and handling. The representation of all defense SNF cladding (with the exception of naval SNF cladding) and commercial SNF cladding in performance assessments assumes the cladding will be breached on emplacement in the repository and will inhibit neither groundwater contacting the fuel matrix nor the release of radionuclides after groundwater contact (SNL 2008 [DIRS 183478], Section 6.3.7.3.1). This representation bounds any errors that may have occurred during the manufacture, fabrication, and handling of cladding.

*Errors in the manufacture and fabrication of engineered features (drip shields)*

Evaluation of undetected errors during manufacture and installation of drip shields is addressed in included FEP 2.1.03.08.0B (Early Failure of Drip Shields). Such errors could lead to early failure of the drip shields. Several general types of manufacturing defects are considered as possible mechanisms that could adversely affect drip shield performance, including weld flaws, base metal flaws, improper weld material, improper base metal, improper heat treatment, improper low plasticity burnishing, improper weld-flux material, poor weld-joint design, surface contamination, mislocated welds, missing welds, handling or installation damage (including gaps between drip shields), and administrative or operational error.

*Deviations from design and non-standard construction.*

Deviations from design and non-standard construction are also addressed by regulatory requirements linked to testing and quality assurance. For example, 10 CFR 63.132 [DIRS 180319], "Confirmation of geotechnical and design parameters" requires:

- (a) During repository construction and operation, a continuing program of surveillance, measurement, testing, and geologic mapping must be conducted to ensure that geotechnical and design parameters are confirmed and to ensure that appropriate action is taken to inform the Commission of design changes needed to accommodate actual field conditions encountered.
- (b) Subsurface conditions must be monitored and evaluated against design assumptions.
- (c) Specific geotechnical and design parameters to be measured or observed, including any interactions between natural and engineered systems and components, must be identified in the performance confirmation plan.

(d) These measurements and observations must be compared with the original design bases and assumptions. If significant differences exist between the measurements and observations and the original design bases and assumptions, the need for modifications to the design or in construction methods must be determined and these differences, their significance to repository performance, and the recommended changes reported to the Commission.

(e) In situ monitoring of the thermomechanical response of the underground facility must be conducted until permanent closure, to ensure that the performance of the geologic and engineering features is within design limits.

In 10 CFR 63.73(a) [DIRS 180319], the NRC requires prompt notification if there is a significant deficiency found in: (1) the characteristics of the Yucca Mountain site, or (2) the design and construction of the geologic repository area, including significant deviations from the design criteria and design bases stated in the application. Significant deviations that are detected during the operational period will be evaluated and, as needed, corrected. Any residual defects or fabrication or construction deficiencies, therefore, will be of a minor nature and will not lead to significant effects on repository performance. Compliance with the requirements described will ensure that significant effects from undetected deviations in design are not expected.

Modifications and deviations from the design are subject to regulatory requirements and review that address deliberate changes and modifications. The manner in which the DOE must address changes, and by which the NRC is informed of the changes, is codified in 10 CFR 63.44 [DIRS 180319]. After the NRC authorizes construction of the repository, changes to the repository design or procedures as described in the SAR will be subject to the requirements of 10 CFR 63.44 [DIRS 180319], "Changes, tests, and experiments," as well as any specific license conditions imposed in accordance with 10 CFR 63.32 [DIRS 180319], "Conditions of construction authorization;" 10 CFR 63.42 [DIRS 180319], "Conditions of license;" or 10 CFR 63.43 [DIRS 180319], "License specification."

The DOE process for controlling changes under 10 CFR 63.44 [DIRS 180319] is subject to the DOE Quality Assurance Program, in accordance with the guidance in NUREG-1804 (NRC 2003 [DIRS 163274], Section 2.5.1.3, Acceptance Criteria 2(7), 2(10), and 3(21)).

The DOE Quality Assurance Program includes the following provisions for controlling design changes (DOE 2007 [DIRS 182051], Section 3.2.6):

- A. Changes to final designs, field changes, and nonconforming items dispositioned "use-as-is" or "repair" shall be justified and shall be subject to design control measures commensurate with those applied to the original design.
- B. Changes shall be approved by the same affected groups or organizations that approved the original design documents.
  - 1. If an organization that originally was responsible for approving a particular design document is no longer responsible, a new responsible organization shall be designated by the OCRWM.

- 2.<sup>1</sup> The designated approving organization shall have demonstrated competence in the specific design area of interest and have an adequate understanding of the requirements and intent of the original design.
- C. The design process and design verification methods and implementing documents shall be reviewed and modified, as necessary, when a significant design change is necessary because of an incorrect design.
- D. Errors and deficiencies in approved design documents, including design methods (i.e., computer software supporting a safety or waste isolation function), that could adversely affect [structures, systems, and components] important to safety or waste isolation shall be documented and action taken to ensure all errors and deficiencies are corrected.
- E. Deviations from specified quality standards shall be identified and formally documented. Procedures shall be established to ensure control of these deviations.
- F. Measures shall be provided to ensure personnel are notified of design changes/modifications that may affect the performance of their duties.
- G. Prior to the issuance of a design change initiated after the construction authorization, the design changes shall be evaluated pursuant to applicable regulatory requirements.

The potential impacts of excavation and construction are considered in excluded FEPs 1.1.02.03.0A (Undesirable Materials Left), 1.1.03.01.0A (Error in Waste Emplacement), 1.1.12.01.0A (Accidents and Unplanned Events during Construction and Operation), 1.1.02.00.0A (Chemical Effects of Excavation and Construction in EBS), 2.2.01.01.0B (Chemical Effects of Excavation and Construction in the Near Field), and 1.1.02.00.0B (Mechanical Effects of Excavation and Construction in EBS). Excluded FEP 2.1.06.01.0A (Chemical Effects of Rock Reinforcement and Cementitious Materials in EBS) considers the effects of cement dust that may blow into emplacement drifts. Improper placement of drip shields is addressed in included FEP 2.1.03.08.0B (Early Failure of Drip Shields). Potential effects from residual organics are considered in excluded FEP 2.1.10.01.0A (Microbial Activity in the EBS). To limit undesired effects from excavation and construction (e.g., corrosion and radionuclide transport impacts), requirements have been established to identify, analyze, and control the use of any materials (including water) that will be present in the repository at closure and could adversely impact postclosure performance. The application of these controls is described in *Total System Performance Assessment Data Input Package for Requirements Analysis for Engineered Barrier System In-Drift Configuration* (SNL 2007 [DIRS 179354], Table 4-1, Parameter Number 02-03).

The provided examples are not exhaustive because the deviation and the degree of deviation (due to the potential inadequacy of the quality assurance, quality control, or testing) cannot always be evaluated a priori and must be evaluated on a case-by-case basis. The DOE approach to demonstrating waste isolation includes a repository system that relies on multiple barriers, the use of multiple lines of evidence related to system performance, and a continuous learning approach to repository design and construction. The subsurface facilities are planned to be

constructed in phases. The development of the subsurface facility will proceed while emplacement operations are conducted in the completed drifts and will be done in a manner that safely accommodates waste package emplacement. Phased construction and operation provides an opportunity for orderly implementation of lessons learned and incorporation of new information that would improve the safety of construction and operations. The repository will implement a management system that includes the evaluation of changes, tests, and experiments. Lessons learned and new information will be evaluated against the criteria in 10 CFR 63.44 [DIRS 180319], and the lessons learned or new information will be implemented following construction authorization or license amendment if any of the criteria are met; otherwise, the proposed changes will be implemented and documented in updates to the SAR. This is consistent with the National Research Council's description of staged development that allows for proposed adaptation without unacceptable impacts on safety or waste isolation (National Research Council 1995 [DIRS 100018], Chapter 3), incorporation of new knowledge on features and processes that determine repository performance, and accommodation of significant changes in repository requirements.

Finally, 10 CFR 63.51 [DIRS 180319] requires the DOE to submit an application to amend the license before permanent closure of a geologic repository. The submission must include an update of the assessment of the performance of the geologic repository for the period after permanent closure. The updated assessment must include any performance confirmation data collected under the program required by Subpart F, and pertinent to compliance with 10 CFR 63.113 [DIRS 180319]. This ensures that effectiveness of the engineered barriers are evaluated with respect to any significant deviations from design during construction and operation of the repository.

In summary, FEP 1.1.08.00.0A (Inadequate Quality Control and Deviations from Design) is excluded from the performance assessments conducted to demonstrate compliance with proposed 10 CFR 63.311 and 63.321 (70 FR 53313 [DIRS 178394]), and with 10 CFR 63.331 [DIRS 180319], on the basis of low consequence. In addition, the regulatory requirements for performance confirmation and quality assurance require that any deviation from design during the operational period be evaluated for potential impact, and that deviations with a significant adverse impact on postclosure performance be corrected.

#### INPUTS:

Table 1.1.08.00.0A-1. Direct Inputs

Input	Source	Description
10 CFR 63. 2007. Energy: Disposal of High-Level Radioactive Wastes in a Geologic Repository at Yucca Mountain, Nevada [DIRS 180319]	10 CFR 63.51	Requires the DOE to submit an application to amend the license before permanent closure of a geologic repository
	10 CFR 63.43	After the NRC authorizes construction of the repository, changes to the repository design or procedures as described in the SAR will be subject to license specification

Table 1.1.08.00.0A-1. Direct Inputs (Continued)

Input	Source	Description
10 CFR 63. 2007. Energy: Disposal of High-Level Radioactive Wastes in a Geologic Repository at Yucca Mountain, Nevada [DIRS 180319] (continued)	10 CFR 63.42	After the NRC authorizes construction of the repository, changes to the repository design or procedures as described in the SAR will be subject to conditions of license
	10 CFR 63.32	After the NRC authorizes construction of the repository, changes to the repository design or procedures as described in the SAR will be subject to conditions of construction authorization
	10 CFR 63.132	Requirements of geotechnical and design parameters
	10 CFR 63.133 and 10 CFR 63.134	Performance confirmation program specifies requirements for the testing and monitoring waste forms, waste packages, and engineered features
	10 CFR 63.113(b) and (c)	Performance objectives
	10 CFR 63.142	Quality assurance criteria
	10 CFR 63.142	Foundation for demonstrating that unanalyzed defects in quality control or deviations from design will not have a significant adverse impact on postclosure performance of the repository
	10 CFR 63.331	Separate standards for protection of groundwater
	10 CFR 63 Subpart G	Requires quality assurance and quality control programs be applied to all systems, structures, and components important to safety
	10 CFR Part 63	Provides a list of requirements that have been incorporated into the performance confirmation program to provide data related to encountered subsurface conditions, functioning of the natural and engineered systems, monitoring and testing
	10 CFR 63.73(a)	NRC requires prompt notification if there is a significant deficiency found in (1) the characteristics of the Yucca Mountain site, or (2) the design and construction of the geologic repository area, including significant deviations from the design criteria
	10 CFR 63.44	List the manner in which the DOE must address changes, and by which the NRC is informed of the changes

Table 1.1.08.00.0A-2. Indirect Inputs

Citation	Title	DIRS
10 CFR 50	Energy: Domestic Licensing of Production and Utilization Facilities. Internet Accessible	181964
10 CFR 63	Energy: Disposal of High-Level Radioactive Wastes in a Geologic Repository at Yucca Mountain, Nevada	180319
70 FR 53313	Implementation of a Dose Standard After 10,000 Years	178394
Altman et al. 1988	<i>Qualification of Existing Data for High-Level Nuclear Waste Repositories: Generic Technical Position</i> . NUREG-1298.	103750
DOE 2007	<i>Quality Assurance Requirements and Description</i>	182051
National Research Council 1995	<i>Technical Bases for Yucca Mountain Standards</i>	100018
SNL 2007	<i>Total System Performance Assessment Data Input Package for Requirements Analysis for EBS In-Drift Configuration</i>	179354
SNL 2007	<i>Analysis of Mechanisms for Early Waste Package/Drip Shield Failure</i>	178765
SNL 2007	<i>Total System Performance Assessment Data Input Package for Requirements Analysis for DOE SNF/HLW and Navy SNF Waste Package Overpack Physical Attributes Basis for Performance Assessment</i>	179567
SNL 2007	<i>Total System Performance Assessment Data Input Package for Requirements Analysis for Subsurface Facilities</i>	179466
SNL 2007	<i>Total System Performance Assessment Data Input Package for Requirements Analysis for TAD Canister and Related Waste Package Overpack Physical Attributes Basis for Performance Assessment</i>	179394
SNL 2008	<i>Total System Performance Assessment Model/Analysis for the License Application</i>	183478

**UNITED STATES OF AMERICA  
NUCLEAR REGULATORY COMMISSION**

**Atomic Safety and Licensing Board**

<b>In the Matter of</b>	)	
	)	
<b>U.S. DEPARTMENT OF ENERGY</b>	)	<b>Docket No. 63-001-HLW</b>
	)	
<b>(High Level Waste Repository)</b>	)	

**CERTIFICATE OF SERVICE**

I hereby certify that the foregoing *State of Nevada's Separate Comments Regarding the Impact of LBP-10-22 on NEV-SAFETY-130, 149, 161, and 162* has been served upon the following persons by the Electronic Information Exchange:

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