



Department of Energy
Office of Civilian Radioactive Waste Management
Yucca Mountain Site Characterization Office
P.O. Box 98608
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OCT 25 1995

Overnight Mail

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Office of Nuclear Material Safety
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U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

TITLE 10 CODE OF FEDERAL REGULATIONS (CFR) PART 60 REQUIREMENTS,
FLOWDOWN REGULATORY COMPLIANCE REVIEW REPORT FOR THE EXPLORATORY
STUDIES FACILITY (ESF) (SCPB: N/A)

References: (1) Ltr, Dreyfus to Bernero, dtd 3/14/95
(2) Ltr, Dreyfus to Paperiello, dtd 8/3/95

In the referenced letters, we provided you with reports documenting our evaluation of the allocation and traceability of the 10 CFR Part 60 requirements applicable to ESF Design Package 2C. Although our evaluations showed the design process to be effective, the process to demonstrate 10 CFR Part 60 requirements flowdown proved cumbersome. In our March 14, 1995, letter, we noted that we had initiated improvements in our design process to enhance our ability to demonstrate compliance and committed to assessing what additional actions might be appropriate. This letter fulfills the commitment made in our August 3, 1995, letter to provide you with a description of any such design process changes made as a result of this assessment, and it completes our responses to the U.S. Nuclear Regulatory Commission letter dated October 13, 1994, regarding "Concerns with Quality Assurance Program."

On the basis of our evaluation, we determined that the two design process improvements noted in our letter of March 14, 1995, are sufficient to provide assurance of effective implementation of and compliance with 10 CFR Part 60 requirements in the design process. These improvements were:

1. Change to Quality Assurance Procedure (QAP)-3-9, Design Analysis (effective February 5, 1995).

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WM-11 PDR

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A new section is required for each design analysis performed under QAP-3-9. In this section, the designer is required to identify specific requirements from the applicable requirements document, such as the ESF Design Requirements Document (ESFDR), and then to identify the design criteria developed in the analysis to satisfy these requirements. These design criteria are then used to develop design specifications and drawings. This improvement provides a mechanism to assure that 10 CFR Part 60 requirements, as traced through our document hierarchy, are implemented into the design of the repository, waste package, and ESF. This change to the design process has been implemented for design analyses originated or revised since the February 5, 1995, revision to QAP-3-9.

2. Modifications to the structure and content of design requirements documents.

Ongoing improvements to these documents (e.g., the ESFDR, Repository Design Requirements Document, and Engineered Barrier Design Requirements Document) will make design requirements derived from 10 CFR Part 60 apparent to the reader. Numerous redundant or unnecessary requirements will be eliminated. While changes are being made to some of the requirements documents to make them better serve the user, the document hierarchy and its purpose have not been changed.

In summary, requirements that are traced through the document hierarchy and into the design analysis are considered to be implemented in the design by inclusion within the design analysis. The design process requires that the requirements be cited and addressed in the analysis. Other design documents, including drawings and specifications, are based on the results of the analyses, but are not required to contain specific references to the requirements that are inputs to the analysis. The design specification/drawing input sheets provide a listing of analyses used.

Some 10 CFR Part 60 requirements that do not apply to the design solutions, such as 10 CFR Part 60.21(c)(ii)(D) and others, will require studies to be performed to evaluate alternatives. The results of such studies will provide documentation in the potential license application that the applicable 10 CFR Part 60 requirements have been addressed.

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In addition, we want to bring to your attention that we are currently in the process of scheduling a Quality Assurance Surveillance of the complete requirements flowdown process. This activity will be the most recent of a number of surveillances we have done in this area; we will keep the U.S. Nuclear Regulatory Commission Onsite Representatives apprised of the schedule and results of this activity.

In conclusion, we have changed our design control process to provide DOE with the ability to more easily demonstrate 10 CFR Part 60 requirements flowdown.

If you have any questions, please contact April V. Gil at (702) 794-7622.



Stephan J. Brocoum
Assistant Manager for
Suitability and Licensing

AMSL:AVG-4675

Enclosure:
Description of Commitment/
Action

OCT 25 1995

cc w/encl:

L. H. Barrett, HQ (RW-2) FORS
R. A. Milner, HQ (RW-30) FORS
A. B. Brownstein, HQ (RW-36) FORS
C. E. Einberg, HQ (RW-36) FORS
P. A. Bunton, HQ (RW-36) FORS
Samuel Rousso, HQ (RW-40) FORS
M. S. Delligatti, NRC, Washington, DC
W. D. Barnard, NWTRB, Arlington, VA
R. R. Loux, State of Nevada, Carson City, NV
Robert Price, State of Nevada, Carson City, NV
Cyril Schank, Churchill County, Fallon, NV
D. A. Bechtel, Clark County, Las Vegas, NV
J. D. Hoffman, Esmeralda County, Goldfield, NV
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Elwood Lowery, Nevada Indian Environmental Coalition,
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ENCLOSURE 1

Description of commitment -

Letter, Dreyfus to Paperiello, dated 8/3/95

"In our March 14, 1995, letter, we also committed to assess our design process to identify actions which would improve our ability to independently evaluate design products for compliance with 10 Code of Federal Regulations Part 60. We are evaluating our design process and will provide a description of any design process changes to you by late September 1995."

Description of fulfillment action(s) -

"This letter fulfills the commitment made in our August 3, 1995, letter to provide you with a description of any such design process changes made as a result of this assessment."