



Department of Energy

Washington, DC 20585

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Mr. Joseph J. Holonich, Director
Repository Licensing and Quality Assurance
Project Directorate
Division of High-Level Waste Management
Office of Nuclear Material Safety
and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Mr. Holonich:

As discussed during the U.S. Nuclear Regulatory Commission/U.S. Department of Energy (NRC/DOE) Management meeting on February 6, 1992, and again at the Technical Exchange on the Erosion Topical Report on May 27, 1992, the NRC staff requested that DOE provide a statement of the purpose and scope of topical reports. Clarification of the use of the topical reports and their relationship to the DOE issue resolution process is provided below.

Issue resolution is the process of interactions or negotiations between the DOE and the NRC staff regarding technical or programmatic concerns involving the implementation of regulatory requirements. Resolution during the pre-licensing phase is only a mutual understanding between the DOE and NRC staffs on an issue. Legal closure does not occur until the license is issued.

Topical reports are one of the many ways by which the DOE can present its position or conclusions on specific regulatory or technical issues to the NRC staff for early review and for purposes of resolution. This is consistent with the intent of the topical report program the NRC has had in place for years for the reactor industry (see NUREG-0390).

Topical reports can serve several purposes: (1) in cases where enough data are available, the report can document how DOE has demonstrated compliance with some portion of the regulations, (2) the report can document a methodology or approach the DOE plans to use in demonstrating compliance in the future, or (3) a combination of the two.

DOE views the use of topical reports in the issue resolution process, as follows.

- a. The DOE internally develops the scope of the issue in detail. This includes development of the scope of the topical report.

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- b. The DOE prepares an annotated outline of the topical report and compiles existing information and data to develop the technical basis for the position or conclusions. The annotated outline may be submitted to the NRC for informational purposes prior to the actual submittal of the topical report. Concurrently, an internal DOE preliminary draft report may be prepared.
- c. The DOE can meet with the NRC staff to discuss the technical basis for the position or conclusions to obtain some early feedback prior to finalizing the topical report.
- d. The DOE will prepare the topical report on the issue and submit it to the NRC staff for review.
- e. Following the NRC staff review of the topical report, NRC may provide comments to the DOE or accept the report. If comments are provided, a meeting may be held to discuss the comments and then the topical report would be revised, as needed, and resubmitted to the NRC staff.
- f. Once the NRC staff is satisfied with the DOE position in the topical report, it can accept the report, which could later be incorporated by reference in a license application. In the interim, the DOE will incorporate the accepted topical report in the annotated outline of the potential license application. Historically, the NRC staff has accepted topical reports in several ways, four of which are identified below.
 1. Safety Evaluation Report (SER) - This report has been used by the NRC staff in the past for documenting NRC's review and acceptance of topical reports in the reactor industry. After issuance of an SER, DOE will publish an approved version of the topical report which will include a copy of the staff evaluation transmittal letter and its enclosed evaluation report.
 2. NUREG - The NRC staff could incorporate the DOE topical report in a staff technical position, which would be issued as a NUREG document.
 3. Regulatory Guide - The topical report could also be incorporated in a regulatory guide.
 4. Rulemaking - If the DOE position or conclusions requires a change in the NRC regulations, a rulemaking could be initiated in accordance with 10 CFR Part 2.

In summary, DOE believes that the process outlined above is consistent with NRC's past practices regarding the review and acceptance of topical reports. NRC's acceptance of a DOE topical report will serve two purposes: 1) it will provide DOE with the regulatory perspective needed to guide and provide a better focus

for programmatic decisions regarding site characterization, and 2) it will provide a mechanism by which information can be incorporated by reference in a potential license application, consistent with the provisions in 10 CFR 60.23. We hope this letter provides the clarification you requested. If you have any questions, please contact Chris Einberg of my staff at (202) 586-8869.

Sincerely,



John P. Roberts
Acting Associate Director for
Systems and Compliance
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cc:

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