

FEB 28 1994

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Mr. Dwight E. Shelor, Associate Director
for Systems and Compliance
Office of Civilian Radioactive Waste Management
U. S. Department of Energy
1000 Independence Avenue, SW
Washington, DC 20585

Dear Mr. Shelor:

SUBJECT: TRANSMITTAL OF THE "TOPICAL REPORT REVIEW PLAN"

The purpose of this letter is to transmit the subject review plan for your information. This document outlines the procedure for the U.S. Nuclear Regulatory Commission staff's review of U.S. Department of Energy Topical Reports.

If you have any questions concerning this review plan, please contact Ms. Charlotte Abrams of my staff at (301) 504-3403.

Sincerely,

Joseph J. Holonich

Joseph J. Holonich, Director
Repository Licensing and Quality Assurance
Project Directorate
Division of High-Level Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure: As stated

cc: R. Loux, State of Nevada
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J. Meder, Nevada Legislative Counsel Bureau
R. Nelson, YMPO
M. Murphy, Nye County, NV
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DIVISION OF HIGH-LEVEL WASTE MANAGEMENT TOPICAL REPORT REVIEW PLAN

1.0 INTRODUCTION

Historically, the purpose of the Nuclear Regulatory Commission topical report program has been to provide a procedure whereby industrial organizations may submit reports on specific important-to-safety subjects to the NRC staff, and have them reviewed independently of any construction permit or operating license review. The benefits resulting from this program are a minimization of duplicative time and effort that applicants and the NRC staff spend on these subjects and efficiencies in NRC staff technical reviews. In the past, a report qualified as a topical report if it met all of the following criteria: (1) dealt with a subject requiring a safety assessment which could be reviewed independently of any specific license application (LA), such as, design, analytical models or techniques or performance testing of components or systems; (2) was capable of being referenced in multiple license applications; (3) contained complete and detailed information on the specific subject presented; and (4) completion of the report review would increase efficiency of the application review.

Although the principal focus of this program has been to increase efficiency by reducing duplicative time and effort on subjects repeated in multiple licensing actions, clear benefits can also be achieved from the use of topical reports in the high-level waste (HLW) program using a similar approach to that outlined above. Under this approach, the U.S. Department of Energy (DOE) can request the NRC staff to review one or more issues, separately and prior to submittal of DOE's LA for a HLW disposal facility, by submitting a topical report. HLW topical reports will focus on designs, methodologies, tests, techniques or analytical models under evaluation during the pre-licensing consultation phase as well as the application to a particular technical issue at a specific site. They can consist of a portion of the information required of an applicant under 10 CFR Part 60. If accepted by the NRC staff, topical reports may be incorporated by reference by DOE in the LA for a HLW disposal facility. In addition, it is expected that topical reports will be referenced in DOE's LA Annotated Outline (AO) for the evolution of the AO to the LA, and will serve as the basis for preparation of portions of the AO.

The NRC staff will review topical reports satisfying appropriate criteria discussed later, and determine if the DOE has acceptably addressed the subject of the topical such that the staff has no questions or disagreements at a particular time on the subject. In its review, the staff may find that the information presented by DOE demonstrates an acceptable method of meeting regulatory requirements. The staff will prepare a safety evaluation (SE) documenting the results of the review and the staff's acceptance of the topical report if the staff finds the topical acceptable for referencing in the LA. At that time, the staff would consider the matters presented in the topical report to be resolved at the staff level unless new information became available. DOE will then be able to reference this topical in its LA. However, acceptance of a topical report by the NRC staff is not a piecemeal

determination of whether DOE's LA complies with NRC requirements. Because the topical report would resolve issues pertaining to only a portion of the geologic repository system, the staff will need to ensure in the LA review that the resolution of issues continues to be acceptable in the context of the overall system. Therefore, the NRC staff will need to evaluate the use of the topical report in the LA when it determines if DOE has acceptably demonstrated compliance with 10 CFR Part 60. In addition, if new information becomes available, the staff may choose to conduct an additional review at any time. Furthermore, issuance of an SE shall not constitute a commitment to issue any authorization or license, or in any way affect the authority of the Commission, the Atomic Safety and Licensing Board, other presiding officers, or the Director, Office of Nuclear Material Safety and Safeguards in any proceeding under the Atomic Energy Act of 1954, as amended.

This review plan documents (1) the purpose of a topical report review, (2) the process for submittal of topical reports, (3) a general format that the NRC staff would expect the reports to take, and (4) the process the NRC staff will use to evaluate topical reports. It is intended for use by both DOE in the preparation of topical reports, and the NRC staff as guidance in its reviews.

2.0 PROCESS FOR SUBMITTAL OF TOPICAL REPORTS

2.1 Procedure for Submittal

When DOE is planning a report which it believes can qualify as a topical, it shall submit a proposed scope and description of content of the topical report (the annotated outline), which NRC and DOE can use as a basis to begin discussions. Within sixty days following submittal of the annotated outline of the topical report, the NRC staff will determine if it may be submitted as a topical report, and will inform DOE as well as all program participants of the results of this evaluation. When the report is completed, DOE will submit the topical report for evaluation to determine if it satisfies the qualification criteria for a topical report and is complete. If the report meets the criteria in Section 4.3, "Acceptance Review," the staff will then begin its review. The NRC staff may also identify the desirability for addressing a matter in a topical report. In such cases, the Project Director, HLPD, will contact DOE, (includes the standard notification of the State of Nevada and affected units of local government) to discuss the desirability of submitting the report. If DOE agrees, it will formally submit the report for review.

2.2 Report Identification

Each topical report should have a unique alphanumerical identification symbol for filing and reference purposes. These symbols can be specified at the discretion of DOE. Any report submitted by DOE containing commercial proprietary information shall include a "-P" after the identification symbol, and in accordance with 10 CFR 2.790 should be accompanied by an affidavit supporting DOE's claim for proprietary treatment. In addition, DOE should separately mark the paragraphs or information in the topical report containing proprietary data as well as all references listed in the report containing proprietary data. NRC expects that DOE would provide copies of proprietary

topical reports to affected states, local governments, and Indian tribes consistent with any agreements for protecting the information developed between DOE and those participants.

Each non-proprietary version of proprietary reports shall have the same identification symbol as the corresponding proprietary report except that it shall include an "-NP" following the identification symbol. NRC accepted versions of topical reports shall include an "-A" following the identification symbol ("-P-A" for proprietary versions). All reports or documents containing responses to NRC comments or NRC requests for additional information regarding a specific topical report shall be identified by the symbol for that report followed by Amendment XX where XX is a sequential amendment number beginning with 1 for the first amendment.

2.3 Revisions to Reports

If DOE determines that a revision is needed to a topical report after it has been found acceptable for review by the NRC, the proposed revision will be submitted to the staff for review in accordance with the same requirements and procedures as apply to new reports. The revision will have the same identification as the base report with the addition of the suffix "Revision 1," etc. The revised report must contain a note on the cover page stating that it supersedes and replaces all earlier versions of the numbered report.

2.4 Correspondence

All correspondence regarding topical reports shall be to and from the Project Director, Repository Licensing and Quality Assurance Project Directorate (HLPD) and the DOE Associate Director for Systems and Compliance consistent with the "Agreement between the U.S. Department of Energy Office of Civilian Radioactive Waste Management and the Nuclear Regulatory Commission Division of High-Level Waste Management During Site Characterization Programs and Prior to the Submittal of an Application for Authorization to Construct a Repository," (The Site Specific Agreement) ratified May 20, 1993.

3.0 CONTENTS OF REPORT

3.1 Abstract

The report shall include an abstract, not to exceed one page in length, which summarizes the contents of the report and the conclusions reached.

3.2 Introduction

The report shall have an introductory section which states the purpose of the report and clearly defines its scope, including restrictions or limitations on the use of the report or its results or conclusions, and applicability.

3.3 Body of the Report

The body of the report will be organized according to the discretion of DOE to suit its needs and the subject matter of the report. It is recommended that long tabulations of data such as site characterization results, computer program descriptions, detailed technical analyses or derivations and the like be included as appendices when they are not information supporting statements or conclusions and are not, in themselves, the subject of the report.

3.4 References

The report shall include a listing of all pertinent references. DOE will furnish the following references upon request:

1. Contractor and participant reports such as Open-File Reports, Sandia reports, Los Alamos reports, etc.
2. Reports published in foreign national journals and books.
3. State publications.
4. Symposium, meeting, and workshop abstracts and papers.
5. Commercial and trade contract report.
6. Academic theses and dissertations.
7. Participant management plans, QA plans, etc.
8. Computer code manuals.
9. Draft, unpublished, or "letter" reports and documents (personal and oral communications are not acceptable references unless documented in letter reports).
10. Manuscripts of "in press" works (manuscripts "in review" or "in preparation" are not acceptable references).
11. Monograph reports and handbooks from Federal agencies (e.g., local USDA soil reports).

3.5 Subject Matter

Diverse or unrelated subjects shall be addressed in separate topical reports to the extent practical rather than combined in one report.

4.0 STAFF REVIEW

4.1 Purpose of Review

Through its reviews, the staff will provide guidance to DOE on what concerns it has with the information submitted and what is needed to resolve concerns. The function of the NRC staff is to review, comment, and determine if the report is acceptable for referencing in the LA including whether DOE has demonstrated an acceptable method to meet regulatory requirements. If the staff has no questions or disagreements regarding DOE's resolution of an issue presented in the topical report, then the staff will so state and consider that issue resolved at the staff level unless new information becomes available. In addition, the staff would ensure in the LA review that the resolution of the issue continues to be acceptable in the context of the overall repository system.

Because the repository is a first-of-a-kind facility, there are several potential limitations on the staff's review. System interfaces are not yet fully defined and the understanding of the site, methodologies, and technologies is still evolving; therefore, important-to-safety or important-to-waste-isolation issues may need to be evaluated in the context of performance of the overall system. This circumstance could constrain the number of issues which can be accepted in the topical report program until integrated evaluations are complete. Therefore, the burden will rest with DOE, as the proponent of the topical report, to demonstrate that the issue presented is appropriate for resolution in a topical report.

4.2 Scoping Review

When DOE is planning a report which it believes can qualify as a topical, it should submit from the DOE Associate Director for Systems and Compliance to the NRC Project Director an annotated outline of the topical well in advance of the planned submittal. The NRC staff will review the annotated outline and, within 60 days of the submittal, will apprise DOE as to whether or not the subject qualifies as a topical report. If needed, a meeting between the NRC staff, DOE and all affected parties may be held to further discuss the annotated outline.

4.3 Acceptance Review

Before the staff will begin its review of any topical report, it will first conduct an evaluation to determine if the report satisfies the qualification criteria for a topical report and is complete. In conducting its review, the staff will evaluate whether the information provided in the topical report acceptably addresses all of the following four criteria:

1. The report deals with a specific important-to-safety or important-to-waste-isolation subject that requires a safety assessment by the NRC staff, such as a design, methodology, test, technique or analytical model, as well as the application to a particular technical issue at a specific site which can be evaluated independent of a LA.

2. The subject of the report is under evaluation during the pre-licensing phase of the program and could be referenced in DOE's LA for the HLW repository.
3. The report contains complete and detailed information on the specific subject presented.
4. NRC's acceptance of the report will result in increased efficiency of the review process for the HLW repository application.

Once the review is complete, the Project Director, HLPD shall notify the DOE Assistant Director for Systems and Compliance via letter whether the NRC will accept the report for review as a topical. This will be not more than 30 days after the submittal of the report.

4.4 Technical Review

4.4.1. Evaluation

The focus of the review will be on whether the design, methodologies, tests, techniques, or analytical models under evaluation, or the application to a particular technical issue at a specific site, which are the subject of the report, are acceptable for referencing in a LA and can be used to demonstrate compliance with 10 CFR Part 60. However, the acceptance of a topical report by the NRC staff is not a piecemeal determination of whether DOE's LA complies with NRC requirements. DOE will still need to demonstrate in the LA that its use of the topical report acceptably demonstrates the requirements of 10 CFR Part 60 have been met. In addition, the staff will identify concerns, so that they can be addressed in a timely manner, such that its ability to complete the review of the topical report and prepare a SE will not be impacted.

4.4.2 Key Technical Uncertainties

In conducting the technical evaluation, each reviewer should identify any existing key technical uncertainties (KTUs) associated with the topical report, and ensure that these are taken into account during the review. To accomplish this, the reviewer should look at the current list of KTUs given in Appendix E of the draft License Application Review Plan (LARP), and determine which, if any, are related to the report. If the staffs review results in concerns with how DOE is addressing the KTUs, these should be documented as open items or should be the basis for developing limitations on the use of the report. KTUs, which are identified by the NRC staff in its development of the draft LARP, are technical uncertainties which pose a high risk of noncompliance with a performance objective of 10 CFR Part 60. They may also be associated with reducing a high risk of noncompliance with a performance objective.

In addition to ensuring that KTUs are considered in the evaluation, the reviewer may also identify potential KTUs as a result of the review of a topical report. If this is the case, the reviewer should contact the Project Manager for LARP development so the potential KTU can be properly analyzed by the LARP team using the Center for Nuclear Waste Regulatory Analyses (CNWRA)

procedure "TOP-001-11: Development of Compliance Determination Strategies." After approval by management, the KTU is subsequently incorporated into the Compliance Determination Strategy associated with the appropriate LARP section that deals with the subject area.

4.4.3 Requests for Additional Information

During the course of its review, the staff may find that the information contained in the topical report is incomplete or that additional information is needed to draw a conclusion. In this case, the staff will prepare a request for additional information. Any request will originate from the appropriate technical Branch Chief, and be transmitted to the Project Director, HLPD. The format for these requests shall be consistent with the standard description of open items (objections, comments, questions) in the Site Characterization Plan Review Plan.

Once HLPD has reviewed the questions to ensure consistency with the requirements of the scope of the review discussed above, it will transmit them to DOE by letter with copies to Affected State, Local Government, and Indian Tribe representatives. Requests for additional information can also be provided at a meeting, but must be included as attachments to the minutes and identified in the transmittal letter. In order to support the established milestones and corresponding review time contained in the appendix, the staff will request that the responses be provided within 60 days of the date of the transmittal letter.

The staff will request that DOE's responses to requests for additional information should be submitted as amendments to the original report. Interactions with DOE to discuss the contents of a topical report or its answers to requests for additional information will be scheduled by HLPD in consultation with the technical review branches. Information provided by DOE, at an interaction, should be included in the accompanying minutes, but also must be formally transmitted as described above.

4.5 Staff Evaluation

When a topical report is found acceptable for referencing in the LA the extent of and conditions for acceptance, if any, should be identified in the staff's draft SE, and in the letter transmitting the draft SE. The SE will include the following major headings, as a minimum: Introduction, Summary, Staff Evaluation, Basis, and Conclusion. For proprietary reports, the transmittal letter will state that both proprietary and non-proprietary versions must be referenced in the LA. DOE may choose to reissue the topical report in an accepted version containing the staff evaluation and letter of transmittal, both of which should be incorporated into the report.

The process for preparing the SE will be to first prepare a draft SE that is transmitted to DOE from the Project Director, HLPD, with copies provided to the Affected State, Local Units of Government and Indian tribes, and made available to the public through the Public Document Room. Approximately four weeks later, an interaction will be held between the NRC, DOE and all affected parties to discuss the draft SE. Following that, the NRC will consider

comments provided at the interaction or any additional written comments submitted. The NRC, at its own discretion, will issue the final SE four weeks later.

4.6 Internal Quality Assurance (IQA)

4.6.1 IQA Requirements

In accord with the IQA plan the IQA requirements for the review of topical reports are as follows:

- (1) Before the reviewers begin their review, ensure through a required training on this Review Plan and subsequent group question-and-answer sessions that reviewers have familiarized themselves with this Review Plan.
- (2) Conduct the reviews and develop the review packages consistent with this Review Plan.
- (3) Conduct IQA reviews of the review packages using the following review criteria:
 - a. Technically defensible;
 - b. Accurately represents information in the topical report, supporting references, and procedures;
 - c. Consistent with appropriate sections of this Review Plan;
 - d. Consistent with the standard description of open items (objections, comments, questions);
 - e. Technically consistent within a discipline and across disciplines;
 - f. Consistent with 10 CFR Part 60;
 - g. Written in a clear, concise, complete, and specific manner;
 - h. Written in an objective and factual tone;
 - i. Written in a grammatically correct manner and with editorial consistency throughout;
 - j. Products transmitted by the Branch Chiefs to the Project Director reflect internal resolution of significant comments;
 - k. Entries into the Open Item Tracking System (OITS) accurately reflect the results of the topical report review with respect to new NRC concerns and to resolution or progress toward resolution of existing NRC concerns.

(4) Document that the requirements above have been satisfactorily completed. The signature of the Section Leader on the review package submitted to the Branch Chief and the signature of the Branch Chief on the review package submitted to the Project Director constitute the documentation that the above requirements have been met. This is not however, a replacement for necessary checklists required by IQA.

4.6.2 IQA Responsibilities

For the review, the lead and the other technical reviewers, Section Leaders, Branch Chiefs, and the Project Manager are jointly responsible for assuring that the IQA criteria are met. In particular, the technical reviewers are responsible for providing input to the lead, who has the responsibility for incorporating the products of the technical reviewers and preparing internal comments for briefings and a review package for transmittal to the Section Leader. The lead is also responsible for keeping the Section Leader informed of and involved in the conduct of the review.

The Section Leaders are responsible for assuring that (1) their staff follow this review plan, and (2) their staff's products are of technically high quality. The lead's Section Leader is specifically responsible for the IQA review of the lead's review package.

The Branch Chiefs are responsible for assuring that all significant internal comments are resolved in the final product transmitted to the Project Director. The lead's Branch Chief is specifically responsible for the IQA review package which is transmitted by the lead's Section Leader.

The Project Manager is responsible for overall project management of the review. Especially for:

(1) assuring that the technical reviewers are trained on the review plan prior to starting their topical report reviews;

(2) coordinating (as necessary) the efforts of the technical reviewers in the different disciplines;

(3) verifying that necessary concurrences and certifications have been obtained for review packages;

(4) preparing letters from the Project Director to DOE that preserves the technical quality of the packages transmitted by the Branch Chiefs and that are written in an objective and factual manner;

(5) updating the OITS by arranging for entry of the new open items resulting from the review and for the recording of progress toward resolution of the existing open items based on the review. This process should involve the following steps:

A. The PM provides an electronic copy of the cover letter and review package to the cognizant reviewers.

- B. The cognizant reviewers complete the OITS data entry form, following the instructions in the Administrative plan for the Open Item Tracking System.

(6) compiling the IQA record of the topical report reviews.

4.6.3 IQA Records

The IQA record contains those documents judged necessary to document the topical report reviews. All other documents not identified as part of the IQA record are unnecessary to retain for IQA purposes. The following documents comprise the IQA record:

- (1) This plan;
- (2) Signed review packages transmitted from the Branch Chief to the Project Director;
- (3) Review packages transmitted by the Project Director to DOE;
- (4) A list of technical leads;
- (5) Records of training in this review plan of topical report reviewers;
- (6) Section Leader IQA checklists;
- (7) A record of arrangements for outside assistance of the reviews (Center for Nuclear Waste Regulatory Analyses);
- (8) A Project Manager checklist that keeps track of the above.

Examples of documents that are not part of the IQA record and, therefore, need not be retained for IQA purposes include:

- (1) Early technical review drafts leading to the review package submitted by the technical lead to the section leader;
- (2) Various drafts between the documents designated above for retention;
- (3) Mark-ups of drafts; and
- (4) Personal notes.

The Quality Assurance Section, Section Leader is available during topical report reviews to provide assistance in determining whether there is an IQA rationale for retaining particular documents.

APPENDIX

Milestones and Times for Review of Topical Reports

<u>Milestone</u>	<u>Time (Wks)</u>	<u>Total Time (Wks)</u>
DOE Submits Report	0	0
Complete Acceptance Review	3	3
Notify DOE	1	4
Staff Prepares Questions	8	12
Questions Provided to DOE	2	14
DOE Submits Responses	8	22
Staff Completes Review	6	28
Issue Draft SE	4	32
Hold Technical Exchange	4	36
Issue Final SE	4	40

The staff's ability to meet this schedule is dependent upon DOE identifying the schedule for providing topical reports at least six months prior to their submittal through the Site Characterization Plan Progress Reports.

The annotated outline does not appear on the above schedule of milestones because the time between the NRC staff acceptance of the annotated outline and the submittal of the topical report is DOE's responsibility.