MEMORANDUM FOR: Division of High-Level Waste Management Staff

FROM: B. J. Youngblood, Director
Division of High-Level Waste Management
Office of Nuclear Material Safety
and Safeguards

SUBJECT: IMPLEMENTATION OF DOCUMENT REVIEW AND APPROVAL PROCEDURE

This Policy Memorandum provides specific guidance to the Division of High-Level Waste Management (HLWM) staff on the document review and approval process to be used within the Division.

The procedure is generic, and covers letters generated by HLWM (HLWM Correspondence Documents), reports and other documents generated by CNWRA and HLWM, and DOE/participant documents. The procedure is intended to be used for document reviews which do not warrant development of a separate, specific procedure.

Every staff member is responsible for the effective implementation of this document review and approval procedure. Staff members should read the procedure carefully and follow the guidance contained within. Questions regarding the implementation of this procedure should be raised with Ken Hooks or your Branch Chief.

B. J. Youngblood, Director
Division of High-Level Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure: Document Review and Approval Procedure

cc: J. Linehan
J. Holonich
R. Ballard
M. Federline
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Enclosure: Document Review and Approval Procedure

cc: J. Linehan
J. Hulonich
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0430-01 PURPOSE

To provide Division of High-Level Waste Management (HLWM) staff guidance regarding the review and approval of correspondence generated within the Division, NRC/CNWRA technical documents, and DOE-generated High-Level Waste (HLW) documents. This procedure conforms to NUREG-1297, "Generic Technical Position On Peer Review For High-Level Nuclear Waste Repositories".

0430-02 PROCEDURE

021 HLWM Correspondence Documents

Document review and approval is evidenced by the concurrence information on the official record copy of a completed document. The concurrence procedure used within HLWM shall be consistent with the procedure presented in Section S of NRC Appendix 0240. The concurrence process shall be as follows:

1. Coordinate correspondence with involved individuals.

2. The originating individual shall record the concurrence data on the official record copy, and on other copies, if desirable.

3. Type the abbreviation of the originating office in the first block on the line titled "Office."

4. Complete the succeeding blocks by inserting the abbreviations of the office through which the memorandum must be cleared; end with the office in which the memo will be signed. When used, place the "THRU" addressee's concurrence block immediately before the signer's block, except when the "THRU" office is the EDO. When the EDO is the "THRU" office, place the addressee's concurrence block after the signer's block. When additional spaces are needed, the concurrence blocks may be divided into halves by drawing a vertical line through the middle of each block. Concurrence information may also be placed immediately above the concurrence blocks when necessary. If this is done, the originator's and signer's blocks shall be the first and last on the printed grid.

5. Type the writer's name and typist's initials in the first block on the line titled "name." The writer's telephone number may be added in this block when it would be useful, such as on a communication requiring coordination of signature(s) outside the organizational unit.
Include the date of preparation on the line titled "Date" in the originator's block.

Concurrence on a document indicates approval with the document in the person's area of expertise and responsibility. Concurrence does not necessarily indicate agreement or approval with the contents of the entire document. However, the last individual on the concurrence chain is responsible for the contents of the entire document.

Responsibilities

1.1 Program Element Managers are responsible for implementation of this procedure.

1.2 Reviewers are responsible for performing their assigned reviews in accordance with this procedure.

1.3 Document authors are responsible for preparing document packages for review and for resolving reviewers' comments.

Definitions

2.1 Concurrence Reviews - Reviews which provide for general concurrence with the author for the overall approach and presentation of the work being reviewed, and provide a basis for consistency among like products of the Center/NRC. Concurrence reviews are performed by individuals cognizant of the applicable technical and procedural requirements, and of the objectives of the work being described or being prescribed.

2.2 Peer - A peer is a person having technical expertise in the subject matter to be reviewed (or a critical subset of the subject matter to be reviewed) to a degree at least equivalent to that needed for the original work.

2.3 Peer Review Group - A Peer Review Group is an assembly of peers representing an appropriate spectrum of knowledge and experience in the subject matter to be reviewed, and should vary in size based on the subject matter and the importance of the subject matter to licensing.
2.4 Peer Review - A Peer Review is a documented, critical review performed by peers who are independent of the work being reviewed.

The peer's independence from the work being reviewed means that the peer (a) was not involved as a participant, supervisor, technical reviewer or advisor for the work being reviewed, and (b) to the extent practical, has sufficient freedom from funding considerations to assure the work is impartially reviewed.

A Peer Review is an in-depth critique of matters such as assumptions, calculations, extrapolations, alternate interpretations, methodology, and acceptance criteria employed, and of conclusions drawn in the original work. Peer Reviews confirm the adequacy of work. In contrast to Peer Review, the term "Technical Review" refers to verification of compliance to predetermined requirements, industry standards, or common scientific, engineering, and industry practice.

2.5 Technical Review - A documented, traceable review performed by qualified personnel who are independent of those who performed the work, but who have technical expertise at least equivalent to that required to perform the original work. Technical Reviews are in-depth, critical reviews, analyses and evaluations of documents, material or data that require technical verification and/or validation for applicability, correctness, adequacy and completeness.

3. Procedure

Center/NRC Technical Documents, Papers and Presentation Materials, Guidance Documents, QA Program Documents, and Administrative/Fiscal Documents shall receive, as applicable, Format, Technical/Peer, Concurrence, Programmatic, and QA Reviews in accordance with this procedure. Draft documents to be submitted, as well as revisions and changes to previously submitted documents, shall likewise be reviewed in accordance with this procedure.

3.1 Initiation of Reviews

(a) Authors/Analysts shall submit completed items requiring review to the cognizant Program Element Manager, along with any supporting documentation needed to perform the review (scientific notebooks, calculation verifications, etc.)
(b) The author shall also provide information for initiating the Document Review to the Program Element Manager.

(c) Program Element Managers shall check the required review types on the Document Review Request (DRR) form (see Attachment 1). For revisions and changes to previously submitted documents, the DRR form shall specify reviews commensurate with the extent of the revision/change, along with a brief justification for any reviews.

(d) A Peer Review shall be used when the adequacy of information (e.g., data, interpretations, test results, design assumptions, etc.) or the suitability of procedures and methods important to licensing cannot otherwise be established through testing, alternate calculations, or reference to previously established standards and practices. In general, the following conditions are indicative of situations in which a Peer Review is required:

* Critical interpretations or decisions will be made in the face of significant uncertainty or subjective judgement, including the planning for data collection, research, or testing;

* Interpretations having significant impact on licensing decisions will be made;

* Novel or beyond state-of-the-art testing, plans, and procedures or analyses are or will be utilized;

* Detailed technical criteria or standard industry procedures do not exist or are being developed;

* Results of tests are not reproducible or repeatable;

* Data or interpretations are ambiguous;

* Data adequacy is questionable--such as, data may not have been collected in conformance with an established QA program.
(e) A Peer Review shall also be used when the adequacy of a critical body of information can be established by alternate means, but there is disagreement within the cognizant technical community regarding the applicability or appropriateness of the alternate means.

(f) If Technical, Peer, or Concurrence reviews are required, the Program Element Manager shall select reviewers based on the criteria described in paragraphs 3.3 and 3.4, and identify them on the DRR form.

(g) If Technical or Peer Reviews are required, instructions to reviewers shall be prepared as specified in paragraphs 3.3(c) and 3.4(c). Separate review instructions shall be prepared for different reviewers, as necessary, when the review assignments are to different criteria.

(h) Review items, the DRR form, and supporting documentation shall be routed for reviews in the order of listing on the DRR form, however, Technical, Concurrence, and Programmatic reviews may be conducted simultaneously. Instructions to reviewers shall also be provided to Technical and Peer Reviewers, as applicable. Any comments shall be resolved as specified below, and the DRR form shall be initialled and dated by the reviewer before proceeding for the next specified review.

3.2 Format Reviews

(a) Format Reviews shall be performed by personnel cognizant of correspondence, report and other document requirements.

(b) Format Reviews shall verify the following:

* Spelling, grammar, and general clarity and readability;

* Conformance to applicable document format requirements;

* Internal and Center document distribution requirements, as applicable, are met.
3.3 Technical Reviews

(a) Formally planned and fully documented Technical Reviews shall be performed to verify the technical correctness of the work against established practices.

(b) Individuals performing Technical Reviews shall have technical qualifications at least equivalent to those required to perform the original work under review. Reviewers shall be independent of the work being reviewed.

(c) The Program Element Manager shall identify those Technical Review items applicable to the work being reviewed. Instructions to Technical Reviewers shall be approved by the cognizant Director. The basis for verification shall be predetermined requirements, industry standards, or common scientific, engineering, and industry practice.

(d) Technical Review comments requiring resolution and the status of each of the review items identified in the Instructions to Technical Reviewers shall be identified. Editorial comments of a minor nature (not requiring resolution) may be made as marginalia on the reviewer's copy of the document.

(e) When checks of calculations are specified in the Instructions to Technical Reviewers, the verifications shall be performed and documented.

(f) The author shall respond to the reviewer's comments, and the reviewer shall indicate concurrence with the responses by signature in the appropriate block in the lower left hand portion of the form. If resolution between the author and reviewer cannot be reached, the Division Director shall serve as final arbiter.

3.4 Peer Reviews

(a) Peer Reviews shall be conducted by individuals technically capable of performing the original work. Peer Reviews shall be planned and fully documented, evaluating the technical adequacy of work based on expert judgement when significant uncertainties in methods or data exist, or when no accepted practices have been established.
(b) In addition to having qualifications equivalent to Technical Reviewers (paragraph 3.3.2), Peer Reviewers cannot have been involved as participants, supervisors, technical reviewers, or advisors in the work being reviewed. Peer Reviews shall be conducted by an individual or by a Peer Review Group of sufficient size and composition to span the technical issues and areas involved in the work to be reviewed, including differing bodies of scientific thought, as appropriate. Technical areas more central to the work to be reviewed should receive proportionally more representation on the Peer Review group.

(c) The Program Element Manager shall identify those Peer Review issues applicable to the work being reviewed. Instructions to Peer Reviewers shall be approved by the Division Director. The basis of the evaluation shall be the reviewer's expert judgement.

(d) Individual reviewer's comments, minutes of Peer Review Group meetings and telephone conference records, as applicable, shall be compiled into a Peer Review Report and presented to the author of the work being reviewed. The report shall include a clear description of the work or issue that underwent the peer review process for each of the issues identified in the Instructions to Peer Reviewers, and individual statements by Peer Review Group members reflecting dissenting views or additional comments, as appropriate.

(e) The author shall respond in writing to each comment requiring resolution. The Peer Review Group shall document concurrence with the resolutions by written memoranda, letters, or teleconference records. If concurrence between the Peer Review Group and author cannot be reached, the Division Director shall serve as final arbiter.

(f) The Peer Review Group Chairman shall verify that resolved comments have been incorporated into the finalized document.
3.5 Concurrence Reviews

(a) Concurrence reviews shall be performed by individuals cognizant of the applicable technical and procedural requirements, and of the objectives of the work being described or being prescribed. These reviews provide general concurrence with the author for the overall approach and presentation of the work being reviewed, and provide a basis for consistency among like products of the NRC.

(b) Concurrence reviews shall verify the following, as appropriate for the type of document being reviewed:

* The document satisfies the technical requirements of the work; methods conform to established practices and the application of the method is appropriate;

* The document reads clearly and the presentation is appropriate for the intended audience;

* The overall objectives of the work being planned or described are met by the document being reviewed.

(c) Concurrence Review comments requiring resolution shall be identified. Editorial comments of a minor nature may be marginalia on the reviewer's copy of the report.

(d) The author shall respond to the reviewer's comments, and the reviewer shall indicate concurrence with the responses by signature in the appropriate block in the lower left hand portion of the form. If resolution between the author and reviewer cannot be reached, the Director, Division of High-Level Waste Management (HLWM) shall serve as final arbiter.

3.6 QA Programmatic Reviews

(a) Performed by the HLWM QA staff, QA reviews verify that the requirements of this procedure, and other applicable procedures are met.

(b) QA reviews shall be conducted by HLWM QA staff cognizant of the applicable QA program and procedural requirements.
(c) QA reviews shall verify the following:

* Required reviews are conducted in accordance with applicable QAP requirements;
* The review item and supporting documentation provide objective evidence that the work was performed in accordance with applicable Operations Plan, Project Plan, and QA Requirements;
* The review item satisfies applicable content and format requirements.

(d) QA review comments requiring resolution shall be documented and forwarded to the author. The author shall provide responses to the comments, and the reviewer shall indicate concurrence with the responses by signature. The reviewer shall verify revision of the review item based on resolution of his comments, if necessary. In cases when satisfactory resolution is not obtained, the Director, (HLWM) shall be final arbiter.

023 DOE-Generated High Level Waste Documents

1. Definitions

1.1 Detailed Technical Review - An in-depth document review which focuses on identifying technical concerns with the content of the report.

1.2 Scoping Review - Brief review to identify whether the document contains data, or discussions of technical issues affecting the direction of the current DOE program. Such contents signify that a detailed technical review is required.

2. General Approach to Reviews

Each document is to receive a very brief scoping review to determine what level of review is needed. In many instances (e.g., compilations of three-year-old previously reviewed data published for the record; position papers out of date relative to current DOE positions) this screening may be all that is needed; on the other hand, in cases where the document contains data and discussions of technical issues affecting
the direction of the current DOE program, a detailed technical review (DTR) will be necessary. Such a review should focus on technical or programmatic concerns that the NRC staff has with the content of, or activities proposed in, the report. Extensive uncritical summary of the text is not useful.

In those cases where it is concluded that a DTR of a particular document is not needed, the reasons for that conclusion should be documented on the Document Scoping Sheet (Attachment 2). Where a DTR is deemed necessary, the format for such a review should ordinarily follow that shown in Attachment 3 (WM Document Review Sheet). Key sections include Brief Summary of Document; Significance to Waste Management Program; Problems, Limitations, or Deficiencies of Report; Action Taken; Action Recommended. This format is adaptable to reviews of any length. The length and detail of discussion under each heading may vary from a paragraph to several pages, depending on what the technical reviewer believes to be appropriate and warranted. Exceptions to the standard format for DTRs are justifiable in reviews of DOE documents where the NRC staff will clearly be expected to transmit comments to the DOE. In such cases the format will be determined during the overall planning for the review, but generally will be the same as that used for objections, comments and questions in the NRC staff's Site Characterization Analysis.

3. Specific Approach

3.1 The PM will provide a copy of the document to the Section Leader (SL) in the appropriate discipline for a scoping review. In cases where more than one discipline should review the document, the PM will provide a copy of the document to all appropriate SL's. In all cases, the PM will provide the SL(s) with a TAC # assigned by PMDA. The PM also will place the scoping request into the HLPD Project Administrative Tracking System, which is to be routinely distributed to the project team and to all HLGE, HLHP, and HLPD SL's and Branch Chiefs (BC's).

3.2 The SL will assign the review to an appropriate staff member and that person will complete the scoping review, routinely within two weeks. If it is concluded that no DTR is needed at that time, the person responsible for the review will transmit that finding and the reasons for it to the PM on the Document Screening Sheet after it has been approved by the SL or SL designee. If a DTR is deemed necessary, the reviewer will transmit that conclusion to the PM verbally.

Materials received a month or more prior to a technical exchange or meeting automatically require detailed review and hence the scoping steps 1 and 2
will not be necessary. The DTR will be conducted according to steps 5 and 6. However, the reviewer is not ordinarily expected to generate the final written review prior to the meeting. Instead, the reviewer will compile the input from all reviews into a set of preliminary comments for NRC use during the technical exchange or meeting and for possible transmission to the DOE prior to the technical exchange or meeting. After a meeting, the PM and reviewer may decide to transmit final written comments to the DOE. If so, the reviewer generates the final review as outlined in steps 5 and 6.

3.3 The PM and the SL decide, based on the document screening sheet, the review, recommendations and any input from other staff members, SLs, or BCs, whether a DTR of the document is warranted at that time.

3.4 If a DTR is deemed necessary, the PM and the SL plan the review, and the PM places a DTR agreement into the HLPD Administrative Tracking System. In the case of major multidisciplinary DOE documents, it may be necessary to involve some or all disciplines in the planning. Planning should incorporate: who is to be involved in the review, responsibilities of the individual reviewers, time frame, scope, and level of detail of the review. In instances where there is no obvious lead reviewer due to the multidisciplinary nature of the document, the PM and the appropriate SLs decide which discipline will be assigned responsibility as lead reviewer. The PM will then have the responsibility for coordinating the review and ensuring that the lead reviewer gets all necessary assistance and input from reviewers from other disciplines. The lead reviewer will have the responsibility for writing the review.

3.5 The lead reviewer, in conjunction with other NRC staff and contractors as determined in the planning phase, critically examines the document at the level of detail agreed upon in planning the review. The lead reviewer prepares the review, incorporating staff and contractor comments as appropriate, and keeps the PM apprised of progress and any problems encountered. The lead reviewer transmits the review to the Project Director (HLPD) from the appropriate BC.

3.6 The PM sends copies of all DTRs to the project team members. If comments are to be sent to the DOE, they are sent with a transmittal letter which, in conjunction with the staff's review, makes clear to the DOE the NRC position concerning the contents of the document reviewed. Concurrence by the Deputy
Director and Director will be required, as appropriate. Copies of the transmittal package are also sent to the State of Nevada and affected units of local government and Indian tribes.
DOCUMENT REVIEW REQUEST FORM
IS CURRENTLY BEING DEVELOPED

Attachment 1
DOCUMENT SCOPING SHEET

FILE NUMBER:

DOCUMENT:

REVIEWER: DATE SCOPING COMPLETED:

DATE APPROVED:

REASON(S) WHY A DETAILED TECHNICAL REVIEW IS NOT NEEDED AT THIS TIME:

Attachment 2
PROBLEMS, DEFICIENCIES OR LIMITATIONS OF REPORT:

ACTION TAKEN:

ACTION RECOMMENDED:

*If an item is not applicable to a particular review, write N/A next to the item.