



Yucca Mountain Site Characterization Project

PROCEDURE

MOL.19980803.0414

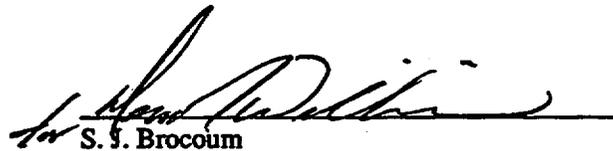
TECHNICAL DOCUMENT PREPARATION

YAP-5.8Q

Revision 1, ICN 0

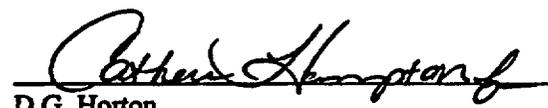
Effective Date: 04/23/98

Approval(s):


S. J. Brocoun
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3/25/1998
Date

Concurrence(s):


D.G. Horton
Director, Office of Quality Assurance

3/27/98
Date

102.2

CHANGE HISTORY

Revision Number	Interim Change No.	Effective Date	Description of Change
0	0	10/25/96	Initial Issue to replace QAP 3.5, <i>Technical Document Preparation</i> , and to satisfy corrective action identified in DR-96-030.
1	0	04/23/98	Complete revision to reflect QAP 5.1, <i>Quality Assurance Program Procedures</i> , and incorporate organizational changes, additional requirements for the preparation of a technical document, and the option to implement a Technical Document Preparation Plan.

1.0 PURPOSE

This procedure describes the requirements and responsibilities necessary for the preparation, review, approval, revision, and change of Yucca Mountain Site Characterization Project (YMP) technical documents.

2.0 APPLICABILITY

This procedure applies to the YMSCO and Affected Organizations that develop and revise technical documents subject to the requirements of the *Quality Assurance Requirements and Description* (QARD), DOE/RW-0333P. Technical documents include those normally associated with, but not limited to, site investigations, design and development, system studies and performance assessment.

NOTE: An alternate YMP procedure that governs the preparation of a technical document may be implemented in place of this procedure provided that the alternate YMP procedure incorporates all the requirements contained in this procedure. In particular, the alternate YMP procedure must conform with the requirement in Paragraph 5.2.2 b) 17).

3.0 DEFINITIONS

Terms in this procedure are used as defined in the *Quality Assurance Requirements and Description* (QARD), DOE/RW-0333P, Glossary. The following definitions are specific to this procedure.

3.1 *Document Change*—A revision to portions of an approved document.

3.2 *Document Change Notice (DCN)*—A method of designating and issuing changes to a document without having to change the revision number and reissue the entire document. With a DCN, the document revision number remains the same, and only the affected pages are issued and marked with the DCN number.

3.3 *Document Revision*—A method of changing a document which involves changing the revision number and reissuing the entire document.

3.4 *Key Words*—Primary words that identify or describe the subject matter of a report or document.

3.5 *Technical Document*—A document that presents information such as data, analysis, interpretations or conclusions.

3.6 *Technical Document Preparation Plan (TDPP)*—A planning document which may be used when the Responsible Assistant Manager (AM) or Director wants to impose administrative or quality assurance (QA) controls in addition to those addressed in this procedure.

4.0 RESPONSIBILITIES

4.1 The Yucca Mountain Site Characterization Office Assistant Manager for Licensing is responsible for the preparation, change, and approval of this procedure.

4.2 The following organizations or positions are responsible for activities identified in Section 5.0 of this procedure:

- a) Responsible AM/Director
- b) Technical Document Preparer

5.0 PROCESS

A brief overview of this process is depicted in the flowchart shown in Attachment 1, YAP-5.8Q Flowchart. Acronyms and abbreviations used in this procedure are defined in Attachment 2, Acronyms and Abbreviations.

PROCESS OUTLINE

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5.1 TECHNICAL DOCUMENT PREPARATION PLAN

5.1.1 Responsible AM/Director:

- a) Determine the need for technical document development.
- b) Determine if a TDPP is required by considering the type, complexity, and organizations affected by the document.

NOTE: A TDPP is required if additional administrative and/or QA controls will be imposed other than those listed in Paragraph 5.2.2 b).

- c) If a TDPP is not required, proceed to Subsection 5.2.

- OR -

- d) If a TDPP is required, assign a Technical Document Preparer to initiate preparation of the TDPP.
- e) Document, in a memorandum to the file, the following:
 - Decision to use a TDPP.
 - Technical Document Preparer.
 - Technical document scope, schedule and completion criteria, and the procedures and processes required for the preparation, use of references, review, and approval of the technical document.
 - Review process to be used, the Affected Organizations that should participate in the review (if applicable), and the method for handling comment resolution of the TDPP review process (if applicable).

5.1.2 Technical Document Preparer:

- a) Prior to preparing the technical document, prepare a TDPP in accordance with this procedure that addresses, at a minimum, items listed in Attachment 3, Content Requirements for Technical Document Preparation Plans.
- b) Submit the TDPP to the Responsible AM/Director for approval.

5.1.3 Responsible AM/Director:

- a) Review the completed TDPP for compliance with Attachment 3.
- b) Instruct the Technical Document Preparer to conduct the review in accordance with the guidance provided in the AM/Director memorandum to the file (Paragraph 5.1.1e).

5.1.4 Technical Document Preparer:

- a) Conduct the review of the TDPP as directed by the AM/Director memorandum to the file (Paragraph 5.1.1e).
- b) Following completion of the review of the TDPP, sign and date the Technical Document Preparer block and submit the TDPP to the AM for approval signature.

5.1.5 Responsible AM/Director:

Approve the TDPP prior to the preparation of the technical document by signing and dating the approval signature/date blocks.

5.2 PREPARATION OF THE TECHNICAL DOCUMENT

5.2.1 Responsible AM/Director:

- a) Assign a Technical Document Preparer to initiate the development of the technical document.
- b) If a TDPP has not been prepared, document in a memorandum to the file (Paragraph 5.1.1e) the following:
 - Decision and justification to not use a TDPP
 - Technical Document Preparer
 - Technical document objective, scope, schedule and completion criteria, and the procedures and process required for the preparation, use of references, review, and approval of the document

5.2.2 Technical Document Preparer:

- a) Initiate the preparation of the technical document in accordance with the TDPP or the AM/Director memorandum to the file (Paragraph 5.2.1b) and the requirements of this procedure.
- b) Ensure that the technical document includes, at a minimum, the following information:
 - 1) Document title.
 - 2) Date of completion.
 - 3) Revision and DCN (if applicable).

- 4) QA record designator.
- 5) Author(s) name(s), organizational/company affiliation(s) (if applicable).
- 6) Signature and date blocks for the Technical Document Preparer and approver of the document.
- 7) Document number (if applicable).
- 8) Security notices (if applicable).
- 9) Contract numbers (if applicable).
- 10) Objective and scope (if applicable).
- 11) Discussion of applicability to the QA program.
- 12) Identification and documentation of inputs, identification of unqualified design input data including the sources, record data tracking numbers or accession numbers, when available, and any prerequisites, special controls, environmental conditions, or processes that will be necessary.
- 13) Identification of assumptions or unqualified data used in the preparation of the technical document. Clearly identify assumptions or data that require confirmation and what impact they may have on the use of the technical document.
- 14) Description of the technical approach and/or evaluation methods used in the preparation of the technical document.
- 15) Key words (to accompany the document upon submittal to the Records Processing Center).
- 16) Table of contents, and a separate list of figures and tables (if applicable).
- 17) All references evaluated will be cited in the technical document's reference list prepared in accordance with AP-17.1Q, *Record Source Responsibilities for Inclusionary Records*, along with a reference/input list that contains data tracking number(s) (see YAP-SIII.3Q, *Processing of Technical Data on the Yucca Mountain Site Characterization Project*) and accession number(s) from the Records Information System database, if available. (The reference/input list shall contain all information necessary to confirm the reference.) This requirement includes those references considered but not used to support technical and/or regulatory positions or conclusions. The Technical Document Preparers will establish the availability of all references by determining if they are in the Records Information System, Technical Information Center, technical databases, or readily accessible in the public domain.

- 18) Rationale for the decision to use references listed in the cited reference list to support technical and/or regulatory positions and/or conclusions along with a rationale for the decision to not include information from those references in the cited reference list that did not support positions and/or conclusions stated in the technical document.
 - 19) Identification of criteria for evaluating alternatives and rationale for rejecting alternatives. Document rationale for any conclusions or recommendations reached. Explain differences from previous similar technical documents.
 - 20) A complete presentation of the information in a clear and logical fashion. Annotate results based on assumptions, unqualified input, or invalidated software (see Attachment 4, Use of Computer Software).
 - 21) Computer software controls and status, if applicable, in accordance with Attachment 4.
- c) Submit the technical document to the Responsible AM/Director for initial review.

5.2.3 Responsible AM/Director:

- a) Review the technical document for adherence to the TDPP, if applicable, the objective and criteria established by the AM/Director memorandum to the file (Paragraph 5.1.1e), and the requirements of this procedure.
- b) Submit the technical document to Document Control Center for initial technical review in accordance with YAP-5.1Q, *Submittal of Documents for Development, Change, Review, and Deliverable Acceptance*.
- c) Following the completion of technical review conducted in accordance with QAP 6.2, *Document Review* (initiated by YAP-5.1Q), approve the technical document by signing and dating the signature/date blocks.
- d) Return to the Technical Document Preparer for signing and dating of Technical Document Preparer signature/date blocks.

5.2.4 Technical Document Preparer:

Sign and date the signature/date blocks of the technical document.

5.2.5 Responsible AM/Director:

- a) Instruct the Technical Document Preparer to submit the final approved TDPP, or the memorandum to the file stating that the TDPP is not required, with the technical document to Technical Publications Management for distribution in accordance with AP-6.1Q, *Distribution, Maintenance, and Use of Controlled and Managed Documents*.
- b) Instruct the Technical Document Preparer to prepare the records package for records retention in accordance with AP-17.1Q.

5.2.6 Technical Document Preparer:

- a) Submit the final approved TDPP, or the memorandum to the file stating that the TDPP is not required, with the technical document to Technical Publications Management.
- b) Prepare the records package for records retention in accordance with AP-17.1Q.

5.3 MODIFICATION OF THE TECHNICAL DOCUMENT

5.3.1 Responsible AM/Director:

- a) Determine if there is a need to modify the technical document as a revision or as a document change.

NOTE: A DCN may be implemented for editorial and minor changes that do not affect the overall technical conclusions of the technical document.

- b) Assign a Technical Document Preparer to process the revision or document change.
- c) If the technical document is being modified as a document change, instruct the Technical Document Preparer to change and mark only the affected pages with a DCN.

NOTE: After five DCNs have been issued to a technical document, additional changes must be incorporated as a revision to the document and must include all the changes from the outstanding DCNs.

5.3.2 Technical Document Preparer:

Revise the technical document at the direction of the Responsible AM/Director in the same manner as the original document.

5.3.3 Responsible AM/Director:

Process and approve revisions or changes to the technical document in the same manner as the original document.

6.0 RECORDS

The documents listed in Subsection 6.1 shall be collected and submitted to the Records Processing Center as a single QA records package in accordance with AP-17.1Q.

The Document Review Record generated by QAP 6.2 will be submitted to the Records Processing Center following the completion of the technical review conducted in accordance with QAP 6.2.

6.1 LIFETIME QA RECORDS

- a) Approved TDPP and revision (if applicable)
- b) Approved technical document
- c) Memorandum to the file from Responsible AM/Director
- c) DCNs

6.2 NONPERMANENT QA RECORDS

None

6.3 NON-QA INCLUSIONARY RECORDS

None

6.4 EXCLUSIONARY MATERIAL

None

7.0 REFERENCES

7.1 DEVELOPMENTAL REFERENCES

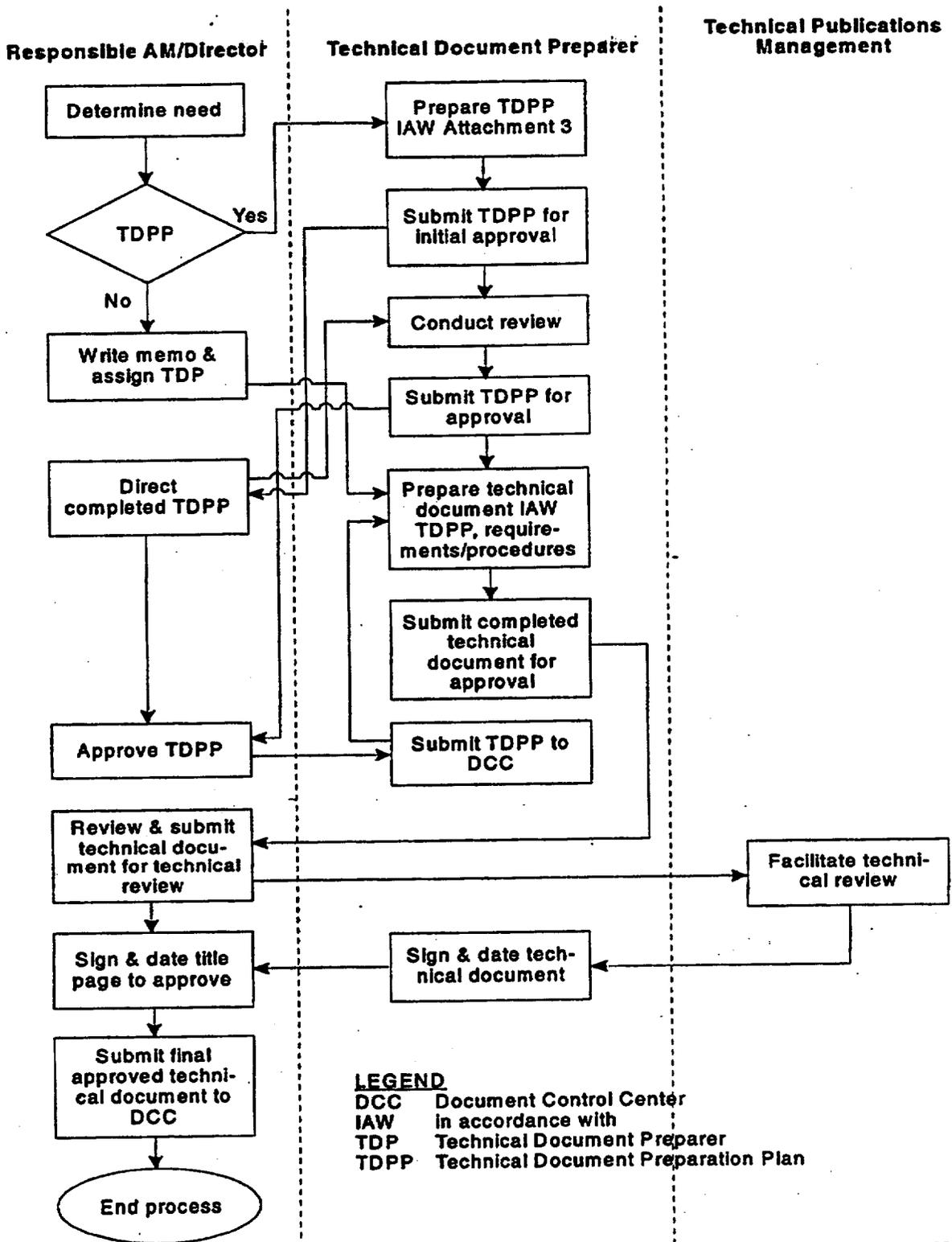
- a) *Quality Assurance Requirements and Description, DOE/RW-0333P*
- b) *QAP 5.1, Quality Assurance Program Procedures*

7.2 IMPLEMENTATION REFERENCES

- a) *AP-6.1Q, Distribution, Maintenance, and Use of Controlled and Managed Documents*
- b) *AP-17.1Q, Record Source Responsibilities for Inclusionary Records*
- c) *QAP 6.2, Document Review*
- d) *YAP-SIIL3Q, Processing of Technical Data on the Yucca Mountain Site Characterization Project*
- e) *YAP-5.1Q, Submittal of Documents for Development, Change, Review, and Deliverable Acceptance*

8.0 ATTACHMENTS

- Attachment 1 - YAP-5.8Q Flowchart**
- Attachment 2 - Acronyms and Abbreviations**
- Attachment 3 - Content Requirements for Technical Document Preparation Plans**
- Attachment 4 - Use of Computer Software**



AM	Assistant Manager
DCN	Document Change Notice
QA	Quality Assurance
QARD	Quality Assurance Requirements Description
TDPP	Technical Document Preparation Plan
YMSCO	Yucca Mountain Site Characterization Office

CONTENT REQUIREMENTS FOR TECHNICAL DOCUMENT PREPARATION PLANS

1.0 Objective and Scope

Address how the technical document will incorporate the objective, scope, schedule, and completion criteria, and the procedures and processes required for the preparation; use of references, review, and approval of the technical document as stated in the AM/Director memorandum to the file (Paragraph 5.1.1e). Describe the range of activities, Affected Organizations, and the limitations of this technical document, including unqualified design input and data. Provide background information that will put the plan and its end products into perspective. Include approval signature/date blocks for the Responsible AM/Director and the Technical Document Preparer.

2.0 Responsibilities

Describe the personnel and organizations responsible for preparation, review, and issuance of each major assignment and the qualifications required of the Technical Document Preparers. Identify the procedures or the processes for interaction with affected parties. Identify the areas of the plan that will be revised when more specific information is available.

3.0 Description of the Technical Document

Identify and describe the technical document expected to result from using this plan. Specify the general format, style, content, and level of detail to be used for the technical document and a table of contents specifying major components of the document. Indicate whether classroom training will be needed by end users of the technical document.

4.0 Technical Approach

Describe the general technical approach to be followed in the development of the technical document. Describe the applicability of the QA program, and provide the additional administrative and/or QA controls that will be required of the technical document other than the minimum items listed under Paragraph 5.2.2 of this procedure. Describe the technical criteria to be followed in implementing additional administrative and/or QA controls. Explain the impacts and reasons if a specific requirement listed under Paragraph 5.2.2 of this procedure will not be met. Describe the use of computer software, if applicable, in accordance with Attachment 2. Specify any requirements for design review, peer review, or other types of reviews and their processes.

5.0 Schedule

List the major schedule that must be accomplished for the preparation, review, and issuance of the technical document. The TDPP need not be revised if the anticipated schedule changes.

USE OF COMPUTER SOFTWARE

This section shall include a list of the software used to support the technical document which is subject to the requirements of the QARD. For validated software, this section shall include a statement indicating that the software used was appropriate for the application and was used only within the range of validation in accordance with the appropriate implementing documents from software development and configuration management. If the software is not validated, or the software is used outside the range of validation, then all resulting output from the software used shall be designated as TBV (to be verified).

The following utilization guidelines apply:

- A. Software approved for QA work - Program name(s), version/revision number(s), and the qualification status of the software.
- B. If software routines are used in the technical document, this section shall include the software title and the version/revision number(s). A description of the use of the software in the technical document, including the user-defined formulas and/or algorithms, inputs, and results (outputs), shall be documented in sufficient detail to allow an independent repetition of the computations.

NOTE: Software Routines can be a computer macro, script file, spreadsheet application, or other software application, either acquired or developed, that generally operates within another program, and stand alone software that can be verified by visual inspection and/or hand calculations.