YUCCA MOUNTAIN PROJECT OFF ¥-AD-002 DOCUMENT APPROVAL SHEE THIS IS ANO. SOMP 406-04 RED STAMP 3 X OF Title QUALITY MANAGEMENT PROCEDURE: PROJECT OFFICE DOCUMENT DEVELOPMENT, REVIEW, APPROVAL AND REVISION PROCESSES []Mon Q **APPROVAL** PROJECT MANAGER: Original Edwin L. Wilmot signed by Signature Date James Blaylock 5/22/90 DIRECTOR OF QUALITY ASSURANCE: _ Signature Date N/A N/A · N/A (OTHER, AS REQUIRED) Signature Date 5/29/90 REVISION 0 EFFECTIVE DATE: ___ **REVISIONS INITIAL AND DATE REVISION 1 REVISION 2** REVISION 3 **REVISION 4** PROJECT MANAGER: DIRECTOR, QA:



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N/A

(OTHER, AS REQUIRED)

EFFECTIVE DATE:

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1.0 PURPOSE AND SCOPE

1.1 PURPOSE

The purpose of this procedure is to assign responsibilities and provide processes for the development, revision, review, and approval or acceptance of Yucca Mountain Project (Project) documents generated by or for the Yucca Mountain Project Office (Project Office). This procedure implements applicable steps in Administrative Procedure (AP)-6.1Q and applicable requirements addressed in the Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance Requirements Document (QARD) and Quality Assurance Program Description Document (QAPD).

1.2 SCOPE

The scope of this procedure includes activities to be performed by individuals who prepare, make revisions to, review, and approve or accept Project documents selected by the Project Office for these processes. This procedure excludes programmatic and policy reviews of documents for publication which are submitted and reviewed under AP-1.3Q, Publications Review and Approval.

2.0 APPLICABILITY

This procedure applies to Project Office personnel and those matrix support individuals assigned by the Project Office to accomplish the processes in this procedure. For those occasions where the Project Office assigns a Project Participant organization to perform activities within the scope of this procedure, applicable sections of this procedure may be included as instructions (addressed in a transmittal letter) to that organization for accomplishment of those activities.

Documents being processed under previous revisions of this procedure or any procedures superseded by the previous revisions may be completed in accordance with those procedures, or may be reprocessed under this procedure. The processes and forms in this procedure are applicable to all other documents selected by the Project Office for processing in accordance with this procedure on and after the effective date of this procedure.

3.0 DEFINITIONS

NOTE: Terms in this procedure are used as defined in the Project Glossary. The following additional definitions are adopted or reiterated for the purposes of this procedure.

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3.1 ANNOTATED OUTLINE

An annotated outline (AO) is an outline providing a sufficient summary of the major topics addressed in a Project-level plan, including a list of the higher-tier documents applicable to the plan.

3.2 FLOWCHART

A flowchart is a drawing depicting the step-by-step progression through a procedure or system using connecting lines and conventional symbols.

3.3 MINOR CHANGE

A minor change is an alteration to an approved document such as an organizational title change; a change to the alpha-numeric identifier of the document; minor wording changes for clarity; editorial, typographical, grammar, punctuation, or spelling corrections; where the basic content of the document does not change.

NOTE: Any other change is considered major.

3.4 REVIEW CRITERIA

Review criteria are a set of written statements which, if satisfied by the document under review, establish the acceptability of the document's content within the reviewing organization's scope of expertise or responsibility.

3.5 SUPPORTING MATERIAL

For the purposes of this procedure, supporting material refers to documentation such as review criteria used for completed internal reviews, copies of or reference to requirements, orders, instructions, policies, or other mandates that support the reason for the request.

4.0 RESPONSIBLE PARTIES

The following Project Office individuals or organizations are responsible for activities identified in Section 5.0 of this procedure:

- 1. Division Director (DD)
- 2. Project Control Branch (PCB)
- 3. Manager, Originating Organization

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- 4. Manager, Reviewing Organization
- 5. Subject Matter Expert (SME)
- 6. Reviewer

5.0 PROCEDURE

NOTE: Flowcharts of the following processes described in this procedure are attached as Figure 1. Other attachments referred to in the procedure are examples only.

RESPONSIBLE PARTY

STEPS

PROCEDURE

DOCUMENTATION INITIATION PROCESS

PCB

- 1. Upon receipt of a Project Document
 Action Request Form (Attachment 1),
 screen and log the request (obtain any
 missing or needed information from the
 requestor), then determine the
 responsible DD, make appropriate
 entries in the Project Document Action
 Initiation form (Attachment 2).
- 2. Assemble and forward a request package (request form, action initiation form, attached document and or supporting material) to the responsible DD.

Responsible DD

- 3. Screen the request for concurrence of need:
 - a. If not in concurrence with the request, check and document justification for rejection on the action initiation form then return with the request package to PCB.
 - b. If in concurrence with the request, complete the Action Initiation Form as appropriate, then return with the request package, to PCB.

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RESPONSIBLE	PARTY
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STEPS

PROCEDURE

NOTE:

DDs may opt to use the Project document Action Initiation Form to initiate action without a request. As an aid in determining if a technical and/or peer review is required, see the Note in the Technical Review Criteria section of Attachment 8.

PCB

- Initiate appropriate document action as follows:
 - a. If the request was rejected, then log and return the request package to the requesting organization, then go to Step 26.
 - b. If request for document development concurred with, then go to Step 5.
 - c. If request for document change concurred with, then go to Step 9.
 - d. If request for document review for approval or acceptance of the submitted document is concurred with, then go to Step 11.

DOCUMENT DEVELOPMENT PROCESS

Assign document number and a technical writer (when applicable), assemble a preparation package, to include any instructions and other document development or revision aids (as appropriate); forward package to the manager of the originating organization that was assigned by the responsible DD.

Manager, Originating Organization

6. Assign a SME; provide the SME with the preparation package; inform PCB of SME assignment.

SME

7. Prepare document as instructed (in conjunction with assigned technical writer, when applicable), then return prepared draft to PCB for processing.

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RESPONSIBLE PARTY

STEPS

PROCEDURE

NOTE:

Attachment 3 provides guidelines for the preparation of Project Office procedures and Project-level plans.

PCB

8. Process the draft (editing, printing, graphics, etc.), then go to Step 10.

DOCUMENT CHANGE PROCESS

- 9. Initiate the appropriate change action:
 - a. If the change(s) is minor, prepare an Interim Change Notice (ICN) (Attachment 4); obtain PCB Manager (or designee) approval, then submit to the Document Control Center for AP-1.5Q distribution. Then go to Step 26.

NOTE: ICNs will normally constitute simple pen and ink changes. Where changes are lengthy or numerous, the document may be revised if so directed by the PCB Manager.

b. If the change(s) is not minor, then return to Step 5 and initiate preparation of a revision as appropriate.

NOTE: Incorporated changes shall be indicated with vertical change bars in the right margin adjacent to the document text that was changed, except for those occasions of complete document revision.

c. If the change is a cancellation or withdrawal of a document, provide information on any interface impact on other procedures, and possible loss of Quality Assurance (QA) requirements compliance as applicable, to the responsible DD. Go to Step 10.

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RESPONSIBLE PARTY

STEPS PROCEDURE

NOTE: The responsible DD shall document justification for cancellation or withdrawal of an approved document.

DOCUMENT REVIEW PROCESS

10. Obtain name(s) of primary reviewer(s) from the manager(s) of the reviewing organization(s).

NOTE: Only qualified (individuals with sufficient technical knowledge of the area under review), independent reviewers shall be assigned to perform technical reviews. PCB shall provide all DDs the opportunity to review Project management plans.

- 11. Assemble review package(s) for each reviewer to include as a minimum:
 - a. Copy of request form
 - b. Copy of document to be reviewed
 - c. Document Review Cover Sheet (Attachment 5) with appropriate entries in Section 1.
 - d. Document Review Sheets (DRSs) (Attachment 6), with document identification number entered.
 - e. Comment Dispute Resolution Sheet (Attachment 7) with document title/subject and identification number entered.
 - f. Document Transmittal/Acknowledgment Sheet with any applicable review instructions.

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APPROVAL, AND REVISION PROCES	SSES	
RESPONSIBLE PARTY ST	<u> TEPS</u>	PROCEDURE
		g. Review criteria (Attachment 8) that has been provided by the responsible DD.
	12.	Transmit review packages to reviewer(s).
Reviewer(s)		Obtain adequate source information to perform the document review (if applicable), then review the document, record comments on DRS(s); return review package to PCB on or before the comment due date.
NO	OTE:	If a secondary reviewer is assigned to replace a primary reviewer, the primary reviewer or manager of the reviewing organization shall complete Section II

ACTION SUBSEQUENT TO REVIEW

PCB

14. Screen review package(s) for completeness and any additional recommended reviews; coordinate and obtain any missing information or forms then:

of the Review Cover Sheet.

- a. If no additional review(s) are recommended, go to Step 18.
- b. Forward review package(s) that recommend additional review(s) to the responsible DD. Attach a new document Action Initiation Form with appropriate entries.

NOTE:

Comments received after the comment due date will be held and considered for the next revision if extension of due date is not requested from reviewer(s) and approved by PCB Manager.

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RESPONSIBLE PARTY	STEPS	PROCEDURE
DD	15.	Determine if recommended review(s) will be performed; document decision on the new Action Initiation Form appropriately, return package(s) and form to PCB.
PCB	16.	If recommended review(s) not concurred with by the responsible DD, go to Step 18.
	17.	If recommended review(s) are concurred with by the responsible DD.
		 Return to Step 10 and repeat process for a technical review if appropriate.
		b. Initiate a peer review in accordance with QMP-03-01 if appropriate, then return to Step 14.
	18.	Forward review package(s) to the SME.
SME	19.	Screen the review package(s).
	20.	If no comments exist on DRS(s), then:
		a. If the document is an AO for a new plan, return to Step 7 and repeat process as necessary.
		b. If the document is not an AO, prepare a final draft for approval; and forward to PCB for processing.
	21.	If comments exist on the DRS(s), document comment responses on the DRS(s) (responses are mandatory for major comments, optional for minor comments); coordinate acceptance of responses with the cognizant reviewer(s), then return to Step 20.a or Step 20.b as appropriate.

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RESPONSIBLE PARTY

STEPS P

PROCEDURE

NOTE:

Comments that cannot be resolved between the SME and the reviewer shall be documented on Comment Dispute Resolution Sheets by the SME and submitted to the responsible DD(s) or the QA Director (for QA issues) for resolution. If not resolved at that level, non-QA issues are elevated to the Project Manager, and if necessary, may be elevated to the OCRWM Director. QA issues may be elevated to the Director, Office of QA, and if necessary, to the OCRWM Director.

APPROVAL PROCESS

PCB

- 22. Process the document, prepare an approval package.
- 23. Obtain required approval or acceptance signatures (as directed by the responsible DD).
- NOTE: For cases where an approval or acceptance cannot be obtained, recycle in accordance with directions from responsible DD.
 - 24. Coordinate determination of the effective date with the affected organization(s). Enter the effective date on the document.

NOTE: Establishment of the effective date shall include training needs, milestones, and other management considerations.

DOCUMENT DISPOSITION PROCESS

25. Prepare the document for disposition in accordance with:

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RESPONSIBLE PARTY

STEPS PROCEDURE

- a. AP-3.3Q, Change Control Process.
- AP-1.5Q, Issuance and Maintenance of Controlled Documents.

NOTE: If the document is not to be issued, return the approved or accepted document to the appropriate organization.

PCB

26. Prepare and submit the records package to the Local Record Center (LRC) in accordance with OMP-17-01.

6.0 REFERENCES

NOTE: Refer to the latest revision of the documents listed below unless otherwise stated.

6.1 REQUIREMENTS DOCUMENTS

OCRWM Quality Assurance Requirements Document, DOE/RW-0214

OCRWM Quality Assurance Program Description Document, DOE/RW-0215

DOE Order 4700.1, Project Management System

Project Glossary, YMP/89-15

6.2 INTERFACE DOCUMENTS

AP-1.5Q, Issuance and Maintenance of Controlled Documents

AP-3.3Q, Change Control Process

AP-6.1Q, Project Office Document Development, Review, Approval, and Revision Control

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7.0 FIGURES AND ATTACHMENTS

Figure 1, QMP-06-04 Flowchart

Attachment 1, Yucca Mountain Project Document Action Request Form

Attachment 2, Yucca Mountain Project Document Action Initiation Form

Attachment 3, Project Office Procedure and Project-Level Plan Preparation Guidelines

Attachment 4, Interim Change Notice (ICN) Form

Attachment 5, Document Review Cover Sheet Form

Attachment 6, Document Review Sheet Form

Attachment 7, Comment Dispute Resolution Sheet Form

Attachment 8, Document Review Criteria

8.0 RECORDS

Records packages of documentation generated as a result of this procedure shall be assembled and submitted to the appropriate LRC in accordance with QMP-17-01, Records Management: Record Source Implementation. Records normally generated or processed by this procedure include:

- 1. Yucca Mountain Project Document Action Request Forms (processed by this procedure)
- 2. Yucca Mountain Project Document Action Initiation Forms
- 3. The approved document, change documentation, or revision documentation
- 4.* DRS (including dispute documentation, if applicable)

*NOTE: DRSs are retained by the PCB until the next issuance of a revision, or the cancellation of the document after which the DRS may be disposed of. The DRSs are not submitted to the LRC for inclusion in the Records Information System.

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GENERAL PROCESSES OVERVIEW FLOWCHART "Document Action Request" (AP-6.1Q) Steps 1-4 **Document Action** initiation Process Step 4.e Steps 5 & 6 Submitted Document Change Document **Document Review** Development **Process** Process Process Steps 7, 8, & 9 Document/ Change Prepared Steps 10-13 Steps 10-13 Document Document Reviewed Reviewed Steps 14-18 Actions Subsequent To Raview Steps 19-21 Comment Responses/Disputes Resolved Steps 22-24 Document Approved Or Accepted Step 25 Document Disposition **Process** Approved Or **CCB** Action Accepted Issue (AP-3.3Q) **Document Returned** (AP-1.5Q) To Requesting Organization Step 26 Records Package to LRC Page 1 of 6 (QMP-17-01) OMP06-04.045/10-5-90

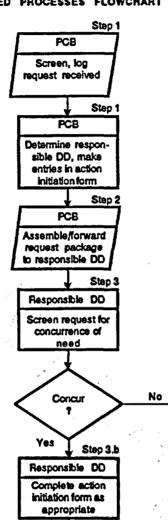
Figure 1 - QMP-06-04 Flowchart

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DETAILED PROCESSES FLOWCHART



Step 3.b

Responsible DD Return form and request package to PCB

PCB Initiate appropriate document action

Step 3.a

Responsible DO

Document rejection; return package to PCB

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SME - Subject Matter Expert MOO - Manager Originating

PCB - Project Control Branch

DD - Division Director

LEGEND

Organization

IAW - In Accordance With DCC - Document Control Center

LRC - Local Records Center

Figure 1 - QMP-06-04 Flowchart (continued)

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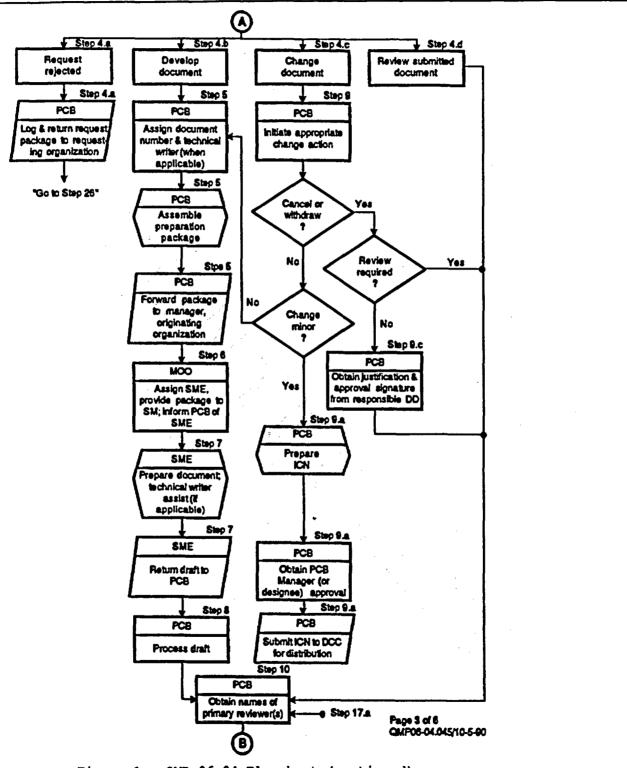


Figure 1 - QMP-06-04 Flowchart (continued)

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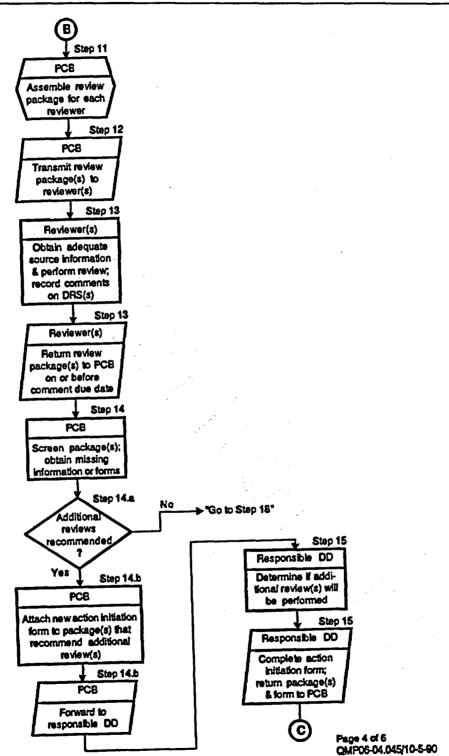


Figure 1 - QMP-06-04 Flowchart (continued)

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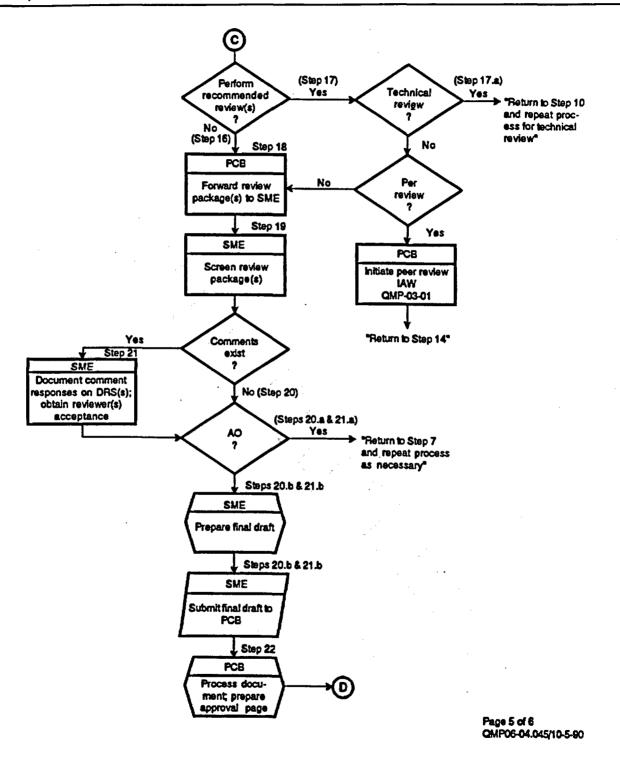


Figure 1 - QMP-06-04 Flowchart (continued)

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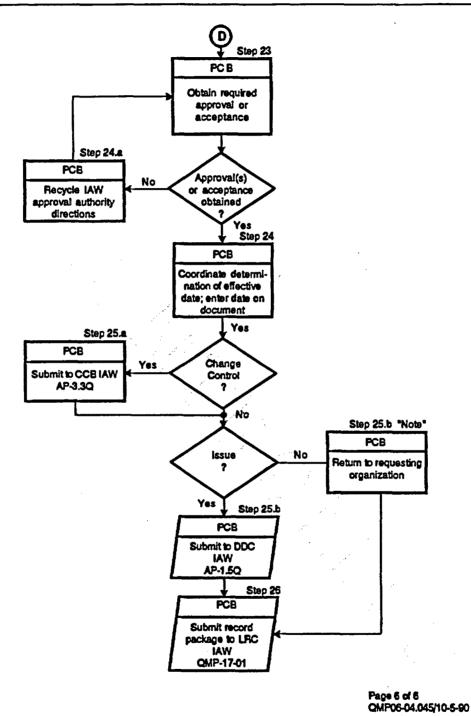


Figure 1 - QMP-06-04 Flowchart (continued)

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		MOUNTAIN PROJECT NT ACTION REQUEST	Y-AD-125 9/90
TO:	PROJECT OFFICE, PROJECT CONTR	IOL BRANCH	j
	Document Title/Subject/Type:	 	· · · · · · · · · · · · · · · · · · ·
	Document Number/Revision: (if any)_		
	Action Requested: (check only one entr Development of new document Change to existing document	ny)	
		·	
	Reason for Request: (briefly identify ne SDR (identify SDR number(s), error or r	red, Le., implements requirement, order, principal information, etc.)	policy; in response to

!			
ı	[] Additional information/supporting re		
FRO	۷:		
i	Requestor (print name)	· ·	panization
l	Phone No.: Mailsto	•	
· .	Request Date:	Requested Action Completion Date:	
	Manager Concurrence:		· -
		Signature	Date
	TPO Approval: (il required)		
	TPO Approvati. (in required)	Signature	Date
	PRO	JECT OFFICE USE ONLY	
· 	Date received:	Request No.:	

Attachment 1 - Yucca Mountain Project Document Action Request Form

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YUCCA MOUNTAIN PROJECT DOCUMENT ACTION INITIATION	Y-AD-124 9/90
Requested Document Action: (PCB make appropriate entries)	
Document Title/Subject/Type:	
[] Request action per attached YMP Document Action Request (Request No) [] Other:	
Responsible DD:	
Print Name and Title	
DD DOCUMENT ACTION INSTRUCTIONS	
1. [] CONCUR WITH REQUEST	
[] REJECT REQUEST Justification	
[] Continued on attached sheet(s)	
2. Documentis: [] Quality Related [] Not Quality Related	
3. Change status: (l'applicable) [] Major change [] Minor change	•
Assigned Originating Organization(s): (If applicable)	
Assigned Reviewing Organization(s):	-
	
	
6. Type of review(s) to be performed:	
7. Approval/Acceptance Signatures required: (names and titles)	-
[] Additional Instructions continued on attached sheets(s)	
Responsible DD Signature Date	
	AP-6.1

Attachment 2 - Yucca Mountain Project Document Action Initiation Form

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QUALITY MANAGEMENT PROCEDURE: PROJECT OFFICE DOCUMENT DEVELOPMENT, REVIEW, APPROVAL, AND REVISION PROCESSES

INTRODUCTION

The guidelines presented in this attachment are applicable to the development of new Project Office procedures (APs, APQs, QMPs, BTPs and BAPs) and Project-level plans. The Project Office PCB may complement these guidelines with additional instructions, source information, style guides, or other information that will assist the originating organization in development of these procedures and plans.

NEW PROCEDURE DEVELOPMENT

- 1. Project Office procedures are developed in two stages:
 - a. First a flowchart of the process is developed, then,
 - b. The flowchart is used to develop the draft procedure.
- 2. Develop a flowchart of the procedure process as follows:
 - a. Draw flow using the following symbols:



PROCESS STEP INPUT/OUTPUT STEP

PREPARATION STEP

b. Identify the sequence of activities (steps) in logical order of occurrence, the responsible individual or organization to be entered in the top portion of each symbol (except for the decision symbol), and identify the applicable procedure Step number, e.g., Step 4, adjacent to each symbol.

NOTE: Acronyms may be substituted in the top portion of the symbols, but must be accompanied with a key on the flowchart.

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3. Develop the procedure using the following format and content guidance (PCB will process approval cover sheet and procedure pages):

1.0 PURPOSE AND SCOPE

Statement of the role the procedure fulfills and what requirement(s) it implements.

2.0 APPLICABILITY

Delineate the boundaries or limits of the activities and organizations to which this procedure applies.

3.0 DEFINITIONS

Define terms or expressions necessary to understand the procedure. General terms are found in the Project Glossary.

4.0 RESPONSIBLE PARTIES

List the individuals or organizations by full name and acronym (if applicable) that are responsible for the activities described in Section 5.0 of the procedure.

5.0 PROCEDURE

Format is in playscript with the identity of who is responsible for the activity addressed in the left column and the associated activity (task) addressed in the right column as demonstrated below:

RESPONSIBLE PARTY STEPS		PROCEDURE		
WHO (e.g., DIVISION DIRECTOR or DD)	1.	ACTIVITY (task)		

6.0 REFERENCES

Reference applicable documents. Enter the full document name and number. Order of entry is Requirements Documents first, followed by Interface Documents (as applicable).

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7.0 FIGURES AND ATTACHMENTS

List by attachment number or figure number in the order they are called out in the procedure (procedure flowchart required).

8.0 RECORDS

List types of records generated by procedure activities. Identify QA Records.

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NEW PROJECT-LEVEL PLAN DEVELOPMENT

- 1. New Project-level plans are developed in two stages:
 - a. An AO is developed, reviewed, and comments resolved and incorporated prior to preparation of a complete draft.
 - b. The complete draft is reviewed, and comments resolved and incorporated prior to approval and issuance.
- 2. For plans not covered by external directives, AO are developed as follows:
 - a. Prepare the AO in paragraph form with each paragraph numbered in the following way:
 - 1.0 INTRODUCTION
 - 1.1 Purpose and Scope
 - 1.2 Objectives and Strategy
 - 1.2.1 Objectives
 - 2.0 ORGANIZATION AND RESPONSIBILITIES
 - 2.1 XXXX
- ETC. -
- b. Use the currently approved Program/Project Hierarchy tree and refer to higher level or to companion documents to the maximum extent possible to ensure consistency with other plans.

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- c. Identify the purpose and applicability of the management system being described; demonstrate this system in a block diagram showing the logical flow as in the example of the Project Management Process (next page of this attachment).
- d. Make clear which organization is responsible for implementation documentation. Do not refer to implementing procedures by name or number, rather, use generic phrases such as:

Implementation of this requirement shall be accomplished by appropriate (organization if appropriate) procedures.

or

Procedures for the implementation of this requirement are the responsibility of __??_.

e. Appropriately number and enter abbreviated, but concise, statements for each of the topics listed below, as applicable, and in the order shown:

Executive Summary

Introduction

- Purpose and Scope

Organization of Plan

- Organization and Responsibilities
- Responsibility assignments, authorities, and interfaces

Objectives and Strategy

- Project policies and requirements for this work area
- Description of management processes and functions, e.g.,
 Systems Engineering Process

Work Plans

- Description of work (requirements)
- Identification of lower-tier plans
- 4. PCB will provide plan preparation materials and forms as needed or requested.

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	INTERIM C	HANGE NOTICE			N-QA-023 8/90
ICN Number:	•	Effective Da	19:	Page	ot
Applies to:					
	Rev.:	_			
REQUIRED CHANGE(S):					
		•			
		·			
					·
			,		
	<u>.</u>				
			·	-	
PCB MANAGER APPROVAL:	Sign	lature		Date	

Attachment 4 - Interim Change Notice Form

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Y-AD-001 4/90

Title

QUALITY MANAGEMENT PROCEDURE: PROJECT OFFICE DOCUMENT DEVELOPMENT, REVIEW, APPROVAL, AND REVISION PROCESSES

DOCUMENT REVIEW COVER SHEET	Y-AD-116 8/90
SECTION I. (PCB make appropriate entries)	
Document Title/Subject	
Document ID No: Draft No: Revision No: [] Q [] Non-Q	
Technical Writer: SME: Print Name Print Name Fother than Technical Writer	_
Technical Writer: SME: Print Name Print Name Other than Technical Writer	
Primary Reviewer: Print Name Title	
Type Review(s) assigned: [] Management [] Regulatory [] QA	
Review Criteria supplied by:	
Review(s) recommended by Reviewer: [] Technical [] Peer	
Review Package to Reviewer:	
Comments due: [] No comments [] Comments to Author:	
[] All comments responded to	
[] Disputed comments resolved:	
Data Comments resorred.	
SECTION II. (Primary Reviewer or equivalent, complete when applicable)	
Secondary Reviewer assigned:Print Name	
Secondary Reviewer is qualified and authorized to conduct review:	
Primary Reviewer:	
Signature Date	,
SECTION III. (DRS instructions)	
Use black ink; number each comment; enter section or step number comment applies to; pla left of Major Comments.	ce*to =
NOTE: A Major Comment is a comment that the reviewer has determined requires resolution prior acceptance. A Minor Comment is a comment other than a major comment.	to document
 t. If a technical or peer review is recommended, enter recommendation as a Major Comment and Comments column along with document section(s) review recommended on. 	Teason in
 Reviewer indicate acceptance of responses by checking "Yes" or "No" and initialing and dating response. "No" checks shall be considered "Disputed" and shall be resolved by next higher lev agement. 	adjacent to rel of man-
d. Reviewer verify final draft and sign acceptance in statement below:	
I verify that all comment dispositions and/or dispute resolutions have been incorporated satisfa	ctorily.
Reviewer Signature Date	
Page 1 of	OND W O

Attachment 5 - Document Review Cover Sheet Form

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Title

QUALITY MANAGEMENT PROCEDURE: PROJECT OFFICE DOCUMENT DEVELOPMENT, REVIEW, APPROVAL, AND REVISION PROCESSES

	DOCUMENT RE (DR				N-QA-041 10/90
Document ID No.:	II THOT	If "NO" checked in acceptance column, see attached CDRS (" Denotes Major Comment)		,age	ď
REVIEW COMMENTS		RESPONSE	75	ACC	EPTANCE INITIAL/DATE
REVIEWED 8Y: Signature	Date	RESPONSE BY:			Date

Attachment 6 - Document Review Sheet Form

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Y-AD-001 4/90

Title

QUALITY MANAGEMENT PROCEDURE: PROJECT OFFICE DOCUMENT DEVELOPMENT, REVIEW, APPROVAL, AND REVISION PROCESSES

YUCCA MOUNTAIN PROJECT COMMENT DISPUTE RESOLUTION SHEET				Y-AD-117 6/90
Document ID No.			Page of	
Document Title/Subject:				· · · · · · · · · · · · · · · · · · ·
DISPUTED COMMENT/R	REASON	RESOLUTION		
	, e			
		·		
	·		•	
Submitted by:		Resolved by:		
Signature	Date	Si	gnature	Date

Attachment 7 - Comment Dispute Resolution Sheet Form

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YUCCA MOUNTAIN PROJECT PROCEDURE

Title

QUALITY MANAGEMENT PROCEDURE: PROJECT OFFICE DOCUMENT DEVELOPMENT, REVIEW, APPROVAL, AND REVISION PROCESSES

INTRODUCTION

Each reviewing organization establishes generic review criteria to be applied to each basic type of review the organization will have to perform. Such criteria should address the organization's areas of expertise and functional responsibility as appropriate to document content.

The following examples (expressed as questions) provide guidance for establishing organization-unique criteria; these examples may be used as stated, or other criteria may be substituted, at the discretion of the manager of the potential reviewing organization:

MANAGEMENT REVIEW CRITERIA

- 1. Does any change to existing policy expressed in the document represent a conscious decision at the appropriate management level?
- 2. Does any condition with, or change to, organizational responsibility assignments represent a conscious decision at the appropriate management level?
- 3. Where the document affects the reviewing organization, are management and administrative impacts acceptable?
- 4. If interfaces between U.S. Department of Energy and participants are involved, is the interface consistent with existing contracts or agreements?
- 5. Are processes as straightforward and simple as feasible in the context of the document's purpose?
- 6. If applicable, will the document cause minimum new paperwork consistent with the document's paperwork (i.e., is duplication of existing paperwork avoided, and is new paperwork essential to the purpose for which the document is being generated?).
- 7. Is the document user friendly, or could it be further simplified or reorganized into a more consistent, logical order?
- 8. Does the document avoid elevating administrative convenience to a requirements level?
- 9. If the document addresses a management approach or methodology, is the reviewing organization satisfied that the approach is as simple and effective as any readily available alternative?

Attachment 8 - Document Review Criteria

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QUALITY MANAGEMENT PROCEDURE: PROJECT OFFICE DOCUMENT DEVELOPMENT, REVIEW, APPROVAL, AND REVISION PROCESSES

REGULATORY REVIEW CRITERIA

- 1. Is the document content consistent with applicable regulatory requirements, if any?
- 2. Does the document content affect existing regulatory commitments and, if so, is it consistent with such commitments?
- 3. If the document makes any commitments or addresses a topic of regulatory interest, is it consistent with existing or intended Program and Project policy?
- 4. If the document will meet a formal submittal requirement, does format and organization of material comply with submittal requirements?
- 5. Is there any contradiction between DOE Orders and regulatory requirements or commitments, and if so, what will be the method of resolution?

TECHNICAL REVIEW CRITERIA

- 1. Are inputs and input sources current, correct, and usable under the requirement for qualified data?
- 2. Are those assumptions within the scope of responsibility of this organization stated explicitly? Are they reasonable?
- 3. If this document involves OCRWM Headquarters (HQ) or Project Office- prescribed processes, is the treatment of such processes consistent with that established direction?
- 4. Is document content consistent with established HQ and Project Office objectives?
- 5. Where applicable and where checked, are analytical approaches and results appropriate?
- 6. Where applicable, are potential interactions with other technical work within the scope of this organization's responsibility addressed adequately?
- 7. In the case of a design document, are the design and the design approach compatible with Program objectives and constraints, and with prescribed systems engineering requirements?

Attachment 8 - Document Review Criteria (continued)

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QUALITY MANAGEMENT PROCEDURE: PROJECT OFFICE DOCUMENT DEVELOPMENT, REVIEW, APPROVAL, AND REVISION PROCESSES

8. Based on the source requirements, is there a need to provide QA interpretations or clarifications to the document requirements?

NOTE: Technical Reviews shall be performed when the information or document under review is within the state-of-the-art and the methodology or application is based on accepted standards, criteria, principles, and practices.

Peer reviews shall be performed when the adequacy of information (e.g., data, interpretations, test results, design assumptions, etc.) or the suitability of procedures and methods essential to showing that the repository system meets or exceeds its performance requirements with respect to safety and waste isolation cannot otherwise be established through testing, alternate calculations or reference to previously established standards and practices.

QUALITY ASSURANCE REVIEW CRITERIA

- Does the document contain those QA requirements applicable to the controls or processes it addresses? (A flowchart or checklist of applicable QA requirements for the specific topic may be desirable for QA reviews).
- 2. Are responsibilities clearly delineated?
- 3. Are specified responsibilities and authority consistent with Project policy?
- 4. Where applicable, does the document clearly distinguish between performing, review, and verification activities?
- 5. Where verification activities are involved, does the document adequately address mechanisms for ensuring the necessary independence and technical competence of the verifier(s)?
- 6. If the document expresses requirements that exceed established QA program requirements, do such additional requirements reflect Project Office policy?
- 7. Does the document contain qualitative and or quantitative data, and if so, are tolerance and parameters provided for this data?
- 8. Based on the source requirements, is there a need to provide QA interpretations or clarifications to the document requirements?

Attachment 8 - Document Review Criteria (continued)

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