

YMPO Quality Management Procedures (QMPs)

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QMP-01-02		Stop Work	0	(4/11/88)
QMP-02-01	1			In Preparation
QMP-02-01		Qualification, Proficiency, Indoctrination, and Training of Waste Management Project Personnel	1	(9/2/88)
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QMP-02-02	2			(10/16/89)
QMP-02-02	3			In Preparation
QMP-02-02		Qualification of Quality Assurance Program Audit Personnel	1	(2/22/88)
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QMP-02-03		Quality Assurance Management Assessment	0	(7/12/89)
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QMP-02-08	3			In Preparation
QMP-02-08		Technical Assessment Review	0	(8/8/88)
QMP-02-09	1			In Preparation
QMP-02-09	2			(5/18/90)
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QMP-04-01	1		(7/14/89)
QMP-04-01		Procurement Document Control	0 (4/11/88)
QMP-04-02		Procurement Document Control (Project Office Initiated)	In Preparation
QMP-04-03		Yucca Mountain Project Office (Project Office) Procurement Actions	In Preparation
QMP-05-01	1		Superseded by QMP-06-04
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QMP-05-01		Preparation and Control of Quality Management Procedures	Superseded by QMP-06-04
QMP-05-02	1		Superseded by QMP-06-04
QMP-05-02	2		Superseded by QMP-06-04
QMP-05-02	3		Superseded by QMP-06-04
QMP-05-02		Preparation and Control of Branch Technical Procedures	Superseded by QMP-06-04
QMP-05-03		Preparation and Control of the NNWSI Project QAP and the WMPO QAPP	0 (5/27/88)

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QMP-06-02		Document Control	1 (12/1/88)
QMP-06-03	1		Superseded by QMP-06-04
QMP-06-03	2		Superseded by QMP-06-04
QMP-06-03		Document Review/Acceptance/ Approval	Superseded by QMP-06-04
QMP-06-04		Project Office Document Development, Review, Approval and Revision Process	0 (5/29/90)
QMP-07-03	1		(11/29/89)
QMP-07-03		Control of Purchased Items and Services	0 (4/11/88)
QMP-07-04	1		In Preparation
QMP-07-04	2		In Preparation
QMP-07-04		Supplier Evaluation/Qualified Suppliers List	0 (11/29/89)
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QMP-17-01	1		(5/29/90)
QMP-17-01		Records Management: Record Source Implementation	1 (10/30/89)
QMP-18-01		Audit System for the Waste Management Project Office	3 (10/3/88)

**YUCCA MOUNTAIN PROJECT OFFICE
DOCUMENT APPROVAL SHEET**

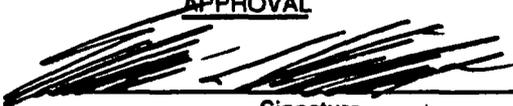
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Title
QUALITY MANAGEMENT PROCEDURE QMP-06-04 PROJECT OFFICE DOCUMENT
DEVELOPMENT, REVIEW, APPROVAL AND REVISION PROCESSES

NO.
 Q
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APPROVAL

PROJECT MANAGER:


Signature

5/22/90
Date

DIRECTOR OF QUALITY ASSURANCE:

James Blaylock
Signature

5/22/90
Date

N/A
(OTHER, AS REQUIRED)

N/A
Signature

N/A
Date

REVISION 0 EFFECTIVE DATE: 5/29/90

REVISIONS

INITIAL AND DATE

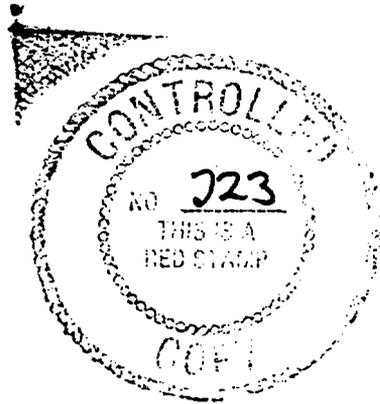
REVISION 1	REVISION 2	REVISION 3	REVISION 4
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PROJECT MANAGER:

DIRECTOR, QA:

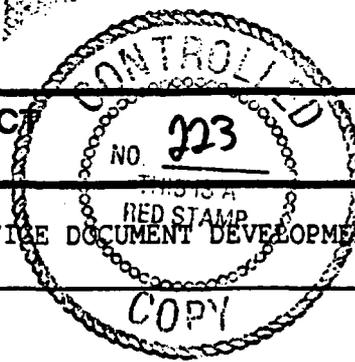
(OTHER, AS REQUIRED)

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QUALITY MANAGEMENT PROCEDURE QMP-06-04 PROJECT OFFICE DOCUMENT DEVELOPMENT,
REVIEW, APPROVAL AND REVISION PROCESSES

1.0 PURPOSE AND SCOPE

1.1 PURPOSE

The purpose of this procedure is to assign responsibility and provide a process to ensure that Yucca Mountain Project Office (Project Office) generated documents are developed, revised, reviewed, and approved in accordance with this procedure, and that documents submitted to the Project Office are reviewed prior to Project Office approval or acceptance. This procedure defines how the Project Office implements AP-6.1Q

1.2 SCOPE

The scope of this procedure includes (1) development criteria for project technical documents; (2) Project Office responsibilities for preparation, review, approval, and revision of Project-level plans, procedures, and requirements documents; and (3) the responsibilities for Project Office review and approval or acceptance of documents Participants are required to submit to the Project Office.

This procedure implements applicable requirements in the Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance (QA) Requirements (RW-0214) and Program Description (RW-0215) Documents.

2.0 APPLICABILITY

This procedure applies to Project Office personnel responsible for development, review, revision, and approval or acceptance of (1) Project-level plans, procedures and technical documents, and (2) documents submitted to the project office for review and approval or acceptance.

3.0 DEFINITIONS

NOTE: Terms in this procedure are used as defined in OCRWM QA Requirements and Program Description Documents, or the Program Glossary. The following additional definitions are adopted for the purposes of this procedure.

3.1 ANNOTATED OUTLINE (AO)

An 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.

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3.2 FLOW DIAGRAM

A flow diagram 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 TECHNICAL DOCUMENT DEVELOPMENT CRITERIA

Technical document development criteria are a set of written statements to be used as a basis for development of technical documents requiring Project Office review, approval or acceptance.

3.6 TECHNICAL DOCUMENT

A document that specifies scientific or engineering requirements, presents scientific or engineering information or data, or describes scientific or engineering processes.

4.0 RESPONSIBLE PARTIES

The following Yucca Mountain Project Office individuals or organizations are responsible for activities identified in Section 5 of this procedure:

1. Division Director (DD)
2. Director, Quality Assurance (DQA)
3. Project Control Branch (PCB)

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- 4. Project Site Manager (PSM)
- 5. Manager, Originating Organization
- 6. Manager, Reviewing Organization
- 7. Author
- 8. Reviewer

5.0 PROCEDURE

NOTE: A flowchart of the following processes described in this procedure is attached as Figure 1.

RESPONSIBLE PARTY	STEPS	PROCEDURE
PCB	1.	Upon receipt of a Yucca Mountain Project Document Development/Change/Review/Request form (Attachment 1), screen and log the request, then: <ul style="list-style-type: none"> a. If the request is for a Change Control Board (CCB) controlled document, then forward the Technical Control Request (Attachment 2) and any supporting documents to the CCB Secretary for action per QMP-03-09. b. If the request is not for CCB controlled document, then determine the responsible DD for acceptance or rejection of the request; forward a request package (request form, supporting documents, and any other decision aids) to the DD.
DD	2.	Review the request for concurrence of need: <ul style="list-style-type: none"> a. Solicit input from other DDs, the PSM, and the DQA as appropriate.

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<u>RESPONSIBLE PARTY</u>	<u>STEPS</u>	<u>PROCEDURE</u>
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DD

- b. If not in agreement with request, then document justification for rejection in Section 6 of the request form and return request package to PCB.
- c. If in agreement with request, then complete appropriate portions in Section 6 of the request form; return request Initiate action as follows:

PCB

- 3. Initiate action as follows:
 - a. If the request was rejected, then log and return the request and any supporting documents to the requesting organization.
 - b. If request for document development, then go to Step 4.
 - c. If request for document change, then go to Step 8.
 - d. If request for document review, then go to Step 9.

NOTE: Reviewing organization(s) are identified on the request form.

DOCUMENT DEVELOPMENT PROCESS

- 4. Assign document number, assemble a preparation package, to include instructions and other document development or revision aids (as appropriate); forward package to the manager of the originating organization.

NOTE: If originating organization is external to the project office, prepare standard transmittal letter for inclusion with preparation package.

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RESPONSIBLE PARTY	STEPS	PROCEDURE
Manager, Originating Organization	5.	Assign an author; provide the author with the preparation package; inform PCB of author assignment.

Author	6.	Prepare document as instructed, then return preparation package to PCB for review process.
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NOTE: Attachment 3 provides guidelines for the preparation of Project Office procedures and Project-level plans. Technical documents prepared by or for the Project Office must meet the Technical Document Development Criteria (Attachment 4) as a minimum.

7. Go to Step 9 to initiate the review process when document is received.

DOCUMENT CHANGE PROCESS

PCB	8.	Initiate the appropriate change action: <ul style="list-style-type: none"> a. If a minor change(s), then prepare an Interim Change Notice (ICN) and forward it to the Document Control Center for distribution; incorporate change during next revision of the document.
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NOTE: Minor changes require PCB management review and approval prior to transmittal to Document Control.

- b. If not a minor change(s), then go to Step 4 and initiate preparation of an ICN or revision.

DOCUMENT REVIEW PROCESS

PCB	9.	Assemble review package(s) to include as a minimum: <ul style="list-style-type: none"> a. Copy of request form
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RESPONSIBLE PARTY	STEPS	PROCEDURE
PCB	b. c. d. e. 10.	Copy of document to be reviewed Document Review Sheets (DRSs) (Attachment 5), with type of review checked in appropriate box(es). ICN form(s), if applicable (example of ICN forms shown in Attachment 6). Guidance, instructions, tracking forms and the review completion schedule. Transmit review packages to all DDs, PSM, manager(s) of reviewing organization(s), and the DQA.
	NOTE:	If a reviewing organization is external to the Project Office, prepare standard transmittal letter and include in the review package along with any review instructions.
DD, DQA or PSM	11.	Screen document: a. If review desired or required, then follow Steps 12 through 15. b. If review not desired or required, then indicate so on the review package and return the package to the PCB.
Manager(s) Reviewing Organization(s), DD(s), DQA or PSM	12.	Assign reviewer(s) by entering name(s) on page 1 of DRS (name and discipline of the qualified, independent reviewer for technical reviews); provide reviewer(s) with review package and established review criteria. Attachment 7 provides examples for guidance in establishing criteria.
Reviewer(s)	13.	Review document as instructed in the review package; record comments on DRS sheet(s); return reviewed document, DRSs and package to appropriate manager.

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Manager(s) Reviewing Organization(s), DD(s), DQA or PSM	14. 15.	Check to ensure review(s) completed adequately. Return completed review package(s) to the PCB.
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ACTION SUBSEQUENT TO REVIEW

PCB	16.	Screen review package(s) for completeness; coordinate and obtain any missing information or forms; forward completed review package(s) to: <ul style="list-style-type: none"> a. Author when review was Regulatory, and/or Management and Technical Review was not recommended. b. Responsible DD when review was Regulatory and/or Management and Technical Review was recommended.
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NOTE: If author is external to the Project Office, prepare a standard transmittal and include with package(s) along with any resolution instructions.

DD	17.	Screen review package(s) received that recommend a Technical Review, then: <ul style="list-style-type: none"> a. If not in concurrence with recommendation, document decision on review package(s), then return to PCB. b. If in concurrence with recommended Technical Review, take appropriate actions to have review completed, inform PCB of action taken, then go to Step 17c.
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NOTE: If technical review is conducted by Project Office personnel, return to Step 7 and repeat review process as necessary.

c. If technical review(s) recommend a

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Peer Review, initiate the review per QMP-03-01 if in concurrence with recommendation, or take appropriate actions. If not in concurrence, inform PCB of review status; go to Step 17d.

d. Upon completion of Technical and/or Peer Review(s), forward any resolved comments to PCB, or inform PCB that the review(s) is complete and no comments exist.

PCB

18. Forward any comments received from DD to author for incorporation into final draft, or inform author that the review(s) is complete and no comments exist.

Author

19. If no comments exist on DRS(s), then:

a. If the document is an annotated outline for a new plan, then return to Step 6 and repeat process as necessary.

b. If the document is not an annotated outline, then prepare a final draft for approval; go to Step 21.

20. If comments exist on the DRS(s) and are annotated as major, resolve the comments with the reviewer(s), document comment resolutions on the DRS(s), obtain reviewer(s) concurrence of disposition provided on the DRS(s), then:

a. If the document is an annotated outline, then return to Step 6 and repeat process as necessary.

b. If the document is not an annotated outline, and no other reviews have been recommended, then prepare a final draft (incorporate comments) for approval; go to Step 21.

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NOTE: Comments that cannot be resolved between the originating organization and the reviewing organization shall be brought to the attention of the responsible DD(S) or the DQA (for quality assurance issues). If not resolved at that level, non-QA issues are elevated to the Project Manager, and if necessary, may be elevated to the Director OCRWM. QA issues may be elevated to the Director, Office of Quality Assurance, and if necessary, to the OCRWM Director.

APPROVAL PROCESS

- | | | |
|--------|-----|---|
| Author | 21. | Submit the final document and review package(s) to PCB for processing. |
| PCB | 22. | Obtain document approvals (as indicated in Section 6 of the request form), then return approved document to manager of the originating organization: <ul style="list-style-type: none"> a. For cases where an approval cannot be obtained, recycle in accordance with directions from approval authority. b. For documents not considered quality affecting, the DQA shall enter "N/A" and initial and date the DQA space on the approval sheet. c. For documents subject to publications review and approval, as required or requested by the requesting organization, comply with AP-1.3Q. |

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ISSUANCE PROCESS

Manager Originating
Organization

23. Determine the effective date of the document in consultation with the PCB and the CCB Secretary (when applicable). Establishment of the effective date shall include training needs, milestones, and other management considerations.

NOTE: PCB coordinates determination of effective date with the manager of the originating organization when that organization is external to the Project Office.

24. Enter the effective date on the document, then prepare the document for issuance or submittal to the Change Control Board, as appropriate, in accordance with:

- a. QMP-03-09, Project Change Control Board Process, and, or
- b. AP-1.5Q, Issuance and Maintenance of Controlled Documents.

PCB

25. Submit the records package to the Local Record Center in accordance with QMP-17-01.

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6.0 REFERENCES

NOTE: Refer to the latest revision of the below listed document.

6.1 REQUIREMENTS DOCUMENTS

OCRWM Quality Assurance Requirements Document, RW-0214

OCRWM Quality Assurance Program Description, RW-0215

DOE Order 4700.1, Project Management System

6.2 INTERFACE DOCUMENTS

AP-1.3Q, Publications Review and Approval

AP-1.5Q, Issuance and Maintenance of Controlled Documents

AP-5.13Q, Readiness Reviews

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

QMP-02-08, Technical Assessment Review

QMP-03-01, Peer Reviews

QMP-03-09, Project Change Control Board Process

QMP-06-02, Document Control

Program Glossary

7.0 FIGURES AND ATTACHMENTS

Figure 1, AP-6.1Q Flow Diagram

Attachment 1, Yucca Mountain Project Document Development/Change/Review/
Request

Attachment 2, Example of Technical Change Request, Change Impact Checklist,
and Preparation Instructions

Attachment 3, Project Office Procedure and Project-level Plan Preparation

Attachment 4, Technical Document Development Criteria

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Attachment 5, Document Review Sheet

Attachment 6, Interim Change Notice (ICN) sheets

Attachment 7, Examples of Review Criteria

8.0 RECORDS

Records packages of documentation generated as a result of this procedure shall be assembled by the Project Control Branch in cooperation with the originating organization, then the PCB will submit the records package to the Local Records Center in accordance with requirements specified in QMP-17-01. At a minimum, the request form, the approved document, DRSS and ICNs shall be considered QA records.

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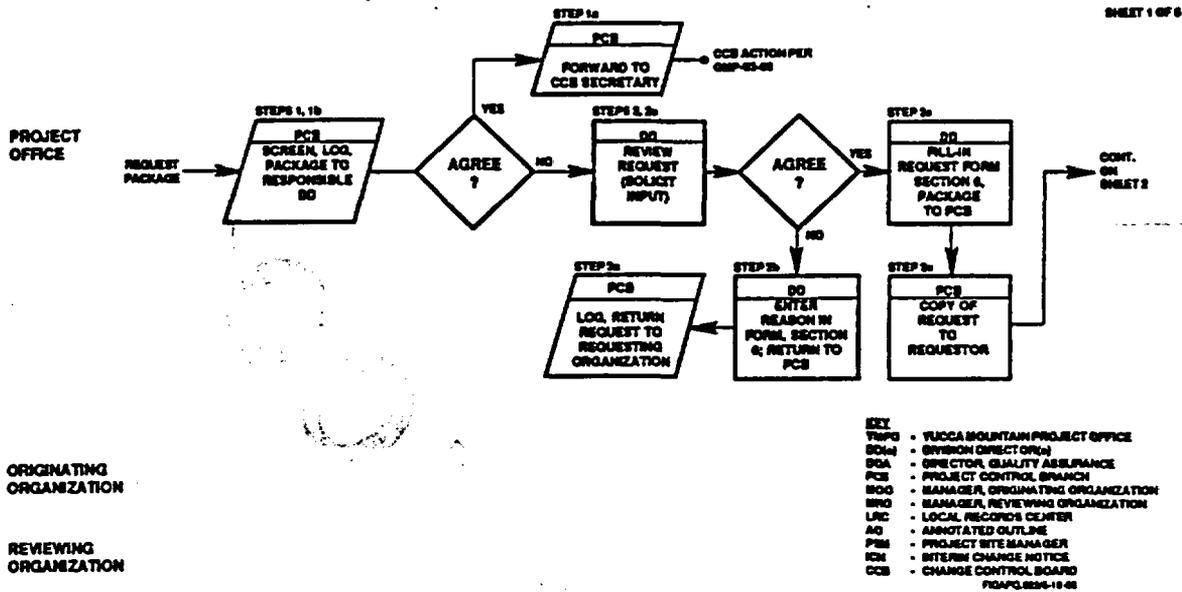


Figure 1. QMP-06-04 flow diagram.

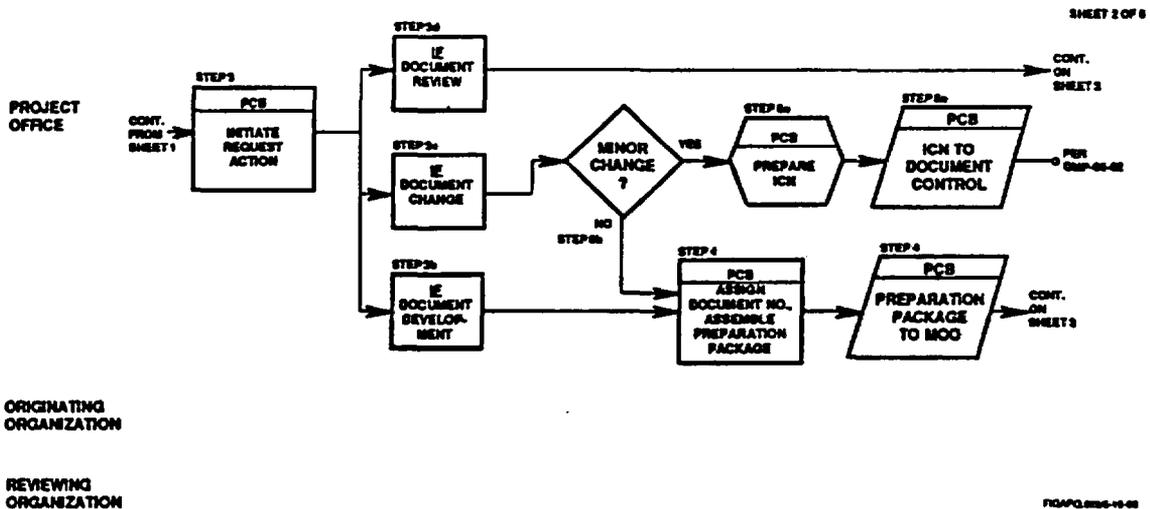


Figure 1. QMP-06-04 flow diagram (continued).

Figure 1 - QMP-06-04 Flow Diagram

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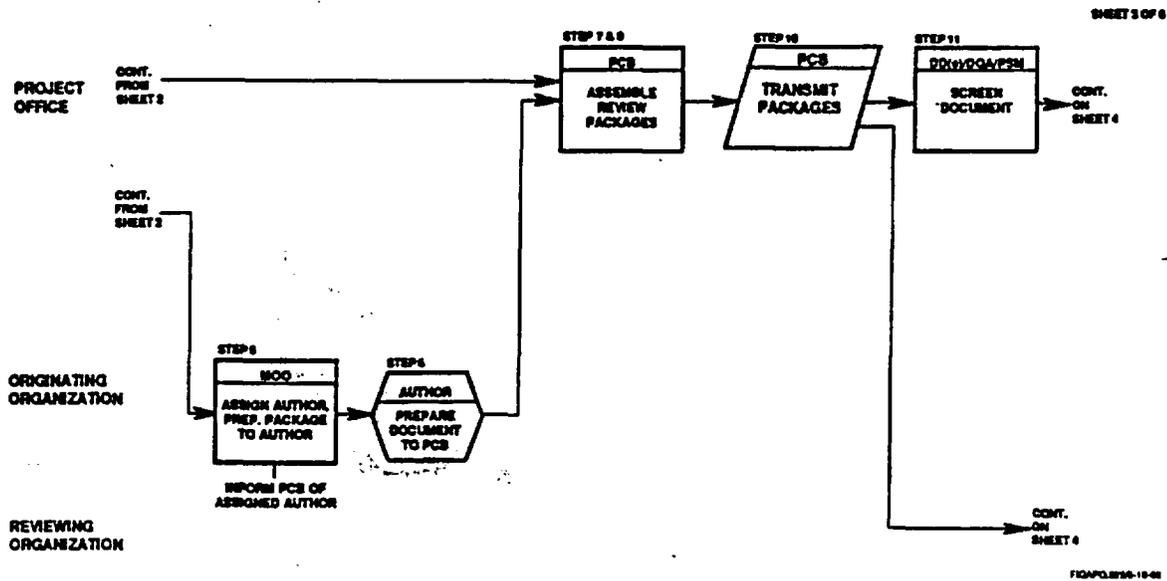


Figure 1. QMP-06-04 flow diagram (continued).

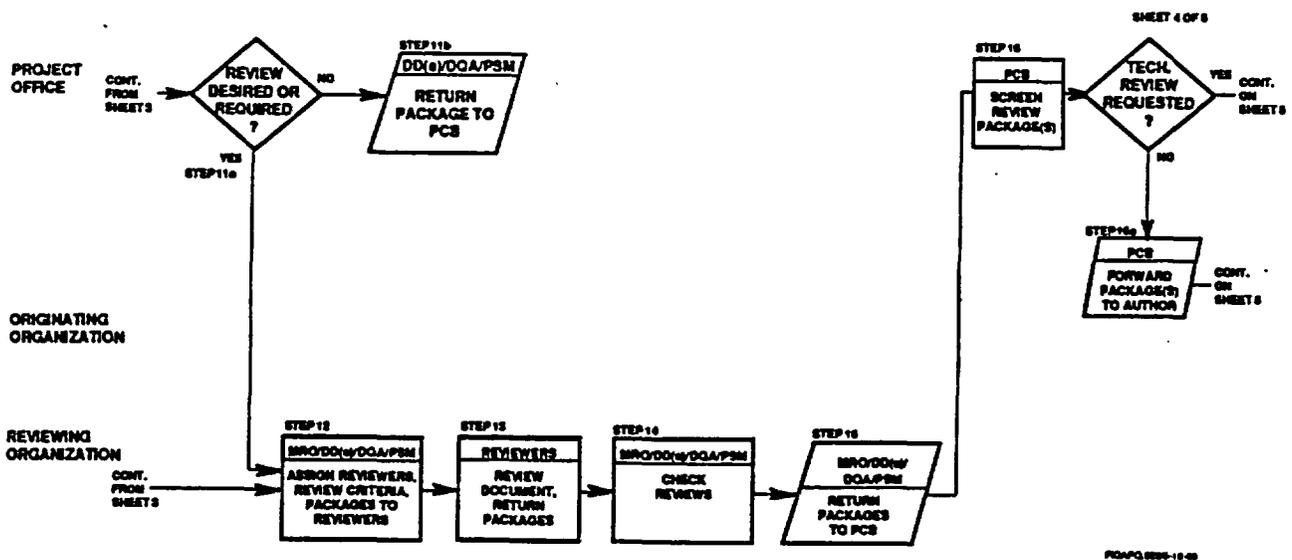


Figure 1. QMP-06-04 flow diagram (continued).

Figure 1 - QMP-06-04 Flow Diagram (continued)

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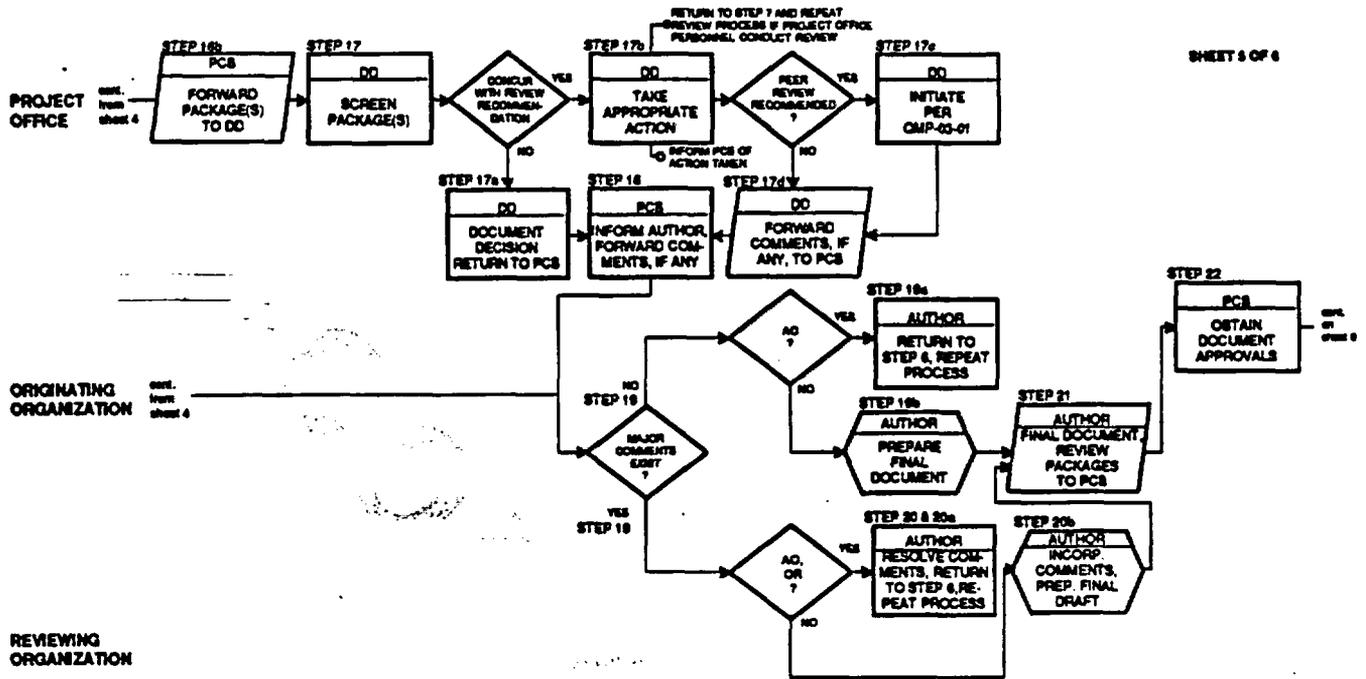


Figure 1. QMP-06-04 flow diagram (continued).

QMP-06-04.0006-10-01

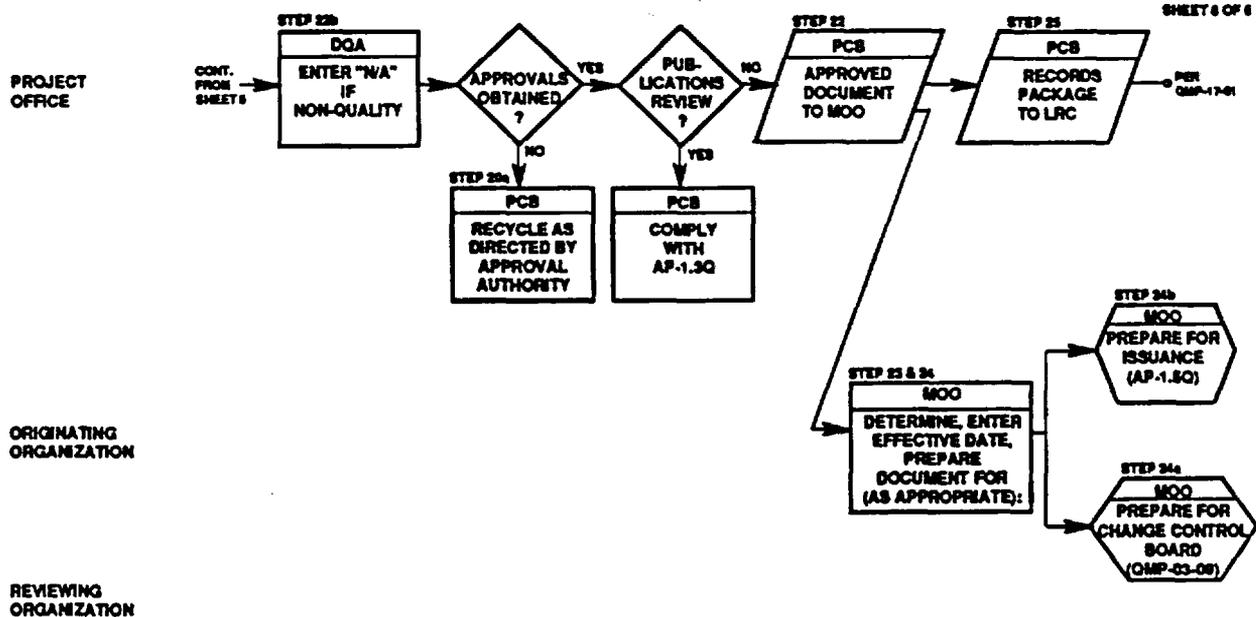


Figure 1. QMP-06-04 flow diagram (continued).

QMP-06-04.0006-10-01

Figure 1 - QMP-06-04 Flow Diagram (continued)

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QUALITY MANAGEMENT PROCEDURE QMP-06-04 PROJECT OFFICE DOCUMENT DEVELOPMENT,
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YUCCA MOUNTAIN PROJECT OFFICE DOCUMENT DEVELOPMENT/CHANGE/REVIEW REQUEST

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Page 2 of 3

Change(s): (Identify document section, change, if major change, and reason)

continuation sheet(s) attached

SECTION 5: REVIEW OF ATTACHED DOCUMENT

a. Type of document: (specify) _____

b. Subject: _____

c. Type Review(s) requested: (check as applicable, if known)

- | | |
|---|--|
| <input type="checkbox"/> Management Review | <input type="checkbox"/> Technical Assessment Review |
| <input type="checkbox"/> Regulatory Review | <input type="checkbox"/> Peer Review |
| <input type="checkbox"/> Quality Assurance Review - Mandatory | <input type="checkbox"/> Publications Review |
| <input type="checkbox"/> Technical Review | |
| <input type="checkbox"/> Other: (specify) _____ | |

d. Recommended review organization(s): (optional)

SECTION 6 FOR PCB AND DD ONLY

SECTION 6: DIVISION DIRECTOR INITIAL REVIEW INSTRUCTIONS

a. Responsible DO: _____
PCB (enter name)

b. If request accepted, then DD check and complete following entries, as appropriate:

Assigned originating organization(s): _____

Concur with recommended reviewing organization(s).

Do not concur with recommended reviewing organization(s): (reason)

Attachment 1 - Yucca Mountain Project Document Development
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Replacement or additional reviewing organizations:

Concur with recommended type(s) of review(s).

Do not concur with recommended type(s) of review(s), direct the following type(s) on this document:

- | | |
|---|--|
| <input type="checkbox"/> Management review | <input type="checkbox"/> Technical Assessment Review |
| <input type="checkbox"/> Regulatory review | <input type="checkbox"/> Peer Review |
| <input type="checkbox"/> Quality Assurance review | <input type="checkbox"/> Publications Review |
| <input type="checkbox"/> Technical review | |
| <input type="checkbox"/> Other: (specify) _____ | |

Document quality related.

Document not quality related.

Technical document meets development criteria.

Required approval(s) are: (enter title(s) and name(s))

Additional instructions:

Rejected: (DD enter reason below)

Responsible DD/Designated Alternate signature

Date

Additional instructions/information attached

Attachment 1 - Yucca Mountain Project Document Development
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YUCCA MOUNTAIN PROJECT TECHNICAL CHANGE REQUEST (TCR)			Y-AD-082 Page 1 of ___ 4/90
1 Originator's Control No.:		2 TCR No.:	
3 TCR Title:			
4 Document No.:		5 Revision No.:	
6 Document Title:			
7 Change Classification:	8 Priority:	9 Affected WBS No(s):	
<input type="checkbox"/> Class 1	<input type="checkbox"/> Emergency	_____	
<input type="checkbox"/> Class 2	<input type="checkbox"/> Urgent	10 CA Designation _____	
<input type="checkbox"/> Class 3	<input type="checkbox"/> Routine	11 Related TCR(s) _____	
12 CI No(s): _____		13 Other Items Affected: _____	
14 Next Higher Assembly: _____		16 Effectivity of Change: _____	
15 Retrofit Requirements: _____			
17 Other Documents Affected: _____			
18 Description of Change:			
19 Reason/Justification for Change:			
20 Technical/Cost/Schedule Impact Analysis (see Change Impact List)			
21 Impact if Change is Not Made: (see Change Continuation Page _____)			
22 Does the change require revision of documents not identified in TCR Package? <input type="checkbox"/> No <input type="checkbox"/> Yes (see Change Continuation Page _____)			
23 Attachments:			
24 Originating Participant:		25 Prepared By:	
		Name _____ Telephone No. _____ Initial _____ Date _____	
26 Submitted By:			
Name: _____		Title: _____	
Signature: _____		Date: _____	
27 CCB Secretary Use:			
Date Received: _____		By: _____	Log Date: _____

Attachment 2 - Example of Technical Change Request, Change Impact Checklist,
and Preparation Instructions

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YUCCA MOUNTAIN PROJECT CHANGE IMPACT CHECKLIST Page 2 of 490					
			Originator's Control No. _____		TCR Number: _____
YUCCA MOUNTAIN PROJECT CHANGE IMPACT CHECKLIST					
Item #	Activity or Document Category	Cont. Sheet #	Section #	Item #	Activity or Document Category
	SITE CHARACTERIZATION				SEE QM ACTIVITY
	Ability to Characterize Site				Design Requirements Document (DRD)
	Site Characterization Plan (SCP)				Design Documents (DD)
	Site Atlas				Construction Documents
	Environmental Assessment (EA)				Construction Items (CI)
	SCP Study Plans				Managed Control Documentation (MCD)
	Test Procedures				Inspections
	Test Operating Procedures				Guidance
	SCP Data Requirements				Drawings
	Available Site Data				Test Procedures
	Geological Survey				Other
	Water Survey				
	Other				
	WASTE ISOLATION CAPABILITY				SYSTEM PERFORMANCE
	Engineered Waste Isolation Barriers				Survey, Radiological & Geographical
	Natural Waste Isolation Barriers				Corrosion
	Fluids on Site				Maintainability
	Other				Reliability
					Service Life
					Electromagnetic Interference
					Systems in Operation During Change Implementation
					Other
	PERFORMANCE ASSESSMENT				LOGISTICAL SUPPORT
	Performance Assessment Models				Logistic Support Plans
	Performance Assessment Computer Software and Models				Facilities
	Data Bases (e.g. RIB)				Utilities
	Other				Other
	QA/RA ACTIVITY DE-REGISTRATION				OTHER CONSIDERATIONS
	List of Items Important to Waste Isolation				Support Systems or Equipment
	Candidate List of Items & Activities Subject to the CALA Process				Personnel Requirements
	List of Items Important to Safety				Scale Plans
	Quality Activities List				Other
	CALA Records				
	QA Requirements Assignment Records				
	Other				
	LICENSING				
	Site License Application Activities				
	Environmental Impact Statement (EIS)				
	Person Papers				
	Survey Analysis Report				
	NRC Regulatory Compliance				
	Agreements with the NRC				
	Concurrences by the NRC				
	Other				
	PERMITTING				
	Environmental Clearance				
	Air Quality				
	Water Quality				
	Other				
	PROJECT PLANS & PROCEDURES				
	Project Milestones & Schedules				
	Project Plans				
	Project Management Plans				
	Project Administrative Procedures				
	Project Control (CMSS) Procedures				
	Project Procurement Procedures				
	Other				

Attachment 2 - Example of Technical Change Request, Change Impact Checklist, and Preparation Instructions (continued)

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**INSTRUCTIONS FOR PREPARATION OF TECHNICAL CHANGE REQUEST (TCR) FORM
Y-AD-082**

- | | |
|---|--|
| <p>Block 1. Control number (if any) for processing within the originating organization</p> <p>Block 2. TCR number obtained from the TAMSS CCD after signature by the TPO in Block 20</p> <p>Block 3. Brief descriptive title indicating the purpose of the TCR. For Field TCRs, begin with "FIELD CHANGE -".</p> <p>Block 4. Document number (if not original submitted)</p> <p>Block 5. Revision number of document submitted for change.</p> <p>Block 6. Brief description of title of document submitted for change.</p> <p>Block 7. Mark the box identifying the change classification for this change</p> <p>Block 8. Mark the box identifying the priority of this change in accordance with the following criteria:</p> <p>Emergency: (1) Correct a hazardous condition that may result in fatal or serious injury to personnel or in extreme damage or destruction of equipment, or</p> <p>(2) A change in operational characteristics that, if not accomplished without delay, may seriously compromise the functionality of the site.</p> <p>Urgent: (1) Correct a potentially hazardous condition, the uncorrected existence of which could result in injury to personnel or damage to equipment, or</p> <p>(2) Correct a condition that may seriously compromise mission effectiveness, or</p> <p>(3) An interface change or a change to meet contractual requirements that may cause schedule slippages or increase cost, or</p> <p>(4) A change that produces net life cycle savings to the government of \$100,000 or more.</p> <p>Routine: (1) All changes that do not fit the criteria for emergency or urgent</p> <p>Block 9. WBS element numbers that are known to be affected by the change.</p> <p>Block 10. Quality Assurance Designation of the activity associated with the document to be changed.</p> <p>Block 11. TCR numbers of any known related CTRs.</p> <p>Block 12. CI number of the CI to be changed, or associated with document changes. May be obtained from the TAMSS CCD or CTRs.</p> | <p>Block 13. CI numbers of the CIs affected by the change or associated with the change.</p> <p>Block 14. Parent document, assembly, drawing, or specification of the item to be changed. If not applicable, enter N/A.</p> <p>Block 15. Effectivity (i.e., identification of the units affected) of the change (i.e., all, serials 1 and 2, units 5 through 8, etc.) If not applicable, enter N/A.</p> <p>Block 16. Record which existing items should be reworked (e.g., installed as a modification lot) if not applicable, enter N/A.</p> <p>Block 17. Enter other documents affected by change.</p> <p>Block 18. Describe the proposed change in sufficient detail to permit ready identification and evaluation. Describe which part of the item or system is being changed and type of change being made. Provide supplemental diagrams and sketches as necessary to clearly portray the proposed change. Identify any applicable dimensions or values. If the proposed change is an interim solution, so state.</p> <p>Block 19. Describe (1) the problem the TCR corrects, or the new capability the TCR provides, (2) the nature of the defect, failure, incident, malfunction, etc., (3) substantiate the need for the change in detail. Identify and summarize any correspondence establishing requirements for the change and any testing accomplished prior to the submission.</p> <p>Block 20. Record the estimated cost or savings associated with implementing the proposed change. Describe the assumptions and basis for the estimate. Record the estimated schedule improvement or slippage. Describe the assumptions and basis for the estimate.</p> <p>Block 21. Record the estimated cost and schedule impact if the change is not incorporated in the Project Baseline. Describe the assumptions and basis for the estimate.</p> <p>Block 22. Mark the appropriate box if other known document changes are needed. If "yes" list the documents by title and identifying number.</p> <p>Block 23. List Attachments to the TCR by title, identifying numbers, and page counts.</p> <p>Block 24. Enter the name of the originating participant submitting change.</p> <p>Block 25. Enter name, telephone number, build, and date of individual submitting change.</p> <p>Block 26. Print the name and title of the submitting authority (TPO or Project Office Division Director). The submitting authority signs and dates.</p> <p>Block 27. Enter date received, name of processor, and date logged.</p> |
|---|--|

Attachment 2 - Example of Technical Change Request, Change Impact Checklist,
and Preparation Instructions (continued)

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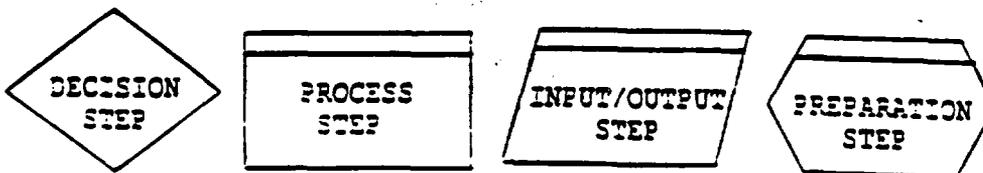
QUALITY MANAGEMENT PROCEDURE QMP-06-04 PROJECT OFFICE DOCUMENT DEVELOPMENT,
REVIEW, APPROVAL AND REVISION PROCESSES

INTRODUCTION

The guidelines presented in this attachment are applicable to the development of new Project Office procedures and Project-level plans. The Project Office Project Control Branch 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 flow diagram of the process is developed, then,
 - b. the flow diagram is used to develop the draft procedure.
2. Develop a flow diagram of the procedure process as follows:
 - a. Draw flow using the following symbols:



- 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 flow diagram.

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

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

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REVIEW, APPROVAL AND REVISION PROCESSES

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 Program 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 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:

<u>RESPONSIBLE PARTY</u>	<u>STEPS</u>	<u>PROCEDURE</u>
"WHO" (e.g., DIVISION DIRECTOR, or DD)	1.	"ACTIVITY" (task)

6.0 REFERENCES

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

7.0 FIGURES AND ATTACHMENTS

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

Attachment 3 - Project Office Procedure and Project-Level
Plan Preparation (continued)

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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 annotated outline 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 with content and format covered by external directives (such as DOE Order 4700.1), the originating organization develops an annotated outline in accordance with those directives.
 3. For plans not covered by external directives, annotated outlines are developed as follows:
 - a. Prepare the annotated outline 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.

Attachment 3 - Project Office Procedure and Project-Level
Plan Preparation (continued)

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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.

Attachment 3 - Project Office Procedure and Project-Level
Plan Preparation (continued)

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The following are the minimum development criteria for technical documents submitted to the Project Office for review, approval or acceptance:

- a. Identification of applicable source documents and requirements;
- b. Selection, review, approval and documentation of input and rationale for exclusion of specific inputs;
- c. Traceability of information used as input to the document and, where the criteria for qualification of existing data apply, verification of the validity of such information. (i.e., a Peer Review or Design Review might be required for data or Design Documents to be used as input);
- d. Traceability from input sources through the process steps to the final product;
- e. Translation of source information into a form suitable for use in the technical document;
- f. Level of detail necessary to permit correct application and structure of the technical document.

Attachment 4 - Technical Document Development Criteria

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DOCUMENT REVIEW SHEET				N-0A-041 4/90	
(Mark only applicable items) 1 Document Author/Originator: _____ 2 Document No.: _____ 2 Draft No.: _____ 3 Document Title: _____ Rev. No.: _____ 4 Comments Due Date: _____ 5 Name of Reviewer: _____ 6 Designee: _____ 7 Technical Discipline: _____ 8 Signature of Reviewer: _____ 9 Date _____ 10 Revised text has been verified and is acceptable: <input type="checkbox"/> Disputed items resolved Signature of Reviewer: _____ Date _____				5 TYPE OF REVIEW <input type="checkbox"/> Management* <input type="checkbox"/> Quality Assurance <input type="checkbox"/> Technical** <input type="checkbox"/> Regulatory* 6 Regulatory & Management Reviewers indicate recommendation for a Technical Review: <input type="checkbox"/> Yes <input type="checkbox"/> No 10 ** Technical Reviewers indicate recommendation for a Peer Review: <input type="checkbox"/> Yes <input type="checkbox"/> No NOTE: "Yes" recommendation must be identified as a major comment below	
11 REVIEWER'S COMMENTS <small>(Identify all Major Comments)</small>			12 AUTHOR'S/ORIGINATOR'S RESOLUTION		
No	Type	Page/Section/Gap	COMMENTS	REASONING	

Attachment 5 - Document Review Sheet

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DOCUMENT REVIEW CONTINUATION SHEET				N-QA-041 4/90	
1 ^a Document No.:		2 ^a Draft No.:		Rev. No.:	
3 ^a Document Title:		4 ^a Name of Reviewer:		5 ^a Date:	
11 REVIEWER'S COMMENTS <small>(Identify as Major or Minor)</small>			12 AUTHORITY/ORIGINATOR'S RESOLUTION		
1 ^b No	2 ^b Type	3 ^b Page/Section	4 ^b COMMENTS	5 ^b Initial & Date	
				Accept	Reject
			6 ^b REASONING		
			7 ^b Initial & Date		
			Accept	Reject	

Attachment 5 - Document Review Sheet (continued)

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INSTRUCTIONS FOR PREPARATION OF DOCUMENT REVIEW SHEET N-QA-041

A QRS is to be completed in typewritten form, or handwritten in black ink. Writing or typing must remain inside the border lines.

PROJECT CONTROL SEARCH

1. Enter the name(s) of the author and his/her organization.
2. Enter the document identification number as stated on the cover page of the document. Enter draft number (if applicable) or N/A.
3. Enter the document title and revision number.
4. Enter the comment due date.
5. Enter the type of review (as directed by the responsible CO).

Major Comment - Comment that the reviewer has determined requires resolution prior to document acceptance.

Minor Comment - Comment other than Major.

MANAGER REVIEWING ORGANIZATION/ODS/OCA/ESM

6. Enter name (print or type) of Reviewer or Designee.
7. Enter the technical discipline of the reviewer when qualified to perform a technical review (if appropriate).

REVIEWER

8. Reviewer sign name in black ink and enter date the review is complete.

NOTE: This signature constitutes verification by the reviewer that the review was completed using established criteria.

REGULATORY AND MANAGEMENT REVIEWERS

9. Check the appropriate box. If a "yes" box is checked, the recommendation shall be identified as a major comment in the Reviewer's Comments section of the QRS.

TECHNICAL REVIEWERS

10. Check the appropriate box. If a "yes" box is checked, the recommendation shall be identified as a major comment in the Reviewer's Comments section of the QRS.

REVIEWER

11.
 - a. Number each comment in sequential order beginning with 1.
 - b. Identify all major comments in Type column (Maj. may be used).
 - c. Enter the page number, and if available the section and line or para. in the document that contains the data being addressed in the comment.
 - d. Enter the comment. If additional space is required, continue the comment on a continuation page and indicate that the comment is continued.

NOTE: For comments minor or suggestive in nature, indicate as in "Type" column.

AUTHOR/ORIGINATOR

12. If the reviewer has documented a minor or suggestive comment that is not addressed, enter N/A.
 - a. Major comments must be addressed. Indicate accept or reject by entering your initials and the date in the appropriate column.
 - b. Enter the reason for the resolution. If more space is required an attachment shall be added. The attachment shall be referenced on the document review sheet. Attachments shall be numbered separately from the document review sheet. See #15 below.

REVIEWER

13. Indicate acceptance or rejection of the author's resolution for major comments by entering in your initials and the date in the appropriate column. Do not enter in additional comments.
14. Reviewer check the disputed items resolved box (if applicable and items resolved), then sign name in black ink and enter the date the verification is acceptable and complete. If this step is not applicable enter N/A. If it is unacceptable do not sign.

ORIGINATOR/AUTHOR AND REVIEWER

15. REVIEWER - Enter the specific page number beginning with Page 1, and the total number pages of comments.

AUTHOR/ORIGINATOR - If additional pages during the resolution process are added the additional pages shall be labeled "ATTACHMENT", and shall be numbered separately from the document review sheets. Enter the page number beginning with Page 1, and the total number pages of attachments. Attachments shall be attached to the document review sheets.

Attachment 5 - Document Review Sheet (continued)

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INTERIM CHANGE NOTICE		N-QA-023 4/90
ICN Number:	Effective Date:	Page of
Applies to:		
Number _____ Rev. _____ Title _____		
REQUIRED CHANGE(S): (Minor <input type="checkbox"/> Yes <input type="checkbox"/> No)		
<u>PARAGRAPH</u>	<u>CHANGE TO</u>	
APPROVALS		
Division Director	Director, QA	Project Manager
Date	Date	Date

Attachment 6 - Interim Change Notice (ICN) sheets

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Title

QUALITY MANAGEMENT PROCEDURE QMP-06-04 PROJECT OFFICE DOCUMENT DEVELOPMENT,
REVIEW, APPROVAL AND REVISION PROCESSES

INTERIM CHANGE NOTICE CONTINUATION PAGE			N-QA-023 4/90
ICN Number:	Applies to:	Effective Date:	Page of
REQUIRED CHANGE (S): (Minor <input type="checkbox"/> Yes <input type="checkbox"/> No)			
<u>PARAGRAPH</u>	<u>CHANGE TO</u>		
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Attachment 6 - Interim Change Notice (ICN) sheets (continued)

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YUCCA MOUNTAIN PROJECT PROCEDURE

Y-AD-001
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Title

QUALITY MANAGEMENT PROCEDURE QMP-06-04 PROJECT OFFICE DOCUMENT DEVELOPMENT,
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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 DOE 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 7 - Examples of Review Criteria

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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- or Project Office-prescribed processes, is the treatment of such processes consistent with that established direction?
4. Is document content consistent with established Headquarters 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 7 - Examples of Review Criteria (continued)

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

NOTE: Project Office Technical Reviews parallel Section 3.1.6 of the QAPD, DOE/RW-0215.

QUALITY ASSURANCE REVIEW CRITERIA

1. Does the document contain those quality assurance requirements applicable to the controls or processes it addresses? (A flowchart or checklist of applicable quality assurance 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 tolerances 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 7 - Examples of Review Criteria (continued).

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