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OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

QUALITY ASSURANCE PROCEDURE

Title: DOCUMENT REVIEW			
Procedure No.: QAP 6.2	Revision: 1	ICN:	Page 1 of 15
Approval: [signature]	Date: 7/1/93	Concurrence: [signature]	Date: 7/1/93

CHANGE HISTORY

Revision No.	Interim Change No.	Effective Date	Description of Change
0	-	05/18/92	Initial Issue
1	-	07/26/93	Revised to incorporate new requirements of OCRWM *Quality Assurance Requirements and Description* (QARD), DOE/RW-0333P, Revision 0. Incorporates standard review criteria for procurement documents previously identified in QAAP 7.1. Incorporates new QAP 5.1 format. Incorporates 1992 QAMA recommendation 10C to review documents for conflicts with other documents. Refer to DAR No. 009.

Add: Ken Hooks 1 Hr Encl
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102.8
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1.0 PURPOSE

This procedure provides a process for the review of documents and resolution of review comments. This process represents the minimum process required and may be supplemented by Local Procedures.

2.0 APPLICABILITY

This procedure applies to individuals who participate in the review of documents for the Office of Civilian Radioactive Waste Management (OCRWM). This procedure is implemented when documents governing quality assurance program procedures, procurement-related documents, or other documents invoke its use or when directed by OCRWM management.

3.0 DEFINITIONS

3.1 *Governing Document* - The document requiring that this procedure be implemented for a particular review.

3.2 *Mandatory Comment* - A comment requiring resolution that identifies and describes (a) conflicts with existing OCRWM requirements, (b) failure to meet stated review criteria, or (c) inadequacies or errors that could adversely impact the suitability of the document for its intended purpose.

3.3 *Review Coordinator* - The OCRWM Associate, Office, or Division Director assigned the responsibility for developing a specific document or the individual designated to accept, for OCRWM, documents submitted by another affected organization.

4.0 RESPONSIBILITIES

4.1 The Director, Office of Quality Assurance (OQA) is responsible for the preparation, change, and approval of this procedure.

4.2 Individuals having responsibilities for implementing this procedure are:

a) Review Coordinators
b) Document Reviewers

Those responsibilities are described in the process outlined in Section 5.0.

5.0 PROCESS

A brief overview of this process is depicted in the flowchart shown in Attachment 9.1.

5.1 INITIATING DOCUMENT REVIEW

The Review Coordinator:

a) initiates the Document Review Record (DRR) (Exhibit QAP-6.2.1) and Comment Sheet (Exhibit QAP-6.2.2) using the instructions provided;

b) determines the review criteria as outlined in Subsection 6.1 including standard review criteria and any additional review criteria specific for the document being reviewed and documents these criteria on the DRR;

c) identifies the organizations or disciplines required to review the document as outlined in Subsection 6.2;

d) identifies the applicable review criteria for each reviewer on the DRR;

e) establishes a reasonable due date for return of the DRRs and Comment Sheets; and

f) signs, dates, and forwards to the reviewing organizations or disciplines, the DRR and Comment Sheet with the document, any referenced exhibits or attachments, and any pertinent background information not readily available to the reviewers.

5.2 DOCUMENT REVIEW

The Document Reviewer:

a) performs the document review using the assigned review criteria to determine the acceptability of the document;

b) records comments or indicates that there are no comments on the Comment Sheet;

c) identifies mandatory comments with an asterisk (*) and identifies nonmandatory comments with a code letter (n);

d) signs the REVIEW COMPLETED BY block on the DRR indicating that the review criteria have been read, understood, and used in completing the document review; and

e) returns the DRR and Comment Sheets to the Review Coordinator.

5.3 COMMENT RESOLUTION

5.3.1 The Review Coordinator:

a) reviews returned comments for possible incorporation into the document;

b) develops responses to comments as outlined in Subsection 6.3;

c) ensures that the document is modified as indicated in the responses to the comments; and

d) forwards the modified document and copies of all DRRs and Comment Sheets with responses to the Document Reviewers for acceptance of responses to mandatory comments and concurrence that the updated document is suitable for the intended purpose.

5.3.2 The Document Reviewers:

a) review the updated document and comment responses;

b) indicate agreement with the responses to their own mandatory comments by initialing and dating the ACCEPT block on the Comment Sheet adjacent to the appropriate response. If a response to a mandatory comment is not acceptable, reviewers leave the accept column blank adjacent to the unacceptable response and return the DRR and Comment Sheets to the Review Coordinator for processing in accordance with Paragraph 5.3.3;

c) sign and date the CONCURRENCE block on the DRR indicating that the updated document is suitable for the intended purpose or document the mandatory comment that forms the basis for withholding concurrence; and

d) return the DRRs and Comment Sheets to the Review Coordinator.

5.3.3 The Review Coordinator:

a) reviews the returned DRRs and Comment Sheets to ensure that all responses to mandatory comments have been accepted and all concurrence signatures obtained;

b) attempts to negotiate an acceptable response with the reviewer if any items are unresolved;

c) directs a dispute to progressively higher levels of management until resolution is obtained when the parties are unable to agree upon resolution for a mandatory comment;

d) reobtains concurrence, from affected reviewers, if additional changes, other than editorial corrections are made to the document during the comment resolution process; and either

e) continues processing documents requiring a change control board review in accordance with Subsection 5.4; or

f) completes the processing of the document, including processing of QA records, in accordance with the governing document following resolution of all mandatory comments and receipt of all concurrence signatures.

5.4 CHANGE CONTROL BOARD REVIEW

The Review Coordinator:

a) processes a final draft, marked "Change Control Board Review Draft", to the board for review and comment; and either

b) completes the processing of the document, including processing of QA records, in accordance with the governing document if board approval is obtained; or

c) performs a documented evaluation of board comments to determine which comments affect the technical content of the document and must be incorporated and which additional comments will be incorporated;

d) ensures that resolution to all board comments affecting technical content of the document are incorporated into a new draft along with any other appropriate changes; and

e) initiates a re-review of the changes to the document, by any disciplines or organizations affected by the changes, in accordance with Subsection 5.1.

6.0 SUPPORTING DETAIL

6.1 DOCUMENTS SUBJECT TO REVIEW

6.1.1 QUALITY ASSURANCE PROGRAM PROCEDURES

QAP 5.1, *Quality Assurance Program Procedures*, requires that newly developed quality assurance program procedures and changes to those procedures be subject to review in accordance with this procedure. Standard review criteria provided in Attachment 9.2 shall be identified on the DRR. Additional review criteria are not normally required for quality assurance program procedures.

6.1.2 QUALITY ASSURANCE REQUIREMENTS DOCUMENTS

When required by procedures governing their development, documents that specify quality assurance requirements are subject to review in accordance with this procedure. Standard review criteria provided in Attachment 9.2 shall be identified on the DRR. Additional review criteria are added as needed for the document subject to review.

6.1.3 TECHNICAL DOCUMENTS

Technical documents developed in accordance with QAP 3.5, *Technical Document Preparation*, are subject to review in accordance with this procedure. Review criteria identified in the TDPP developed in accordance with QAP 3.5 shall be identified on the DRR. These review criteria may include the standard review criteria provided in Attachment 9.2 and/or additional review criteria identified in the TDPP. Additional review criteria specific to the document being reviewed may also be added to the DRR.

6.1.4 PROCUREMENT DOCUMENTS

When required by procedures governing their development or change, procurement documents are subject to review in accordance with this procedure. Standard review criteria provided in Attachment 9.2 shall be identified on the DRR along with any additional review criteria as needed for the specific document subject to review.

6.1.5 DOCUMENTS SUBMITTED BY OTHER AFFECTED ORGANIZATIONS

When OCRWM review and acceptance of documents submitted by an affected organization is required by the QARD, the review is performed in accordance with this procedure. These documents should be completed and approved by the supplier prior to submittal for OCRWM review. The Review Coordinator may invoke the standard review criteria in Attachment 9.2 and/or any additional review criteria specific to the document being reviewed, including any acceptance criteria identified or referenced in the OCRWM procurement documents. The Review Coordinator must select only those review criteria that would apply to the document being reviewed. For example, criteria concerning the format of an OCRWM document would not be applied to the supplier's document.

6.1.6 OTHER DOCUMENTS

OCRWM organizations may elect to use this procedure for the review of other types of documents not described above. Standard review criteria provided in Attachment 9.2 should be specified as applicable, and the Review Coordinator develops any additional criteria appropriate for the document subject to review.

6.2 SELECTION OF REVIEWERS

6.2.1 For the initial issue of a document, each organization or discipline affected by the document shall be required to review the document. Governing documents may identify organizations or disciplines required to review a specific document. The Review Coordinator selects additional organizations or disciplines if needed to encompass all areas of expertise covered in the document subject to review. The Office of Quality Assurance is included among the required reviewers whenever the document subject to review establishes QA requirements or prescribes work subject to QARD requirements. In addition, for the initial issue of a Local Procedure (LP) that supplements a Quality Assurance Procedure (QAP), the Responsible Director for the QAP is included among the required reviewers.

6.2.2 For changes to documents, only those organizations or disciplines affected by the change are required to review the document. However, the Office of Quality Assurance shall review changes to documents if they reviewed the previous version, regardless of whether they are affected by the change. In addition, for changes to a LP that supplements a QAP, the Responsible Director for the QAP is included among the required reviewers regardless of whether his organization is affected by the change.

6.2.3 Appropriate review criteria are designated for each reviewing organization or discipline. For example, when reviewing a technical document, some organizations may be assigned to review for technical adequacy, others for compliance with QA requirements, and others for management concerns.

6.2.4 All reviewers shall have documented evidence of required training and experience, and access to appropriate background information to ensure the adequacy of the review. The Review Coordinator shall require that reviewers from external organizations who have qualifications documented in accordance with their own OCRWM-accepted QA program provide a statement to OCRWM indicating that their qualifications have been evaluated and are acceptable.

6.2.5 All sections of the document shall receive an independent review; reviewers shall not review any portion of a document that they directly participated in developing, or were responsible for preparing.

6.3 COMMENT RESOLUTION

6.3.1 The Review Coordinator is responsible for ensuring that responses to mandatory comments are documented on the Comment Sheets and obtaining acceptance of the Document Reviewer. Comments may be provided by reviewers other than the designated reviewers, however, these comments will be considered non-mandatory and resolution of these comments is not required. The Review Coordinator may change the designation of comments incorrectly designated as mandatory, providing justification for the change in the RESPONSE block, and obtaining the acceptance of the Document Reviewer.

6.3.2 For documents submitted by another affected organization, the Review Coordinator may require the organization to resolve comments that have not been designated mandatory by the OCRWM reviewers.

6.3.3 Each comment is considered during the comment resolution process. The Review Coordinator responds to non-mandatory comments as time permits and provides information copies of those responses to the Document Reviewer. Responses to non-mandatory comments, if provided, do not require acceptance of the Document Reviewer.

6.3.4 Comments returned after the due date will be considered by the Review Coordinator if possible; however, those that are not considered are returned to the reviewer. The reviewer may then elect to request further changes in accordance with the governing document or other appropriate means.

7.0 QUALITY ASSURANCE RECORDS

If "Q" is indicated in Block 1 of the DRR, then the documents listed in Subsections 7.1 and 7.2 shall be collected and maintained as QA records in the QA Records Package generated in accordance with the governing document and in accordance with QAAP 17.1, *QA Records Management* or AP-1.18Q, *Records Management: Las Vegas Record Source Responsibilities*. If no governing document exists, the documents listed in Subsections 7.1 and 7.2 shall be collected and maintained in a QA Records package in accordance with QAAP 17.1, *QA Records Management* or AP-1.18Q, *Records Management: Las Vegas Record Source Responsibilities*.

7.1 LIFETIME QUALITY ASSURANCE RECORDS

No lifetime QA records are generated as a result of implementation of this procedure.

7.2 NONPERMANENT QUALITY ASSURANCE RECORDS

Completed DRRs and copies of the documents reviewed (approved documents or review drafts) shall be designated as nonpermanent quality assurance records. Documented evidence of the qualifications of external reviewers shall also be designated as nonpermanent quality assurance records and shall have the same retention schedule as the document review records.

8.0 REFERENCES

8.1 *Quality Assurance Requirements and Description* (QARD), DOE/RW-0333P

9.0 ATTACHMENTS

9.1 QAP 6.2 FLOWCHART

9.2 STANDARD DOCUMENT REVIEW CRITERIA

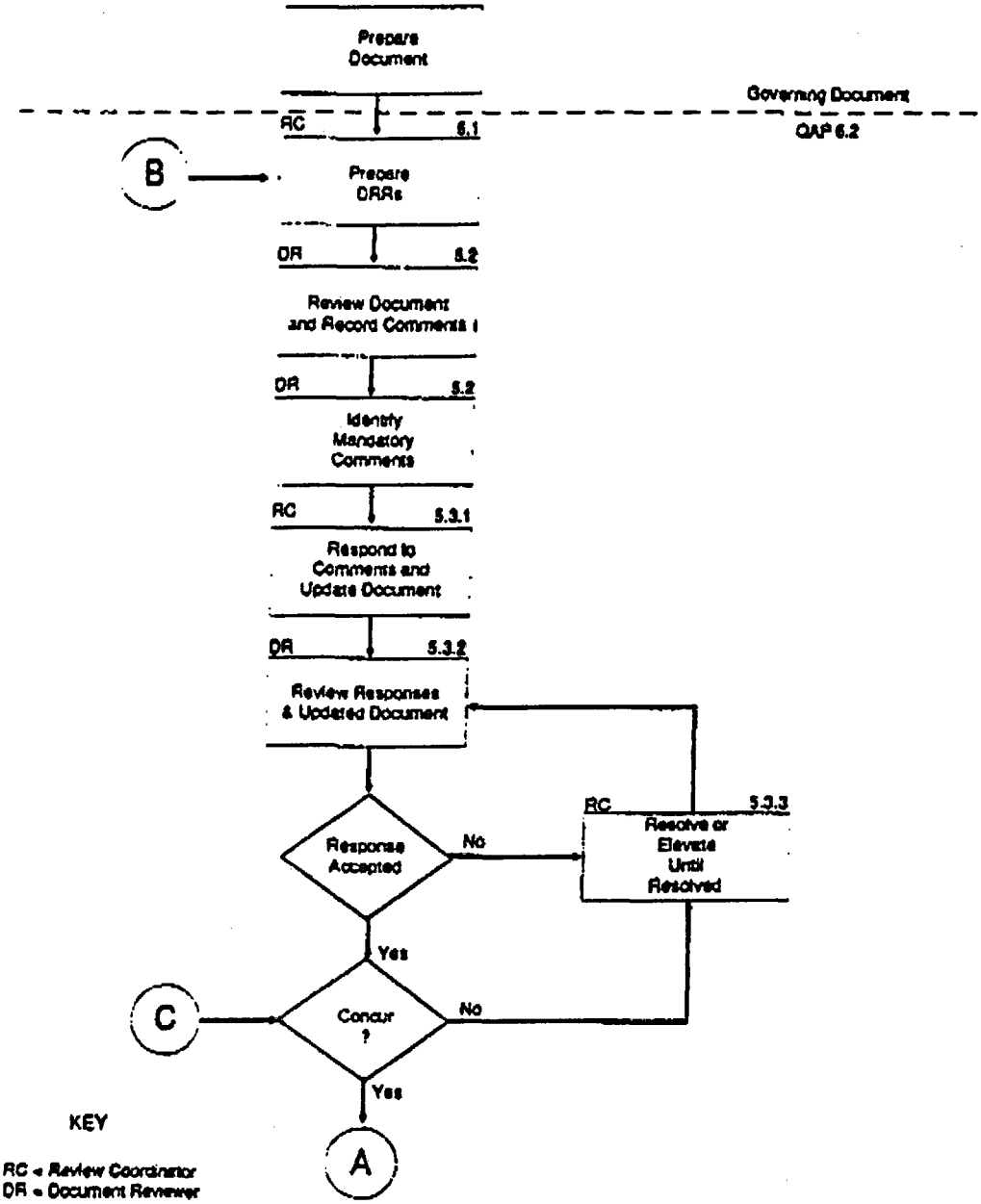
10.0 EXHIBITS

Exhibits are controlled separately from this procedure. Exhibits may be copied for use when implementing this procedure. Alternative formats may be substituted provided that the alternate format is suitably controlled to ensure that all information shown on the exhibit is included. Exhibits referenced in this procedure include:

Exhibit QAP-6.2.1 - Document Review Record (DRR)
Exhibit QAP-6.2.2 - Comment Sheet

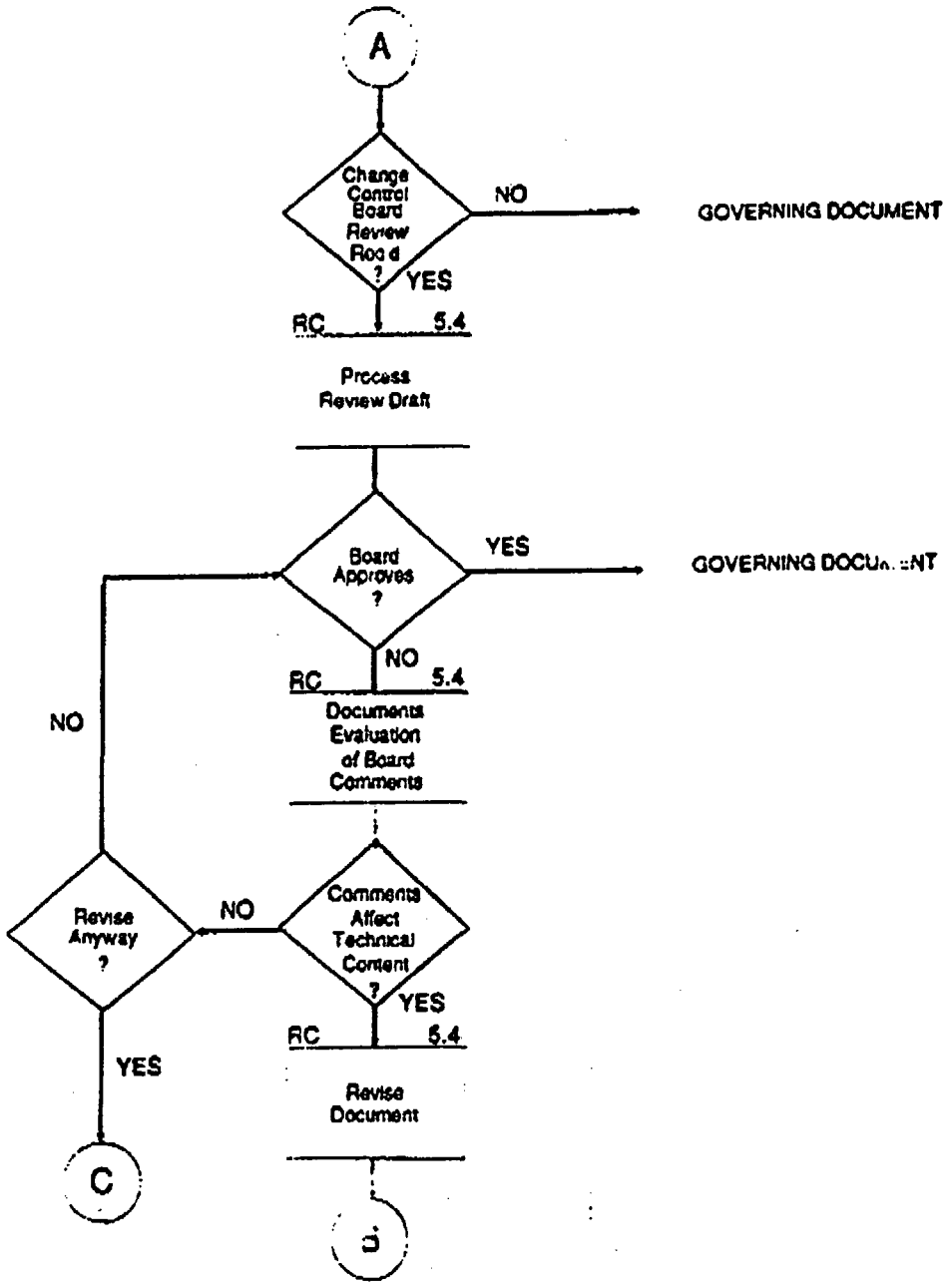
ATTACHMENT 9.1

QAP 6.2 FLOWCHART



ATTACHMENT 9.1 (continued)

QAP 6.2 FLOWCHART



ATTACHMENT 9.2
STANDARD DOCUMENT REVIEW CRITERIA

These standard review criteria are used as applicable to determine the acceptability of the document reviewed:

1.0 MANAGEMENT REVIEW CRITERIA

1.1 Does any change to existing policy expressed in the document represent a deliberate and appropriate decision?

1.2 When the document affects the reviewing organization, are management and administrative impacts acceptable?

1.3 Are processes as straight forward and simple as feasible?

1.4 Is the document user friendly, or could it be further simplified or reorganized into a more consistent, logical order?

1.5 Does the document avoid elevating administrative convenience to a requirement level?

1.6 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?

1.7 Are the purpose and scope of work clearly specified?

1.8 Are the activities, documents, materials, or data and the individuals or organizations to which the document applies adequately described?

1.9 Are all individuals or organizations responsible for implementing the document delineated?

1.10 Are the responsibilities clearly delineated and in accordance with established organizational divisions of responsibility or as established in approved procurement documents?

1.11 Are the requirements delineated in the document implementable?

1.12 Are terms defined adequately to ensure consistent interpretation of the document?

1.13 Are all the supporting details necessary and sufficient?

1.14 Does the document use the required content, format, and style?

1.15 Do the exhibits specify the minimum information required?

1.16 Are all the exhibits and attachments consistent with the document being reviewed?

ATTACHMENT 9.2 (continued)
STANDARD DOCUMENT REVIEW CRITERIA

1.17 Are all actions requested in approved DARs incorporated?

1.18 Has the document change history and referenced DAR been reviewed to ensure that the proposed change does not conflict with a previously implemented requirement?

1.19 Have the correct organizations or disciplines been assigned to review the document? Are the review criteria adequate and correct?

1.20 Has the document been reviewed to ensure that it does not conflict with other documents?

2.0 TECHNICAL REVIEW CRITERIA

2.1 Is the document prepared in accordance with the TDPP?

2.2 Are document input sources appropriate, current, correct, and useable? Do the inputs meet applicable requirements for qualified data?

2.3 Are any assumptions used in the development of the technical document stated explicitly? Are they reasonable?

2.4 Is document content consistent with established OCRWM objectives?

2.5 In the case of a design document, is the design approach compatible with OCRWM objectives and constraints and with prescribed systems engineering requirements?

2.6 Are calculations sufficiently detailed such that a technically qualified person can understand the analysis?

2.7 Have the computer programs required by the technical document been verified?

2.8 When applicable, are potential interactions with other technical work addressed adequately?

2.9 Are analytical and design approaches and results reasonable and appropriate?

2.10 Does the final document correctly incorporate technical input? Is there adequate, complete, accurate and traceable flow of requirements from source documents to the final document?

2.11 If referenced standards contain conflicting requirements, is the requirement that governs designated?

2.12 If the technical document is for design purpose, are the following requirements evident: basic functions of items, performance, regulatory, technical, security, and safety

ATTACHMENT 9.2 (continued)
STANDARD DOCUMENT REVIEW CRITERIA

2.13 Are applicable interfaces identified and documented such as for work performed in sequence or for product received from another affected organization?

2.14 Are the responsibilities for interface requirements delineated?

2.15 If there are any constraints on required interfaces, are they described adequately?

2.16 Are any unverified portions of design documents clearly identified as such?

2.17 Are units of measure consistent, compatible, and appropriate?

2.18 Does the document contain qualitative and quantitative data, and if so, are any necessary tolerances and parameters provided for this data?

3.0 QUALITY ASSURANCE REVIEW CRITERIA

3.1 Are specified responsibilities and authority consistent with OCRWM policy or other applicable requirements?

3.2 When applicable, does the document provide for involvement of the QA organization?

3.3 Are terms that are defined in the QARD used in a context consistent with QARD definitions?

3.4 Are all QA Records to be generated during the implementation of the document identified and correctly classified? Is the procedure for handling those QA records identified? Is the responsibility for submitting records to the records management system clearly delineated?

3.5 Do the process and controls defined adequately, completely, accurately and correctly address the applicable QA requirements?

3.6 Is the item or activity to which the document applies clearly identified?

3.7 Is there adequate traceability of information used as input to the document?

3.8 Are methods for qualifying any unqualified input specified? Is qualification to be tracked?

3.9 Are the applicable requirements of the source documents incorporated into the document? For a Local Procedure (LP) that supplements a Quality Assurance Procedure (QAP), does the LP correctly and completely incorporate the content of the QAP that it supplements?

3.10 Does the document include or reference appropriate quantitative and qualitative acceptance criteria for determining that prescribed processes have been satisfactorily accomplished?

ATTACHMENT 9.2 (continued)
STANDARD DOCUMENT REVIEW CRITERIA

3.11 Are adequate, complete, and correct technical requirements identified including drawings and specifications; codes, standards, and regulations; technical acceptance criteria; and traceability requirements, where appropriate?

3.12 Are the technical and quality assurance program deliverables, including QA records, required to be generated and submitted completely and clearly specified?

4.0 PROCUREMENT DOCUMENT REVIEW CRITERIA

4.1 Is the scope of work clearly specified?

4.2 Are adequate, complete, and correct technical requirements identified, including drawings and specifications; codes, standards and regulations; acceptance criteria; and traceability requirements, where appropriate? If applicable, are revision levels or change status of these documents identified?

4.3 Are adequate, complete, and correct quality assurance requirements appropriate to the scope of work identified as outlined in applicable procurement procedures?

4.4 Do procurement documents require the supplier to submit an implementing document on organization and a matrix indicating where applicable QARD requirements are addressed or a documented quality assurance program implementing the appropriate or specified portions of the QARD, for OCRWM acceptance prior to the start of work? If the supplier is not required to submit either of the above, does the procurement document require that the supplier work to the specific sections and implementing procedures of the OCRWM QA program?

4.5 Do the procurement documents require the supplier to incorporate the appropriate quality assurance program requirements in subtier procurements?

4.6 Do the procurement documents contain provisions for access by OCRWM (or designee authorized by OCRWM) to the supplier's facility and records for audit and surveillance to verify compliance with QA requirements?

4.7 Do the procurement documents contain provisions for establishing hold points (such as provisions for performance of readiness reviews, when applicable) beyond which work may not be initiated or continued without purchaser authorization?

4.8 Have the items or services required to be provided by the supplier been completely and clearly specified?

4.9 Has adequate acceptance criteria for each item or service been identified?

ATTACHMENT 9.2 (continued)
STANDARD DOCUMENT REVIEW CRITERIA

4.10 Do the procurement documents specify the records to be developed by the supplier and submitted to OCRWM for information or review and acceptance? Are record storage requirements, retention times and turnover or disposition requirements and schedules identified?

4.11 Have methods for the disposition of items or services that do not meet procurement document requirements been established between OCRWM and the supplier?

4.12 For procurement of items, have any necessary spare or replacement parts or assemblies been identified? If spare parts or assemblies are identified, has the technical and quality assurance information required for ordering been included?

4.13 Are the procurement documents composed in an appropriate form such that they are contractually and legally binding on both parties?

5.0 EXTERNAL COMMITMENT REVIEW CRITERIA

5.1 Is the document content consistent with applicable regulatory requirements?

5.2 Does the document content affect existing regulatory or other external commitments and is it consistent with such commitments?

5.3 If the document makes any commitment or addresses a topic of regulatory interest, is it consistent with OCRWM policy?

5.4 If the document will meet a formal submittal requirement, does format and organization of material comply with submittal requirements?

5.5 Is there any contradiction between the document, DOE orders, regulatory requirements or commitments?

QUALITY ASSURANCE PROCEDURE

6.2 REV. 1

The following number is for OCRWM records management purposes only and should not be used when ordering this publication.

Accession No.: HQ0.930706.0002

PAGE 1 OF 1
DAR No. 009

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.

DOCUMENT ACTION REQUEST

Signature on this document represents the signer's acknowledgment that the applicable procedure has been read, understood, and complied with.

SECTION I - Action Request

[1]DOCUMENT TITLE:	[2]DOCUMENT NO.	[3]REV/ICN (current)	[4] ☒Q ☐Non-Q
Document Review	QAP 6.2	0	

[5]TYPE OF ACTION REQUESTED: ☐ Develop New Document ☒ Change Existing Document ☐ Cancel Document

[6]DESCRIPTION OF ACTION REQUESTED:

1) Allow only orgs affected by document or a change as required reviewers. Require ext'l reviewers to document qualifications (CAR 93-007)
2) Add review of rev. history and reqmt flowdown (DAR 006 & CAR HQ-92-012) to std. review criteria.
3) Add Standard Review Criteria for procurement docs.
4) Incorporate new QAP 5.1 format/content
5) Add interface with PCCB

[7]DOCUMENTS AFFECTED:

QAAP 7.1, Revision 1 - delete review criteria from Attachment II

[8]REASON FOR ACTION REQUESTED:

Incorporate the requirements for document review specified in section 2.2.9 of the DOE/RW-0333P QARD, Revision 0.

Incorporate Corrective Action from CARs HQ-92-012 (See DAR 006) and HQ-93-007.

[9]RELATED REPORT NUMBER:

CARs HQ-92-012, HQ-93-007

[10]REQUESTED BY:

Patricia White
Print Name

CER — 703-276-9300
Organization — Phone No.

Signature — 3/11/93 Date

SECTION II - Action Initiation

[11]REQUEST: ☒Approved ☐Rejected	[12]MAJOR CHANGES: ☒Yes ☐No	[13]PRIORITY: ☒Immediate ☐Hold
[14]MODIFICATION METHOD: ☐ICN ☒Revision ☐Cancel ☐N/A		[15]CCB ACTION: ☐Yes ☒No

[16]COMMENTS:

[17]PREPARER ASSIGNED:	[18]RESPONSIBLE DIRECTOR:
Patricia White, CER	R.W. Cl for — 3/1/93 (Signature — Date)

SECTION III - Action Review

[19]RECOMMENDED TRAINING: ☐Read ☒Follow Initial Assignment ☐N/A

☐Other: _____ No. of Days Required: 5

[20]TRAINING:	[21]RESPONSIBLE DIRECTOR:
Christine M. Yukawa 6-18-93 (Signature — Date)	3/1/93 (Signature — Date)

Exhibit 5.1.1