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OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT QUALITY ASSURANCE ADMINISTRATIVE PROCEDURE

TITLE: ESTABLISHING QUALITY ASSURANCE CONTROLS			
Procedure No.: QAAP 2.3	Revision: 0	Date: 6/19/89	Page: 1 of 16
Director, OCRWM Date: 5/5/89		Director, OQA Date: 5/9/89	

1.0 PURPOSE

The purpose of this procedure is to delineate the process for determining whether requirements of the QAR document (QARD) are applicable to work performed by OCRWM and for specifying the quality assurance (QA) controls that are to be implemented for all work.

2.0 SCOPE

This procedure applies to and shall be used to plan and manage all work within OCRWM. OCRWM-managed PROGRAM participants who perform work in accordance with their respective QA programs shall establish QA controls as specified in documents prepared by OCRWM in accordance with QAAP 4.2, "Establishing Procurement Quality Assurance Controls."

3.0 REFERENCES AND DEFINITIONS

3.1 REFERENCES

3.1.1 "Quality Assurance Requirements for the Civilian Radioactive Waste Management Program," (QAR), DOE/RW-0214, 1988.

3.1.2 "Quality Assurance Program Description for the Civilian Radioactive Waste Management Program," (QAPD), DOE/RW-0215, 1988.

3.2 DEFINITIONS

3.2.1 The definitions of standard terms may be found in the Glossary contained in reference 3.1.1.

3.2.2 PROGRAM - U.S. Department of Energy's Civilian Radioactive Waste Management Program.

3.2.3 Function - An OCRWM office responsibility directed towards satisfying PROGRAM objectives consistent with those approved by the Director, OCRWM, and the Assistant Secretary, Management and Administration in accordance with DOE orders and procedures.

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3.2.4 Work - An activity or set of activities having clearly defined products or expected results that are undertaken by an OCRWM office to satisfy a function.

3.2.5 Task - A work subelement assigned to or expected of OCRWM or other PROGRAM participants.

3.2.6 Design Activities - Activities related to the design process including data collection and analyses that are used to support design development and verification.

3.2.7 QA Controls - QAAPs, IIPs, and other DOE documents identified by the QA Program to be implemented in the conduct of work to assure the achievement of quality.

3.2.8 Radiological Safety - For the purposes of this procedure, the safety of workers or the public from exposure to radiation from high-level radioactive waste.

3.2.9 Work Breakdown Structure (WBS) - A structure which logically defines the relationships of work products or elements to each other and to the total radioactive waste management system.

4.0 RESPONSIBILITIES

4.1 DIRECTOR, OCRWM

The Director, OCRWM, or designee is responsible for function definitions and, if necessary, work and task definitions and associated QA Controls Matrices and QA Controls Basis Sheets for the Office of the Director. The Director, OCRWM, or designee is also responsible for approval of the QA Controls Document that will be developed in accordance with Section 6.0.

4.2 ASSOCIATE DIRECTORS

The Associate Directors or designees are responsible for function definitions, and, if necessary, work and task definitions and associated QA Controls Matrices and QA Controls Basis Sheets for their Offices.

4.3 DIRECTOR, OQA

The Director, OQA, or designee is responsible for function definitions and, if necessary, work and task definitions and associated QA Controls Matrices and QA Controls Basis Sheets for the Office of Quality Assurance. The Director, OQA, or designee is also responsible for reviewing the QA Controls Document, concurring with the QA Controls Basis Sheets, and issuing and controlling the QA Controls Document.

4.4 ASSOCIATE DIRECTOR FOR PROGRAM ADMINISTRATION AND RESOURCES MANAGEMENT

The Associate Director for Program Administration and Resources Management (ADPARM) or designee is responsible for developing, coordinating, securing approval of, and maintaining current OCRWM mission and function statements.

5.0 GENERAL

5.1 Planning for the application of appropriate QA procedural controls to assure the quality of items and activities required for the achievement of PROGRAM objectives is required by the QARD and QAPD. To effectively plan and selectively apply QA procedural controls for work (also known as "grading"), work products must be clearly defined. Only then can a determination be made whether or not the work needs to be conducted in accordance with the QARD requirements and which procedural controls are applicable.

5.2 Determining whether QA requirements must be applied to work and the specific procedural controls to be applied is a management responsibility. The most important decision is whether the work is subject to QARD requirements and the most difficult decisions involve the selection of appropriate QA procedural controls. As a minimum, the following OCRWM work shall be considered subject to the QARD requirements:

5.2.1 Design activity work or site characterization work for those elements directly related to radiological safety and waste isolation and directly associated with siting, design, or construction of items and activities for processing, handling, transportation, storage, or disposal of spent nuclear fuel or high-level waste; and

5.2.2 Work that is direct input into the license application or the radiological safety sections of the environmental impact statement or indirectly supports the technical arguments in the license application or the radiological safety sections of the environmental impact statement.

5.3 The selective application of QA procedural controls (grading) shall depend upon the type of work being conducted and its purpose or use. The following factors may be considered when specifying QA procedural controls:

5.3.1 Consequence of failure;

5.3.2 Importance of data;

5.3.3 Complexity of function;

5.3.4 Reliability of data or product;

5.3.5 Reproducibility of data;

5.3.6 Uniqueness of product;

5.3.7 Degree of functional product demonstration;

5.3.8 Degree of standardization in industry;

5.3.9 History of quality;

5.3.10 Impact on schedule or cost or both;

5.3.11 Impact on environmental quality;

5.3.12 Impact on occupational health and safety;

5.3.13 Impact on public health and safety;

5.3.14 Impact on safety and waste isolation;

5.3.15 Need for special controls or processes; and

5.3.16 Significance to the licensing process.

5.4 Specifying QA procedural controls requires both the identification of existing procedures that need to be implemented and the identification of new substitute or alternative procedures that need to be developed to control the work. This process may include the specification of applicable DOE Orders.

5.5 The QARD establishes the minimum number of audits to be conducted for work performed in accordance with QARD requirements. For planning, the actual number of audits and frequency and scheduling of QA surveillances shall be determined through discussions between the Director, OQA, and the Director, OCRWM, or the Associate Directors. Decisions made during these discussions shall be documented on Attachment III, QA Controls Basis Sheet. This information provides the Director, OQA, with information concerning work that is being implemented within OCRWM and shall assist the Director, OQA, in planning OQA activities and identifying needed resources to meet OQA audit and surveillance commitments.

5.6 QAPD Sections 8 through 15 have not been included on Attachment IV, QA Controls Reference, because those Sections are applicable to the control of items. The QAPD states that work requiring controls from these sections will be delegated by OCRWM to Project Offices and other PROGRAM participants.

6.0 PROCEDURE

OCRWM Program activities and associated QA controls shall be identified in a QA controls document. The QA Controls Document shall provide descriptions of each Office's applicable function, work, or task definitions and identify the applicable QA controls to be implemented. The QA Controls Document shall be formatted as outlined in Attachment I, Format for QA Controls Document and prepared in accordance with the following subsections.

6.1 RESPONSIBILITY DEFINITION

The Director, OCRWM; the Director, OQA; and the Associate Directors shall develop descriptions of their assigned responsibilities at a function and, if necessary, a work or task level. These descriptions shall be at the level of detail required to 1) define the purpose and outputs; and 2) identify the applicable QA controls that are necessary to assure the achievement and verification of quality requirements. These descriptions shall be consistent with approved mission and function statements.

6.2 QA PROGRAM APPLICABILITY

For each description that shall have applicable QA requirements and QA controls specified, a determination of the applicability of the QARD shall be made in accordance with Subsection 5.2. The results of, and the basis (that is justification) for, the determination shall be documented on Attachment II, QA Controls Matrix and Attachment III, QA Controls Basis Sheet, respectively.

6.3 APPLICABLE QA CONTROLS

The QA controls applicable to each description shall be identified and documented as follows:

6.3.1 QARD REQUIREMENTS ARE APPLICABLE

When the QARD is applicable, the QAPD shall be implemented. This shall be documented on the associated QA Controls Matrix form. The applicability of QAPD Subsections and associated QA controls are established as follows:

- The asterisked QAPD subsections (requirements) listed on Attachment IV, QA Controls Reference are always applicable.
- The applicability of QAPD Subsections 3, 4, and 7 is dependent on the scope of the defined function, work, or task and must be separately evaluated in accordance with Subsection 5.3. The applicability of these Subsections shall be documented on the associated QA Control Matrix form.

- The applicability of the QA controls (QA Program documents) associated with the applicable QAPD Subsections is also dependent on the scope of the defined function, work, or task and must be separately evaluated in accordance with Subsection 5.3. The applicable QA controls shall be documented on the associated QA Controls Matrix form.

- In those cases where QA controls and QAPD Section 3, 4, and 7 are not applicable, a justification shall be documented on Attachment III, QA Controls Basis Sheet.

- A review of the existing and planned QA controls shall also be performed to determine if they provide sufficient QA controls to satisfy the applicable QA program requirements. When additional or alternate QA controls are required, these QA controls shall be identified on the QA Controls Matrix form. The Office identifying the need for additional or alternate QA controls shall either develop the necessary QA controls or take the actions necessary to have the QA controls developed. Additional or alternate QA controls shall be developed and implemented in accordance with existing QA program requirements and on a timely basis, commensurate with work or task schedules.

- Based on a review of the purpose, scope, and relative program importance of the function, work, or tasks; plans for QA surveillances and audits shall be developed and documented on Attachment IV, QA Controls Basis Sheet.

6.3.2 QARD REQUIREMENTS ARE NON-APPLICABLE

- When the QARD is non-applicable, the implementation of the QAPD is not required. This is documented on the associated QA Controls Matrix. The QAPD subsections, QA controls on Attachment IV, and the considerations in Subsection 5.3 may be used as guidance to determine if any QA controls or requirements are necessary. These QA controls or requirements are documented on the associated QA Controls Matrix form.

- When additional or alternate QA controls are necessary, these QA controls are documented on Attachment II, QA Controls Matrix. The Office identifying the additional or alternate QA controls shall ensure that the QA controls are developed and implemented. Justification for not specifying an identified QA control found on Attachment IV is not required.

- Based on a review of the purpose, scope, and relative program importance of the function, work, or tasks; the need for QA surveillances and audits shall be evaluated and the evaluation results documented on Attachment IV, QA Controls Basis Sheet.

6.4 QA CONTROLS DOCUMENT PREPARATION

Each Office shall submit function, work, and task definitions; associated QA Controls Matrices; and QA Controls Basis Sheets to OQA for incorporation into the QA Controls Document.

6.5 QA CONTROLS DOCUMENT REVIEW AND APPROVAL

6.5.1 ADPARM shall review and concur with the function, work, and task definitions for conformance to approved mission and function statements.

6.5.2 The Director, OQA, shall review the QA Controls Document in accordance with QAAP 2.5, "Quality Assurance Program Document Review." The Director, OQA, shall concur with and sign the QA Controls Basis Sheets. OQA concerns with the QA Controls Basis Sheets shall be resolved as specified in QAAP 2.5, "QA Document Review."

6.5.3 The Director, OCRWM, shall review and approve the QA Controls Document prior to issuance.

6.6 QA CONTROLS DOCUMENT CONTROL

6.6.1 The QA Controls Document shall be maintained as a controlled document by OQA in accordance with QAAP 6.1, "Controlled Documents."

6.6.2 Revisions to the QA Controls Document shall be accomplished in accordance with Subsections 6.1 through 6.5. The responsible Office Director or Associate Director shall provide revisions to ADPARM. QA Controls Basis Sheets shall be prepared for those revisions to the QA Controls Matrices where the identified QA controls found in Attachment IV, QA Controls Reference for mandatory QAPD requirements, are to be deleted.

7.0 RECORDS

7.1 Documentation generated as a result of this procedure shall be maintained in accordance with requirements specified in QAAP 17.1,"QA Records Management". As a minimum, the QA Controls Document and the associated QA Controls Basis Sheets are considered QA records.

8.0 ATTACHMENTS

8.1 Attachment I - Format for the QA Controls Document

8.2 Attachment II - QA Controls Matrix

8.3 Attachment III - QA Controls Basis Sheet

8.4 Attachment IV - QA Controls Reference (2 sheets)

8.5 Attachment V - Flow Diagram for QAAP 2.3

ATTACHMENT I

FORMAT FOR QA CONTROLS DOCUMENT

Title Page

Table of Contents

Section 1.0 - Office of the Director

1.1 Function Definition #1

1.1.1 Work Definition #1 (Related to Function Definition #1)

1.1.1.1 Task Definition #1 (Related to Work Definition #1)

1.1.1.2 Task Definition #2

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1.1.2 Work Definition #2 (Related to Function Definition #1)

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1.2 Function Definition #2

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Figure 1.0 - QA Controls Matrix forms (Attachment II)

Figure 2.0 - QA Controls Basis Sheets (Attachment III)

Section 2.0 - Office of Program Administration and Resources Management

Section 3.0 - Office of Facilities Siting and Development

Section 4.0 - Office of Systems Integration and Regulations

Section 5.0 - Office of External Relations and Policy

Section 6.0 - Office of Quality Assurance

Appendices and Attachments

ATTACHMENT II

QA CONTROLS MATRIX (EXAMPLE)

Page ___ of ___

QA PROGRAM DOCUMENTS FOR IMPLEMENTATION	QARD REQUIREMENTS APPLY? (YES/NO)	QAPD REQUIRED? (YES/NO)	QAPD SECTION 3.0	QAPD SECTION 4.0	QAPD SECTION 7.0	APPLICABLE QA CONTROLS / FUNCTION, WORK, OR TASK — Subsection # / Title	Related WBS #:	Related WBS #:	Related WBS #:	Related WBS #:	Notes:

ATTACHMENT III

QA CONTROLS BASIS SHEET (Example)

PAGE __ of __

Applicable Function/Work/Task: _____ *Rev. No.* __
Subsection Number and Title

QARD Applicability? ___ *Yes* ___ *No*
Justification:

Justification for NOT Specifying QAPD Requirements and Associated QA Controls:

Audit and Surveillance Plan:

Approval Signature: _____ *Date:* _____

OQA Concurrence: _____ *Date:* _____

ATTACHMENT IV

QA CONTROLS REFERENCE (Example)

QAPD SUBSECTION		REFERENCE QA PROGRAM DOCUMENTS EXISTING AND (PLANNED)
1 Organization		
*1.0 General		QAPD
*1.1.11	Delegation of Work	QAPD
*1.1.12	Resolution of Disputes	QAPD
*1.1.13	Resolution of Allegations	(DOE/RW-ZZZZ) (QAI 2.X)
*1.1.14	Stop Work Authority	QAAP 16.2
2 Quality Assurance Program		
*2.0 General		QAAP 2.5 QAPD
*2.1.1	QA Requirements	QAR
*2.1.2	QA Program Description	QAPD
*2.1.3	QA Administrative Procedures	QAAP 5.1
*2.1.4	Implementing Line Procedures	QAAP 5.2
*2.1.5	Delegated Work	QAPD
*2.1.6	QA Program Controls	QAPD
2.1.7	Readiness Reviews	QAAP 2.6
*2.1.8	Quality Levels and Graded Quality Assurance	QAAP 2.3
*2.1.9	Personnel Selection, Indoc., Training, and Qualification	QAAP 2.1 QAAP 2.2
*2.1.10	Surveillance	QAAP 18.3
*2.1.11	Management Assessment	QAAP 2.7
*2.1.12	Quality Assurance Management-Information Reporting & Tracking	QAAP 2.9
3 Design Control		
3.0 General		QAPD
3.1.1	Systems Engineering	DOE/RW-0051
3.1.2	Scientific Investigation	QAPD
3.1.3	Processing of Data	QAPD
3.1.4	Design Process	DOE/RW-0043 (QAAP 3.5)
3.1.5	Computer Software	QAPD
3.1.6	Readiness Review for Design Activities	QAAP 2.6 QAAP 3.2
3.1.7	Design Verification	QAAP 3.1 QAAP 3.2
3.1.8	Second-Level Design Reviews	QAAP 3.3
3.1.9	Design Change Control	DOE/RW-0051 (QAAP 3.4)
3.1.10	Design Error and Design Deficiency Control	QAAP 16.1

ATTACHMENT IV (Cont'd)

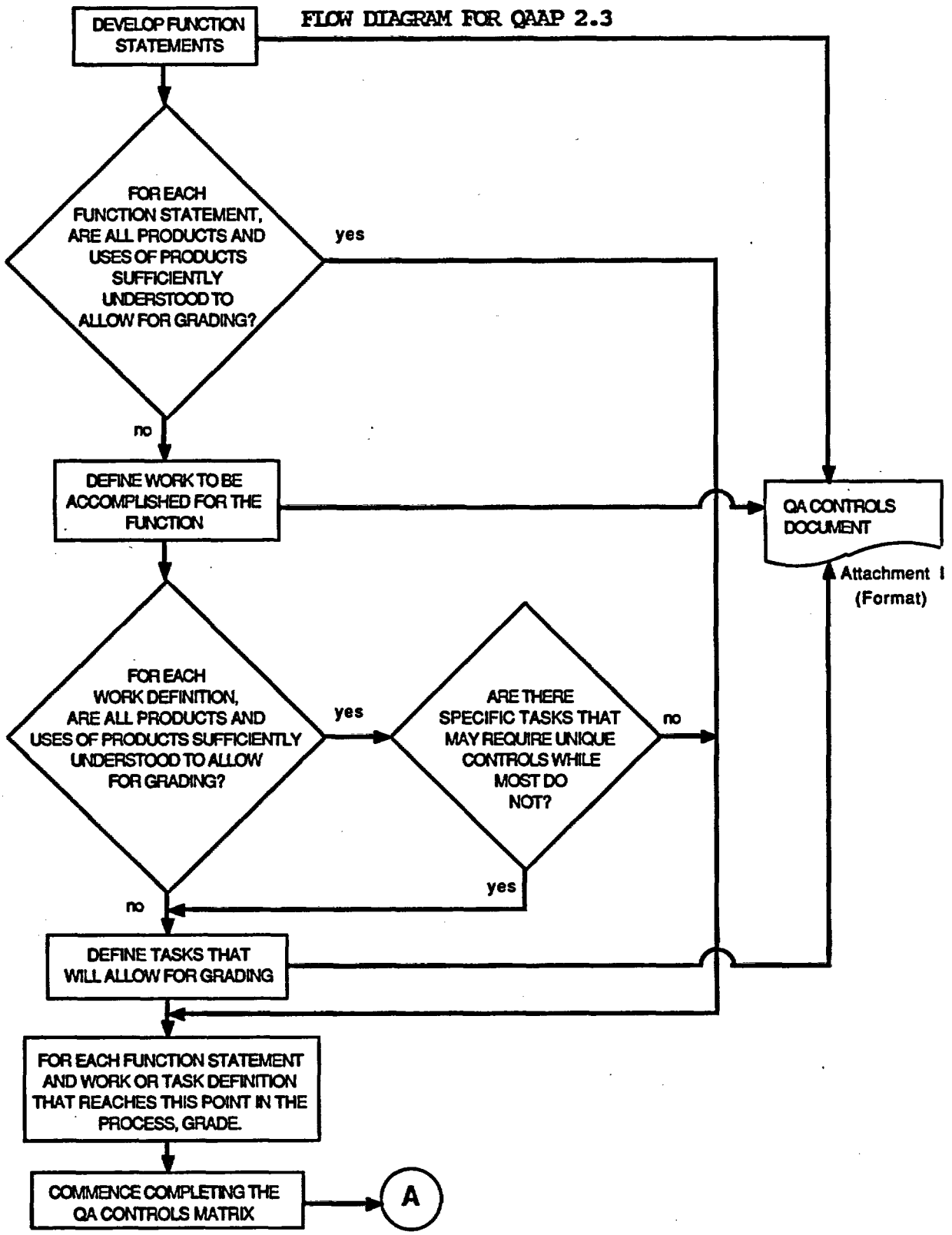
QA CONTROLS REFERENCE (Example)

QAPD SUBSECTION	REFERENCE QA PROGRAM DOCUMENTS EXISTING AND (PLANNED)
4 Procurement Document Control	
4.0 General	QAPD
4.1 OCRWM Procurement Document Control	QAAP 4.1 (QAAP 4.2)
5 Instructions, Procedures, and Drawings	
*5.0 General	QAPD
*5.1 OCRWM Instruction, Procedures, and Drawings	QAAP 5.1 QAAP 5.2
6 Document Control	
*6.0 General	QAPD
*6.1 OCRWM Document Control	QAAP 6.1
7 Control of Purchased Items and Services	
7.0 General	QAPD
7.1 OCRWM Control of Purchased Items and services	QAAP 7.1
16 Corrective Action	
*16.0 General	QAPD
*16.1 OCRWM Corrective Action	QAAP 16.1 QAAP 2.9
17 Quality Assurance Records	
*17.0 General	QAPD
*17.1 OCRWM QA Records System	DOE/RW-0194 (QAAP 17.1) (QAAP 17.2)
18 Audits	
*18.0 General	QAPD
*18.1 OCRWM Audit Program	QAAP 18.1 QAAP 18.2

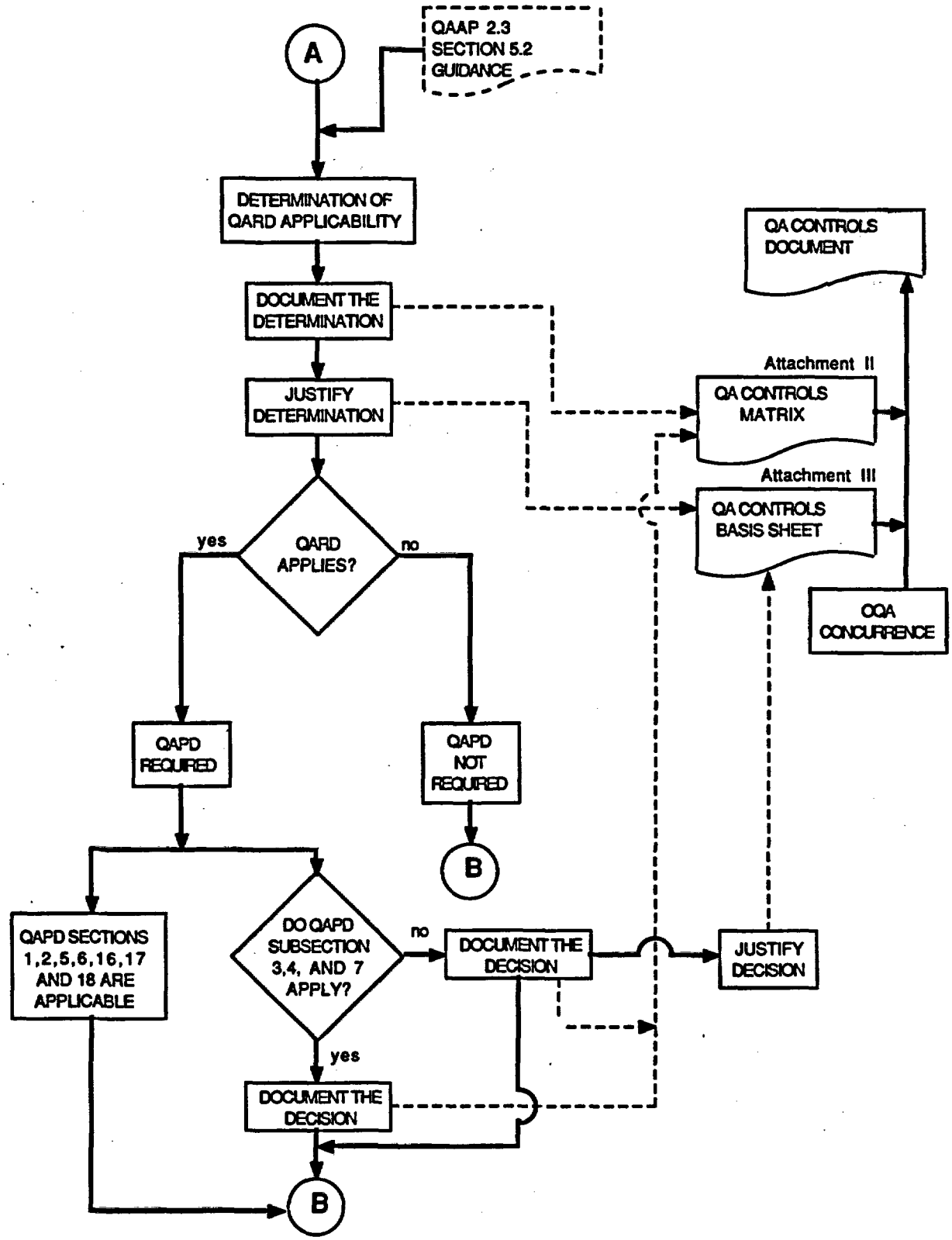
* The asterisked QAPD Subsections are always applicable, if "YES" was answered for the applicability of the QARD for the defined function, work, or task on the pertinent QA Controls Matrix form.

ATTACHMENT V

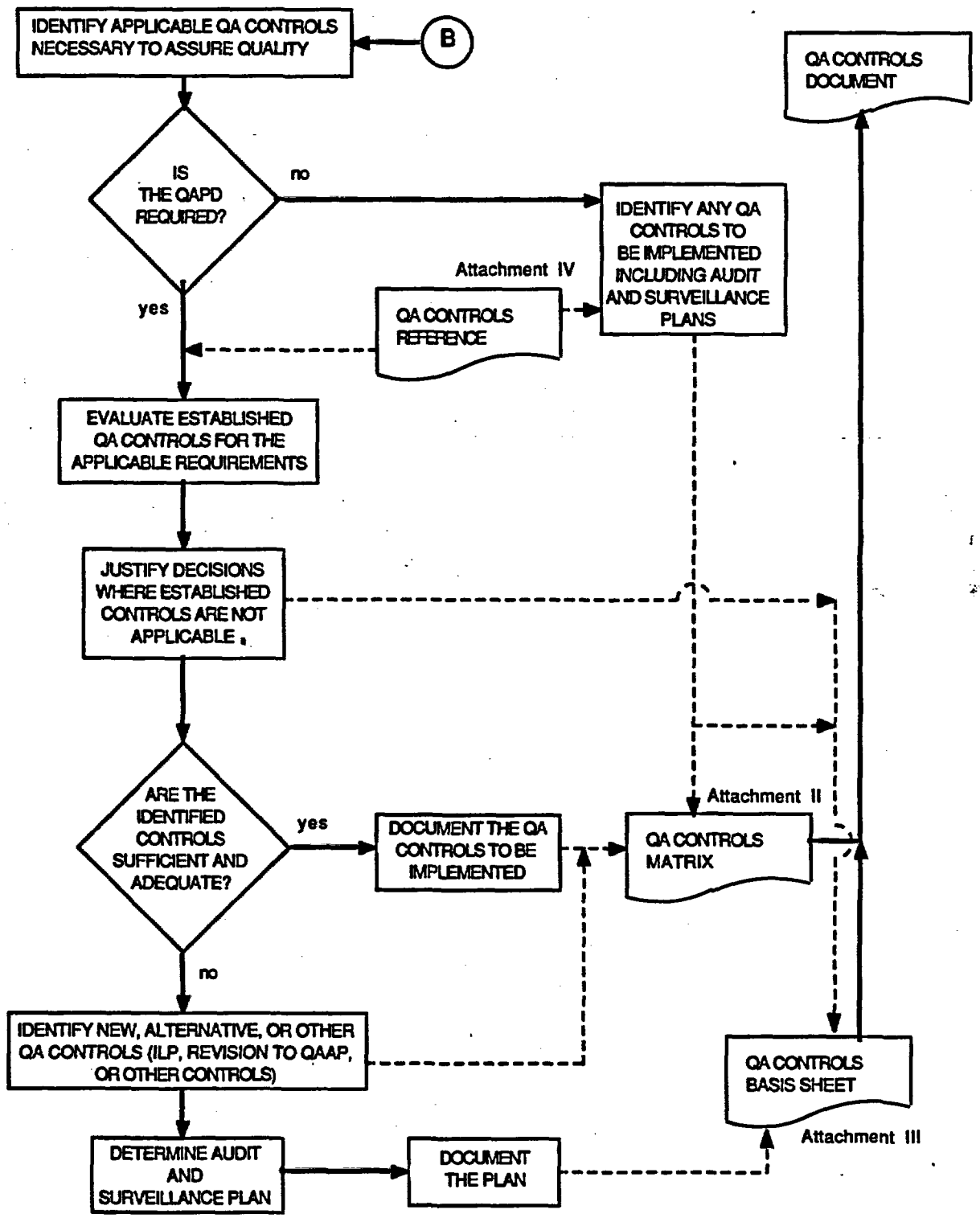
FLOW DIAGRAM FOR QAAP 2.3



ATTACHMENT V (Cont'd)



ATTACHMENT V (Cont'd)



QUALITY ASSURANCE ADMINISTRATIVE PROCEDURES

2.3

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

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