

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

ORIGINATING ORGANIZATION  
RW-3  
DATE OF TRANSMITTAL  
09/22/89

SECTION A

DOCUMENT TRANSMITTAL

TO: KENNEDY, JIM  
SECTION LEADER, QUALITY ASSURANCE SECTION  
REPOSITORY, LICENSING & QA PROJECT DIRECTORATE, NRC  
US NUCLEAR REGULATORY COMMISSION

WASHINGTON DC 20555-0000  
00277

DOCUMENT(S) TRANSMITTED:

For Controlled Copy No. 00277, DOE/RW-0197, "Quality Assurance Administrative Procedures Manual":

- 1) Table of Contents, Rev.6;
- 2) QAAP 4.2, "Establishing Procurement Quality Assurance Controls"

INSTRUCTIONS TO RECIPIENT:

RESPONSE DUE DATE

11/03/89

- 1) Remove Table of Contents, Rev.5, and replace with new Table of Contents, Rev.6. 2) Insert QAAP 4.2, Rev.0, behind proper tab in manual. 3) Destroy removed copies or mark as "superseded". 4) Acknowledge receipt and completion of above instructions by signing and dating in Section B below and return this Transmittal by the indicated due date.

SECTION B

ACKNOWLEDGMENT

COMMENTS:

ACKNOWLEDGEMENT SIGNATURE:

DATE:

RETURN SIGNED TRANSMITTAL TO:

US DEPARTMENT OF ENERGY, OCRWM RW-3  
1000 Independence Ave. SW  
Washington DC 20585 ATTN: Ms. Jennings

SECTION C

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OFFICE OF CIVILIAN  
RADIOACTIVE WASTE MANAGEMENT  
QUALITY ASSURANCE ADMINISTRATIVE PROCEDURE

TITLE: TABLE OF CONTENTS

Procedure No.:	Revision:	Date:	Page:
N/A	6	09/22/89	1 of 1

<u>No.</u>	<u>Title</u>	<u>Rev.</u>	<u>Effective Date</u>
2.1	Indoctrination and Training	0	03/27/89
2.3	Establishing Quality Assurance Controls	0	06/19/89
2.5	Quality Assurance Program Document Review	0	03/27/89
2.6	Readiness Review	0	03/27/89
2.7	Management Assessment	0	06/19/89
2.9	Quality Assurance Program Status Reporting	0	10/02/89
3.1	Technical Document Review	0	03/27/89
3.2	Design Review	0	03/27/89
3.3	Peer Review	0	03/27/89
3.5	Preparation of Technical Documents	0	08/14/89
4.1	Procurement Document Review	0	07/10/89
4.2	Establishing Procurement Quality Assurance Controls	0	10/23/89
5.1	Preparation of Quality Assurance Administrative Procedures	0	03/27/89
5.2	Preparation of Implementing Line Procedures	0	09/11/89
6.1	Document Control	0	09/11/89
7.1	Control of Purchased Services	0	09/11/89
16.1	Corrective Action	0	03/27/89
16.2	Stop Work	0	07/17/89
18.1	Certification of Audit Personnel	0	03/27/89
18.2	Audit Program	0	03/27/89
18.3	Surveillance Program	0	03/27/89

16



OFFICE OF CIVILIAN  
RADIOACTIVE WASTE MANAGEMENT  
QUALITY ASSURANCE ADMINISTRATIVE PROCEDURE

TITLE:

ESTABLISHING PROCUREMENT QUALITY ASSURANCE CONTROLS

Procedure No.: QAAP 4.2	Revision: 0	Date: 10/23/89	Page: 1 of 14
Director, OCRWM <i>[Signature]</i>	Date: 9/18/89	Director, OQA <i>[Signature]</i>	Date: 9-13-89

1.0 PURPOSE

1.1 The purpose of this procedure is to delineate the process for determining OCRWM Quality Assurance (QA) Program requirements and other QA controls applicable to the OCRWM procurement process.

2.0 SCOPE

2.1 This procedure is implemented for OCRWM procurements when QAAP 7.1, "Control of Purchased Services," is specified in the OCRWM Quality Assurance Controls Matrix developed in accordance with QAAP 2.3, "Establishing Quality Assurance Controls," for the associated OCRWM work. This procedure supplements standard OCRWM procurement processes to ensure that OCRWM QA requirements and other QA controls are adequately specified for each aspect of the procurement process.

3.0 REFERENCES AND DEFINITIONS

3.1 REFERENCES

- 3.1.1 "Quality Assurance Requirements Document" (QARD), DOE/RW-0214, 1988.
- 3.1.2 "Quality Assurance Program Description Document" (QAPD), DOE/RW-0215, 1988.

3.2 DEFINITIONS

- 3.2.1 Definitions of standard terms may be found in the Glossary contained in reference 3.1.1.
- 3.2.2 Contract - A mutually binding legal relationship obligating the seller to furnish items and services and the buyer to pay for them. It includes all types of written commitments that obligate the Government to expend appropriated funds. In addition to bilateral instruments, contracts include awards and notices of awards; job orders or task letters issued under basic ordering agreements; letter contracts; orders, such as purchase orders under which the contract becomes



effective by written acceptance or performance; and bilateral contract modifications. For purposes of this QAAP, the term "contract" also includes interagency agreements, grants, cooperative agreements, work authorizations, and other similar instruments.

- 3.2.3 OCRWM Direct-Support Contractor - An OCRWM contractor who provides services in accordance with the QAPD (that is, a contractor who performs work in accordance with OCRWM QAAPs and ILPs).
- 3.2.4 OCRWM-Managed Contractor - An OCRWM contractor who provides services in accordance with a QA program accepted by OCRWM that meets the applicable QARD requirements.
- 3.2.5 Procurement Initiator - The person designated by the responsible Associate Director to initiate the procurement process.
- 3.2.6 PROGRAM Participant - An organization, company, or individual who performs work for OCRWM.
- 3.2.7 QA Controls - QA criteria, Quality Assurance Administrative Procedures, Implementing Line Procedures, and other DOE QA program documents identified for implementation to achieve quality assurance in the conduct of work.
- 3.2.8 QA Controls Basis Sheets - A document that provides the basis (justification) for the conduct of the grading process in the establishment of QA requirements and QA controls.
- 3.2.9 QA Controls Document - An OCRWM document containing function, work, and task definitions and specific QARD and QAPD requirements and QA controls applicable to the definitions. (See QAAP 2.3 for its development.)
- 3.2.10 QA Controls Matrix - A form in the QA Controls Document that relates function, work, or task definitions to specific QA requirements and QA controls.
- 3.2.11 QA Controls Specification - An OCRWM procurement provision that identifies the QA criteria and QA controls that an OCRWM contractor or potential OCRWM contractor shall meet or implement or both in the conduct of a specific work scope.
- 3.2.12 Radiological Safety - For purposes of this procedure, the safety of workers or the public from exposure to radiation or radioactivity from radioactive waste.



- 3.2.13 Service - The time and effort of personnel engaged to perform identifiable tasks rather than furnish or supply an item. Services include consulting, engineering, research and development, and other technical tasks.
- 3.2.14 Supplier - Any individual or organization furnishing services in accordance with a contract. Includes a contractor or agency under contract.
- 3.2.15 Task - A work subelement assigned to or expected of OCRWM or other PROGRAM participants.
- 3.2.16 Work - An activity or set of activities having clearly defined products or expected results that are undertaken by an OCRWM office or PROGRAM participant to satisfy a function.

4.0 RESPONSIBILITIES

4.1 ASSOCIATE DIRECTORS

Associate Directors or their designees are responsible for ensuring that QA requirements, QA controls, and QA controls bases are adequately specified for procurements within their assigned areas.

4.2 DIRECTOR, OQA

The Director, OQA or designee is responsible for:

- 4.2.1 Providing support in determining the applicability of and specifying QA requirements and QA controls for procurements, and
- 4.2.2 Preparing and maintaining this QAAP.

4.3 ASSOCIATE DIRECTOR FOR PROGRAM ADMINISTRATION AND RESOURCES MANAGEMENT

The Associate Director for Program Administration and Resources Management (ADPARM) or designee is responsible for:

- 4.3.1 Interfacing with the DOE procurement organization, and
- 4.3.2 Ensuring that procurement QA controls and bases are specified in solicitations, contracts, and modifications, as appropriate.



5.0

GENERAL

- 5.1 Planning for application of the appropriate QA requirements and controls to ensure the quality of items and activities required for achievement of PROGRAM objectives is required by the QARD and QAPD. To effectively plan and selectively apply QA requirements and QA controls for procurements, products or deliverables must be clearly defined in accordance with QAAP 7.1, "Control of Purchased Services". Only then can it be determined whether or not the work needs to be performed in accordance with the applicable QARD and QAPD requirements and which OCRWM QA controls are to be invoked, if any.
- 5.2 Determining whether OCRWM QA Program requirements shall be applied to a procurement and the specific QA requirements and QA controls to be applied is a management responsibility. As a minimum, the following OCRWM procurements shall be considered subject to OCRWM QA Program 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 associated with activities for processing, preparation, handling, transportation, storage, or disposal of spent nuclear fuel or high-level waste; and
- 5.2.2 Work that is directly used in the license application or the radiological safety sections of the environmental impact statement or indirectly supports technical arguments in the license application or radiological safety section of the environmental impact statement.
- 5.3 In addition to the criteria above for mandatory application of the OCRWM QA Program requirements, other considerations may justify application of QA requirements and QA controls to a procurement. These considerations include:
- 5.3.1 Consequences of failure;
- 5.3.2 Importance of data;
- 5.3.3 Complexity of service;
- 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 products from the source;
- 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 radiological safety and waste isolation;
- 5.3.15 Need for special controls or processes; and
- 5.3.16 Significance to the licensing process.

- 5.4 For items and services procured from an OCRWM-managed contractor and determined to be subject to OCRWM QA Program requirements, specific QA requirements (QARD sections or subsections) to be applied to the service shall be specified and justified. QARD Sections 1,2,5,6,16,17, and 18 are mandatory for OCRWM-managed contractors subject to the QARD. The remaining 11 QARD Sections shall be evaluated for their applicability.
- 5.5 For procurement of OCRWM direct-support services only (that is, where the direct-support contractors provides services in accordance with OCRWM QA program procedures), the applicable QAPD subsections and QA controls shall be specified and justified consistent with the corresponding OCRWM QA Controls Matrix for the OCRWM work. Additional QA controls (for example, DOE Orders, Regulatory Guides, NUREGs, and industry standards) may be specified as appropriate to the service being procured.
- 5.6 When changes are made to the defined procurement scope, the specified QA requirements and QA controls shall be reassessed and modified as necessary.

6.0 PROCEDURE

- 6.1 During the procurement process, it is required by QAAP 7.1, "Control of Purchased Services," that QA requirements and QA controls for the procurement be specified. The procurement initiator (initiator) shall determine the applicable OCRWM QA requirements and QA controls that are applicable to the procurement in accordance with QAAP 2.3 and the QA Controls Document.
- 6.2 For the procurement's work scope, the initiator shall determine the applicability of the OCRWM QA Program requirements by using the applicable QA Controls Matrix and QA Controls Basis Sheet found in the QA Controls Document. If the work scope fails to fall within the scope documented on the existing QA Basis Sheet, the initiator shall implement QAAP 2.3 for the procurement's work scope prior to completing this procedure.
- 6.3 The initiator shall document the determination and appropriate justification in Block 1 on the applicable Procurement QA Controls Specification, Attachment I or II.



**6.4 NON-APPLICABILITY OF OCRWM QA PROGRAM**

**6.4.1** Where the OCRWM QA Program is not required to be imposed, the initiator shall specify "none" in Block 2 of the applicable Attachment I or II and shall include the pertinent information in the procurement documents in accordance with QAAP 7.1.

**6.5 APPLICABILITY OF OCRWM QA PROGRAM FOR OCRWM-MANAGED CONTRACTORS**

**6.5.1** For procurement of items and services from an OCRWM-managed contractor where it is necessary to apply OCRWM QA Program requirements, the initiator shall specify the QARD sections or subsections to be imposed in accordance with Subsection 5.4. These requirements shall be documented on the Procurement QA Controls Specification, Attachment I.

**6.5.2** The initiator shall justify not imposing a QARD section or subsection on the Procurement QA Controls Basis Sheet, Attachment III.

**6.5.3** The initiator shall specify that the OCRWM-managed contractor shall submit, for OCRWM acceptance, QA program description documents meeting the specified QARD requirements and a procedure consistent with QAAP 2.3 for establishing QA requirements and QA controls.

**6.6 APPLICABILITY OF OCRWM QA PROGRAM FOR OCRWM DIRECT-SUPPORT CONTRACTORS**

**6.6.1** For procurement of services from an OCRWM direct-support contractor where it is necessary to apply the OCRWM QA Program requirements, the initiator shall specify applicable QAPD subsections and any other QA controls on the Procurement QA Controls Specification, Attachment II.

**6.6.2** The initiator shall justify not specifying a QA control identified as applicable to the corresponding OCRWM function, work, or task on the applicable QA Controls Matrix. Justification shall be documented on the Procurement QA Controls Basis Sheet, Attachment IV.

**6.7** The initiator may specify and must justify other appropriate QA requirements, such as industry standards, NRC NUREGs and regulatory guides, and DOE orders on the Procurement QA Controls Specification. Justification shall be documented on the applicable Procurement QA Controls Basis Sheet, Attachment III or IV.



6.8 The initiator shall ensure that the information contained in the Procurement QA Controls Specification and, if applicable, Procurement QA Controls Basis Sheet are included in the solicitation and subsequent contract as a contractual requirement in accordance with QAAP 7.1.

6.9 The ADP/ARM shall initiate and coordinate the review and approval process for each solicitation and subsequent contract that specifies the procurement QA controls and procurement QA controls basis in accordance with QAAP 4.1, "Procurement Document Review."

#### 6.10 MAINTENANCE

In accordance with the revision requirements of QAAP 7.1, the QA requirements and QA controls specified for work provided by an OCRWM contractor shall be evaluated and controlled in accordance with Subsections 6.1 through 6.9 of this procedure for any change in work scope.

#### 7.0 RECORDS

7.1 Documentation resulting from implementation of this procedure shall be maintained as part of the contract in accordance with requirements specified in QAAP 17.1, "QA Records Management."

#### 8.0 ATTACHMENTS

8.1 Attachment I - Procurement QA Controls Specification for OCRWM-Managed Contractors

8.2 Attachment II - Procurement QA Controls Specification for Direct-Support Contractors

8.3 Attachment III - Procurement QA Controls Basis Sheet for OCRWM-Managed Contractors

8.4 Attachment IV - Procurement QA Controls Basis Sheet for Direct-Support Contractors

8.5 Attachment V - Flow Diagram for QAAP 4.2



ATTACHMENT I (EXAMPLE)

PROCUREMENT QA CONTROLS SPECIFICATION FOR OCRWM-MANAGED CONTRACTORS

1. Complete either a or b.

a. Basis for Specifying QARD Implementation

The work scope requires implementation of QARD requirements because.....

b. Basis for not imposing QARD Requirements

The work scope does not require implementation of a QA Program because.....

2. QARD Applicability

The contractor shall develop and implement a QA Program that meets the following referenced criteria of the OCRWM Quality Assurance Requirements Document, DCE/RW-0214 (QARD):

[ ] NONE

- |   |  |  |
|---|--|--|
| <ul style="list-style-type: none"> <li>[ ] 1 Organization           <ul style="list-style-type: none"> <li>[ ] 1.0 General</li> <li>[ ] 1.1 Quality Assurance Program Management</li> <li>[ ] 1.2 Delegation of Work</li> <li>[ ] 1.3 Dispute Resolution</li> <li>[ ] 1.4 Allegation Resolution</li> <li>[ ] 1.5 Stop Work Provisions</li> </ul> </li> <li>[ ] 2 Quality Assurance Program           <ul style="list-style-type: none"> <li>[ ] 2.0 General</li> <li>[ ] 2.1 Quality Assurance Program</li> <li>[ ] 2.2 Reporting Independence of Personnel</li> <li>[ ] 2.3 Planning</li> <li>[ ] 2.4 Readiness Reviews</li> <li>[ ] 2.5 Quality Levels and Graded Quality Assurance</li> <li>[ ] 2.6 Personnel Selection, Indoctrination, Training, and Qualification</li> <li>[ ] 2.7 Surveillance</li> <li>[ ] 2.8 Management Assessment</li> <li>[ ] 2.9 Quality Assurance Management-Information Reporting and Tracking</li> </ul> </li> <li>[ ] 3 Design Control           <ul style="list-style-type: none"> <li>[ ] 3.0 General</li> <li>[ ] 3.1 Design Error and Deficiency Control</li> <li>[ ] 3.2 Design Changes</li> <li>[ ] 3.3 Computer Software Control</li> <li>[ ] 3.4 Technical Reviews</li> <li>[ ] 3.5 Peer Reviews</li> <li>[ ] 3.6 Scientific Investigations</li> </ul> </li> <li>[ ] 4 Procurement document Control           <ul style="list-style-type: none"> <li>[ ] 4.0 General</li> <li>[ ] 4.1 Review</li> <li>[ ] 4.2 Applicability of Purchaser's QA Program</li> </ul> </li> </ul> | <ul style="list-style-type: none"> <li>[ ] 5 Instructions, Procedures, and Drawings           <ul style="list-style-type: none"> <li>[ ] 5.0 General</li> <li>[ ] 5.1 Reviews</li> <li>[ ] 5.2 Procedure List</li> </ul> </li> <li>[ ] 6 Document Control           <ul style="list-style-type: none"> <li>[ ] 6.0 General</li> <li>[ ] 6.1 Control</li> <li>[ ] 6.2 Control Systems</li> <li>[ ] 6.3 Controlled Documents</li> </ul> </li> <li>[ ] 7 Control of Purchased Items and Services           <ul style="list-style-type: none"> <li>[ ] 7.0 General</li> <li>[ ] 7.1 Suppliers' Quality Assurance Program</li> </ul> </li> <li>[ ] 8 Identification and Control of Materials, Parts, Components, and Samples           <ul style="list-style-type: none"> <li>[ ] 8.0 General</li> <li>[ ] 8.1 Samples</li> </ul> </li> <li>[ ] 9 Control of Processes           <ul style="list-style-type: none"> <li>[ ] 9.0 General</li> <li>[ ] 9.1 Applicability</li> <li>[ ] 9.2 List of Special Processes</li> <li>[ ] 9.3 QA Involvement in Qualification Activities</li> <li>[ ] 9.4 Evidence of Accomplishment</li> </ul> </li> <li>[ ] 10 Inspection           <ul style="list-style-type: none"> <li>[ ] 10.0 General</li> <li>[ ] 10.1 Applicability</li> <li>[ ] 10.2 Records</li> </ul> </li> <li>[ ] 11 Test Control           <ul style="list-style-type: none"> <li>[ ] 11.1 General</li> <li>[ ] 11.2 Applicability</li> <li>[ ] 11.3 Precision and Accuracy</li> </ul> </li> </ul> | <ul style="list-style-type: none"> <li>[ ] 12 Control of Measuring the Test Equipment           <ul style="list-style-type: none"> <li>[ ] 12.0 General</li> <li>[ ] 12.1 Accuracy of Calibration Standards</li> </ul> </li> <li>[ ] 13 Handling, Storage and Shipping           <ul style="list-style-type: none"> <li>[ ] 13.0 General</li> <li>[ ] 13.1 Samples</li> </ul> </li> <li>[ ] 14 Inspection, Test, and Operating Status           <ul style="list-style-type: none"> <li>[ ] 14.0 General</li> <li>[ ] 14.1 Applicability</li> </ul> </li> <li>[ ] 15 Control of Nonconforming Items           <ul style="list-style-type: none"> <li>[ ] 15.0 General</li> </ul> </li> <li>[ ] 16 Corrective Action           <ul style="list-style-type: none"> <li>[ ] 16.0 General</li> <li>[ ] 16.1 Trend Analysis</li> <li>[ ] 16.2 Significant Conditions Adverse To Quality</li> </ul> </li> <li>[ ] 17 Quality Assurance Records           <ul style="list-style-type: none"> <li>[ ] 17.0 General</li> <li>[ ] 17.1 Compliance with OCRWM Records-Management Program</li> </ul> </li> <li>[ ] 18 Audits           <ul style="list-style-type: none"> <li>[ ] 18.0 General</li> <li>[ ] 18.1 Technical Considerations</li> <li>[ ] 18.2 Project Office Audits</li> <li>[ ] 18.3 Analysis of Audit Data</li> <li>[ ] 18.4 Internal Audit Scheduling</li> <li>[ ] 18.5 External Audit Scheduling</li> </ul> </li> </ul> |
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**ATTACHMENT I (Cont'd)**

**3. Other QA Requirements**

The contractor shall implement additional QA requirements as follows:

None

As follows

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**4. The contractor shall submit for OCRWM acceptance:**

- a. QA program description documents (that is QA Plan, QA Manual, or other description documents) that conform to the referenced QARD requirements.
- b. a matrix identifying how the contractor's QA program complies with each QARD requirement specified in the contract.
- c. a procedure defining the process by which QA controls for work performed by the contractor will be established.

Work shall not proceed until these documents are approved by OCRWM.



**ATTACHMENT II**

**PROCUREMENT QA CONTROLS SPECIFICATION  
FOR DIRECT-SUPPORT CONTRACTORS**

1. Complete either a or b

a. Basis for Specifying QA Program Implementation

The work scope requires implementation of the below-specified QA requirements because.....

b. Basis for not Imposing OCRWM QA Program Requirements

The work scope does not require implementation of a QA program because.....

2. QAPD Applicability

The contractor shall implement the following subsections of the OCRWM Quality Assurance Program Description Document, DOE/RW-0215 and QA controls in performance of the contracted work:

2.1 QAPD Subsections

NONE

1. ORGANIZATION

1.0 General

1.1.11 Delegation of Work

1.1.12 Resolution of Disputes

1.1.13 Resolution of Allegations

1.1.14 Stop Work Authority

2. QUALITY ASSURANCE PROGRAM

2.0 General

2.1 OCRWM Quality Assurance Program

2.1.1 Quality Assurance Requirements

2.1.2 Quality Assurance Program Description

2.1.3 Quality Assurance Administrative Procedures

2.1.4 Implementing Line Procedures

2.1.5 Delegated work

2.1.6 Quality Assurance Program Controls

2.1.7 Readiness Reviews

2.1.8 Quality Levels and Graded Quality Assurance

2.1.9 Personnel Selection, Indoctrination, Training and Qualification

2.1.10 Surveillance

2.1.11 Management Assessments

2.1.12 Management Information Reporting and Tracking

3. DESIGN CONTROL

3.0 General

3.1 OCRWM Control of Design Activities

3.1.1 Systems Engineering

3.1.2 Scientific Investigations

3.1.3 Processing of Data

3.1.4 Design Process

3.1.5 Computer Software

3.1.6 Readiness Reviews for Design Activities

3.1.7 Design Verification

3.1.8 Second-Level Design Reviews

3.1.9 Design Change Control

3.1.10 Design Error and Design Deficiency Control

4. PROCUREMENT DOCUMENT CONTROL

4.0 General

4.1 OCRWM Procurement Document Control

4.1.1 Procurement Document Preparation, Revision, Review, and Approval

5. INSTRUCTIONS, PROCEDURES, AND DRAWINGS

5.1 OCRWM Document Control

5.1.1 Control

6. DOCUMENT CONTROL

6.0 General

6.1 OCRWM Document Control

6.1.1 Document Preparation, Revision, Review, and Approval

6.1.2 Issuance and Distribution

6.1.3 Controlled Documents

7. CONTROL OF PURCHASED ITEMS AND SERVICES

7.0 General

7.1 OCRWM Control of Purchased Items and Services

7.1.1 Control

16. CORRECTIVE ACTION

16.0 General

16.1 OCRWM Corrective Action

16.1.1 Control

16.1.2 Trend Analysis

16.1.3 Significant Conditions Adverse to Quality and Corrective Action

17. QUALITY ASSURANCE RECORDS

17.0 General

17.1 OCRWM QA Records System

17.1.1 QA Records

18. AUDITS

18.0 General

18.1 OCRWM Audit Program

18.1.1 Audit Program Implementation

18.1.2 Audit Process

18.1.3 External Audits



**ATTACHMENT II (Cont'd)**

**2.2 QA Controls**

The contractor shall implement the following QA controls in the performance of OCRWM work.





**OCRWM QA  
ADMINISTRATIVE  
PROCEDURE**

**Procedure No.:**

**QAAP 4.2**

**Revision:**

**0**

**Page:**

**13 of 14**

**ATTACHMENT IV**

**PROCUREMENT QA CONTROLS BASIS SHEET  
FOR DIRECT-SUPPORT CONTRACTORS**

**1. QAPD Justification**

Provide justification for not imposing each QAPD section or subsection identified as applicable in the appropriate QA Controls Matrix on the Procurement QA Controls Specification - Direct Support Contractors.

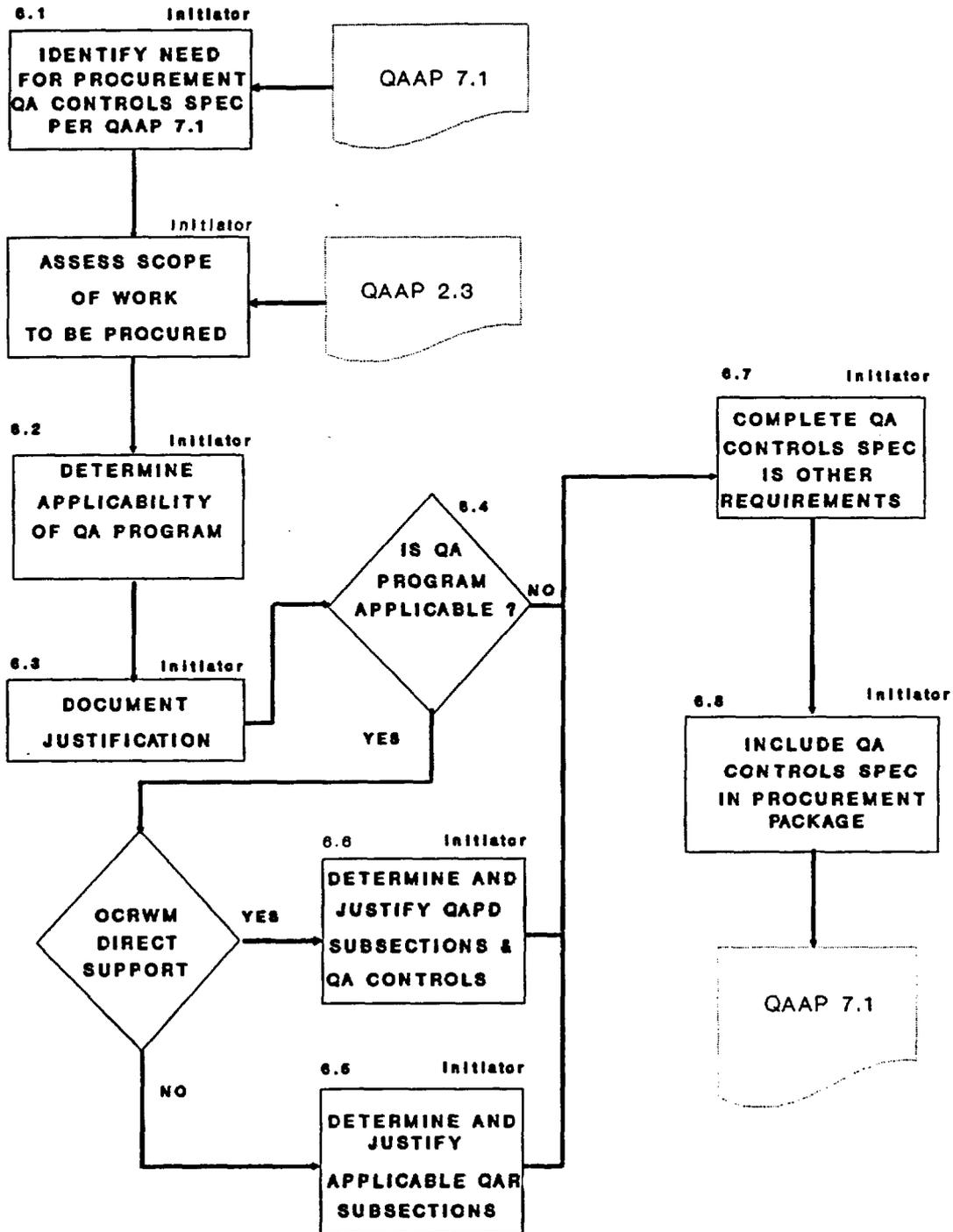
**2. QA Controls Justification**

Provide justifications for not specifying QA Controls found in the applicable QA Controls Matrix for the work.



ATTACHMENT V

ESTABLISHING PROCUREMENT QUALITY ASSURANCE CONTROLS



**QUALITY ASSURANCE ADMINISTRATIVE PROCEDURES**

**4.2**

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

**Accession No.: HQO.890109.0014**