OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT QUALITY ASSURANCE ADMINISTRATIVE PROCEDURE

Title: QA RECORDS MANAGEMENT			
Procedure No.: QAAP 17.1	Revision: 2	Date: 12/09/91	Page 1 of 22
Concurrence: R.W. Cl for DH Date: 11/4/91		Approval: Date: 11/12/91	

1.0 PURPOSE

This procedure establishes responsibilities and methods for the management and control of quality assurance (QA) records.

2.0 SCOPE

This procedure applies to the Office of Civilian Radioactive Waste Management (OCRWM) Headquarters (HQ) processes for identifying, originating, collecting, packaging, validating, and controlling documents and other evidential materials that provide evidence of the quality of work subject to QA program requirements. Detailed instructions for those QA records processing activities of the Quality Records Center (QRC) and the OCRWM HQ Central Records Facility (CRF) are provided in separate implementing procedures.

3.0 REFERENCES AND DEFINITIONS

3.1 REFERENCES

3.1.1 *Quality Assurance Requirements Document*, (QARD), DOE/RW-0214.

3.1.2 *Quality Assurance Program Description Document*, (QAPD), DOE/RW-0215.

3.2 DEFINITIONS

3.2.1 Draft document - a document (other than a final document) that proposes or reflects a DOE/OCRWM position, policy, plan or intended purpose and that is transmitted by a supervisory official of the originating organization for formal review and comment or concurrence within DOE, or formally transmitted outside DOE for review and/or comment, or, in the case of affected organizations, provided to OCRWM as a scheduled deliverable. (See definition of preliminary draft, Subsection 3.2.2.)

3.2.2 Preliminary draft - a document that is under development or preparation reflecting work in progress. The process of finalization may require iterations and revisions that may be transmitted freely within DOE (including affected organizations) if the document is marked "PRELIMINARY DRAFT." Preliminary drafts are excluded from capture in the records management system and are not retained beyond completion of a subsequent iteration.

3.2.3 Privileged record - a record that contains nonsecurity-classified information and requires protection against unauthorized disclosure.

3.2.4 QA record - an individual document or other evidential material that has been completed and approved or accepted and that furnishes evidence that work has been properly performed or that items comply with QA program requirements.

a) One-of-a-kind record - a record that cannot be duplicated or microfilmed, or that may lose its character and integrity when microfilmed. Such records may include, but are not limited to, radiographs, multicolor maps, map overlays, and seismographic charts.

b) Special-process records - records that cannot be filmed on 16mm roll film; but can be filmed on 35mm film (oversized documents) or duplicated without loss of value and stored in dual storage facilities.

3.2.5 QA record-in-progress - an individual document or other material that is being developed by the record originator and will become a QA record upon completion.

3.2.6 QA records list - a list of the types of QA records and QA records packages expected to be developed, by task or activity.

3.2.7 QA records package (QRP) - a collection of related QA records supporting one topic or completed activity.

3.2.8 QA training and qualification records (DOE System 80 records) - the QA records containing information generated as a result of implementing personnel qualification, indoctrination and training, and certification procedures that provide evidence that DOE and contractor personnel have adequate education, training, and experience to perform activities subject to QA program requirements.

These records are maintained as privileged records under DOE System 80 of the Privacy Act.

3.2.9 Quality Records Center (QRC) - a designated unit within OCRWM that receives and files QA records as they are completed; stores and protects the records on a temporary basis; and assists the originating organization with the assembly, validation, and transmittal of QA records packages to the CRF for final processing and permanent storage.

3.2.10 Record Originator - the individual who generates the QA records associated with a particular activity or task.

3.2.11 Responsible Director - the OCRWM Associate, Office, or Division Director whose organization has responsibility for a particular activity or task subject to QA program requirements that generates QA records.

3.2.12 Working file - the microfilm file of completed QA records packages that are maintained in the QRC for reference or other official use by OCRWM personnel.

3.2.13 Definitions of other quality assurance related terms are found in the Glossary contained in reference 3.1.1.

4.0 RESPONSIBILITIES

4.1 RESPONSIBLE DIRECTORS

Responsible Directors are responsible for:

4.1.1 Ensuring that a QA records list for their assigned OCRWM activities is developed, maintained, and provided to the QRC;

4.1.2 Ensuring that a list of persons within their organizations having the authority to assemble, review, and validate QA records packages is prepared, maintained, and provided to the QRC;

4.1.3 Ensuring that logs are maintained for tracking QRPs established by their organizations; and

4.1.4 Ensuring that QA records originated within their organizations that are considered privileged are properly identified, marked, and handled prior to submittal to the QRC.

4.2 DIRECTOR, OFFICE OF QUALITY ASSURANCE (OQA)

In addition to the responsibilities listed in Subsection 4.1, the Director, OQA is responsible for managing DOE System 80 for QA training and qualification records.

4.3 ASSOCIATE DIRECTOR, OFFICE OF PROGRAM AND RESOURCES MANAGEMENT (ADPRM)

In addition to the responsibilities listed in Subsection 4.1, the ADPRM is responsible for:

4.3.1 Establishing a QRC and a CRF for OCRWM to ensure that QA records are processed and maintained in accordance with this procedure; and

4.3.2 Preparing and maintaining this procedure in coordination with the Director, OQA.

4.4 DIRECTOR, INFORMATION MANAGEMENT DIVISION (IMD)

The Director, IMD is responsible for ensuring operation of the QRC and CRF in accordance with this procedure.

4.5 RECORD ORIGINATORS

Record originators are responsible for:

4.5.1 Ensuring that QA records are identified (marked), reviewed, and submitted to the QRC when completed;

4.5.2 Ensuring that QA records-in-progress are protected from deterioration, damage, or loss until transferred to the QRC; and

4.5.3 Ensuring that QA records packages are assembled, reviewed, and validated on a timely basis upon completion of the associated activity.

4.6 QRP VALIDATORS

QRP validators are responsible for assembling, reviewing, and validating QA records packages.

5.0 GENERAL

5.1 Organizations that originate or are responsible for QA records shall use the QRC as the temporary storage location for collection and retention of those QA records. Temporary storage at the QRC ends upon validation of a QA records package. The individual having primary responsibility for an activity or task shall ensure that QA records for

that activity or task are identified, marked, reviewed, and submitted to the QRC in accordance with the detailed requirements in Section 6.0.

5.2 The QRC shall be responsible for control of QA records and for filing the hardcopy QA records in appropriate QA records packages until the QRP is validated. Assembly and validation of QA records packages shall be accomplished in the QRC and in accordance with Subsection 6.7.

5.3 QA training and qualification records, including certification records, shall be managed as a special system of records (DOE System 80) within the OCRWM records management system. DOE System 80 records are generated in accordance with QAAP 2.1, *Indoctrination and Training*, QAAP 2.2, *Verification of Personnel Qualifications*, and QAAP 18.1 *Qualification of Audit Personnel*. They are maintained for review during the performance of audits and surveillances by DOE, NRC, affected state and local governments, and other Federal Government agencies. Access to DOE System 80 records is limited to authorized supervisors and records management personnel, and to QA audit and surveillance personnel to verify compliance with QA program requirements.

6.0 PROCEDURE

6.1 GENERATION OF LISTS OF QA RECORDS AND QA RECORDS PACKAGE VALIDATORS

6.1.1 Responsible Directors shall develop and maintain a list of QA records and QA records packages (QRPs) expected to be generated as a result of activities under their responsibility. See Attachment I for an example of a QA records list.

6.1.2 Responsible Directors shall generate, and forward to the QRC, a list of personnel within their organizations who are authorized to assemble, review, and validate QRPs. This list shall include the printed name, written signature, and initials of each authorized validator.

6.1.3 Responsible Directors shall ensure that QA records lists and QRP validation personnel lists are reviewed at least annually and changes are submitted to the QRC.

6.2 ESTABLISHING QA RECORDS PACKAGE IDENTIFICATION NUMBERS

6.2.1 Each Office, Division, or Branch shall maintain a log of the specific QA records packages they have established and the associated QRP identification numbers assigned.

6.2.2 The record originator shall identify to the QRC activities requiring a new QRP, obtain a unique QRP identification number from the QRC, and enter the number in the organizational log.

6.2.3 Prior to transmittal of an individual QA record to the QRC, the record originator shall identify a specific QA records package to which that record shall be assigned.

6.3 MARKING, REVIEW, CONTROL, AND DISTRIBUTION OF QA RECORDS BY RECORD ORIGINATORS

6.3.1 The record originator shall send a QA record to the QRC as soon as it is completed and approved or accepted, in accordance with Paragraphs 6.3.2 through 6.3.4.

a) One-of-a-kind and special-process records shall be submitted to the QRC in accordance with Subsection 6.4.

b) QA training and qualification records shall be submitted to the QRC and receive special handling in accordance with Subsection 6.6.

6.3.2 The record originator shall mark the letters "QA" in the upper right-hand corner of the first page of the QA record.

6.3.3 The record originator shall ensure that:

a) The QA record is properly authenticated by:

1) A signature or initials and date, or

2) An attached cover letter or statement by the individual or organization responsible for the content.

b) The QA record is complete, including all attachments and enclosures. All blocks on forms shall be filled in or marked "NA" unless the form states that only applicable items should be marked.

c) Written and typed QA records are legible, reproducible, and microfilmable in accordance with the following:

1) A distinct image of the character or pictorial information must be formed on the record medium (paper).

2) The information should be recorded with an indelible medium, preferably black ink, against a light background. Pencil is not an acceptable means for recording information on a QA record.

3) QA records must be easily legible without conjecture or magnification.

4) QA records shall not contain correction fluid or correction tape of any kind.

5) QA records shall not have any handwritten information added, corrected, or scratched out, with the exception of corrections made in accordance with Subsection 6.8. If other information has been added to a record previously submitted to the QRC, it constitutes a new and separate record.

6) QA records shall not contain stamps or other marks that obliterate the text.

7) Photocopies submitted for processing must be as close in appearance to the original as possible and, preferably, not more than a second generation copy (i.e., a copy of a copy of the original).

d) QA records that are drafts (see Subsection 6.5) are marked "Draft."

NOTE: Actions described in Paragraphs 6.3.2 and 6.3.3 are summarized in checklist form in Attachment II. Record originators may use the checklist to ensure that review actions are completed.

6.3.4 Subsequent to a satisfactory review and any necessary corrections, the record originator shall prepare a QA Record Transmittal (see Attachment III for typical format) and submit the QA record to the QRC.

a) The record originator shall review the organization's log of established QRPs (see Subsection 6.2) and determine the appropriate QRP identification number to which the QA record being transmitted should be assigned. If an appropriate QRP has not been previously identified, the record originator shall have one established and add it to the log in accordance with Subsection 6.2.

b) The QA Record Transmittal shall include, for each record being submitted, the QA record title or subject, identifying number if any (i.e., DOE/RW-XXXX), the record date, number of pages, the assigned QRP identification number, special instructions/comments if appropriate, and name and location of the person submitting the record.

c) See Subsection 6.4 for additional considerations for submittal of one-of-a-kind and special-process records.

d) See Subsection 6.6 for additional considerations for submittal of QA training and qualification records.

6.4 SUBMISSION OF ONE-OF-A-KIND AND SPECIAL-PROCESS RECORDS TO THE QRC

6.4.1 The record originator shall submit one-of-a-kind and special-process records to the QRC in accordance with Subsection 6.3 and the following additional instructions:

a) The record originator shall submit two copies of special-process records that cannot be filmed on aperture cards. If the cost or difficulty of generating duplicates is prohibitive, the originator shall identify that condition on the transmittal of the original to the QRC.

b) The QRC shall evaluate QA records in electronic format on a case-by-case basis to determine appropriate requirements for submittal.

6.4.2 The QRC shall be responsible for maintaining record traceability for special-process and one-of-a-kind records received and transferred to the CRF for processing and storage.

6.5 SPECIAL REQUIREMENTS - DRAFT DOCUMENTS

6.5.1 Preliminary drafts of documents shall not be identified or maintained as records.

6.5.2 Draft versions of QA records-in-progress issued for formal review and comment or concurrence prior to approval of the final document, and associated documents, shall be identified and processed as QA records.

a) Draft documents shall be marked "Draft" on the front page of the document.

b) Comments on drafts and the resolution of those comments shall be recorded as a separate document, and not as handwritten notes on the draft document.

c) Copies of draft documents, associated comments, and comment resolutions shall be filed and retained in the QA records package of the final approved document.

6.6 SPECIAL REQUIREMENTS - QA TRAINING AND QUALIFICATION RECORDS (DOE SYSTEM 80)

6.6.1 The record originator (supervisor) shall submit QA training and qualification records (DOE System 80 records) to the QRC in accordance with Subsection 6.3 and the following additional instructions:

a) DOE System 80 records shall be identified as "Privileged" records.

b) The QA Record Transmittal shall clearly identify the transmittal as DOE System 80 records and shall include the special instruction: "PRIVILEGED RECORDS - SPECIAL PROCESSING REQUIRED."

c) DOE System 80 records when transmitted shall be marked "Eyes Only."

6.6.2 The QRC shall be responsible for maintaining QA training and qualification records packages in locked cabinets with controlled access.

6.7 ASSEMBLY, PROCESSING, AND SUBMITTAL OF QA RECORDS PACKAGES

6.7.1 The record originator shall notify the QRC when the activity or activities for a given QRP are complete and request a list of the QA records that have been received and retained under that QRP identification number. The QRC will also assemble all such records into a package for review at the QRC. In most cases, the record originator shall perform the activities of the QRP validator, although another individual whose name appears on the originating organization's validation personnel list may be assigned.

6.7.2 The QRP validator shall review the package and individual records to:

a) Arrange the documents in a logical sequence (e.g. chronological order).

b) Purge any exact duplicates, incomplete records, or other records that do not belong in the QRP, and identify any missing records needed to complete the package. Note that QRPs shall contain letters, memoranda, transmittals or other cover sheets that:

1) Request or provide directions to accomplish a technical or quality-related task;

2) Provide technical or quality-related information, not provided in other records, regarding the activity or task; or

3) Provide evidence of authentication.

c) Identify one-of-a-kind or special-process records, if any, that are to be indexed to the QA records package and included in the Table of Contents (Paragraph 6.7.5).

d) Verify that each QA record is properly marked, includes evidence of authentication, and is correct, complete, and reproducible in accordance with Paragraph 6.3.3.

6.7.3 The QRP validator shall ensure that any needed corrections made during the above review are properly performed in accordance with Subsection 6.8.

6.7.4 The QRP validator shall, with QRC assistance, obtain, review, verify, and insert any missing records.

NOTE: The QRP may be held until the missing records are inserted or it may be processed as follows:

a) Insert a slip sheet into the QA records package for each missing QA record identifying the document title, date, revision number (if any).

b) Enter the slip sheets on the Table of Contents with a note that missing QA records will be submitted as a subsequent revision to the QRP.

c) Subsequently obtain and process the missing QA records in accordance with this procedure and submit as a QRP revision.

6.7.5 Upon completion of 6.7.1 through 6.7.4, the QRP validator with assistance of the QRC, shall complete a QA Records Package Table of Contents as follows:

a) List all records in the package in chronological or other logical order.

b) Provide a description and storage location for one-of-a-kind and special-process records that are part of the records package but are being handled separately.

c) Identify QA training and qualification records packages as DOE System 80 records and provide special instructions on the Table of Contents, such as "PRIVILEGED RECORDS - SPECIAL PROCESSING REQUIRED."

d) Enter the QRP identification number and revision number in the upper right corner of the Table of Contents.

6.7.6 The QRP validator shall perform a final inventory of the package to verify that the Table of Contents accurately reflects the QA records contained in the package.

6.7.7 The QRP validator shall sign and date the "Validated By:" block on the Table of Contents.

NOTE: Actions described in Paragraphs 6.7.2 through 6.7.7 are summarized in checklist form in Attachment IV. QRP validators may use this checklist to ensure actions are completed.

6.7.8 The QRC shall process the completed QRP in accordance with QRC and CRF procedures.

6.8 CORRECTIONS TO RECORDS

6.8.1 Corrections to QA records shall be made by the record originator or individual authorized by the originating organization.

6.8.2 Documents may be corrected prior to QRP validation by:

a) Drawing a single line through incorrect information, inserting corrected or additional information where appropriate, and initialing and dating the entries (see Paragraph 6.3.3(c) for relevant precautions); or

b) Superseding the incorrect document and replacing it with a corrected version that has undergone appropriate review and approval.

6.8.3 The corrected document shall be transmitted to the QRC in accordance with this procedure as a new and separate QA record.

6.8.4 If corrections are made to a QA record after the associated QA records package has been validated, the revised document must be processed as a revision to the previously submitted QA records package in accordance with Subsection 6.7.

6.9 PROTECTION OF QA RECORDS

Until QA records are submitted to the QRC, the record originator shall ensure that documents and other materials that will become QA records are protected from deterioration, loss, or damage. To the degree practicable, the record originator shall observe the following precautions while handling and processing materials that will become QA records:

a) Keep liquids a reasonable distance from records to protect against damage from spillage.

b) Keep smoking materials and other heat sources a reasonable distance from records to protect against damage which could result.

c) Keep magnetic media records a reasonable distance from sources of magnetic fields (including telephones).

d) When not in use or attended, keep documents or materials designated to become QA records locked in a secured area (e.g., locked desk, locked file cabinet, locked office).

6.10 REPLACEMENT OF LOST OR DAMAGED QA RECORDS

The record originator shall replace, restore or develop a substitute QA record following determination that a record has been lost or damaged to a degree that it is no longer complete or legible. Replacement QA records shall be processed and controlled in accordance with this procedure. If a replacement or substitute QA record cannot be produced and processed, a Corrective Action Request (CAR) shall be initiated and resolved in accordance with QAAP 16.1, *Corrective Action.*

6.11 OCRWM WORKING FILE AND RETRIEVAL OF QA RECORDS

6.11.1 The QRC shall maintain a microfilm copy of QA records packages to be used as the OCRWM Working File. The QA records may be reviewed on microfilm at the QRC. Copies made from the working file microfilm may be requested from the QRC.

6.11.2 Copies of privileged records shall not be distributed. Privileged records, including DOE System 80 records, may be reviewed on microfilm at the QRC by authorized personnel with approval from the Responsible Director.

7.0 RECORDS

QA records lists, authorized QA records package validator lists, and QA Records Transmittals are considered QA records and shall be handled in accordance with this procedure. QA Records Package Tables of Contents are incorporated into each records package and are not maintained as separate QA records.

8.0 ATTACHMENTS

8.1 ATTACHMENT I - Example of a QA Records List

8.2 ATTACHMENT II - QA Record Transmittal Checklist

8.3 ATTACHMENT III - QA Record Transmittal

8.4 ATTACHMENT IV - QA Records Package Review Checklist

8.5 ATTACHMENT V - QA Records Package Table of Contents

8.6 ATTACHMENT VI - QAAP 17.1 Flowchart

ATTACHMENT I
EXAMPLE OF A QA RECORDS LIST

Technical Document Review Records Packages

- Document or Draft Reviewed
- Transmittals (Letters, Memos, Transmittal Forms that transmit documents and/or identify review instructions and criteria)
- Reviewer qualification statements
- DRRs (completed Document Review Records; documentation of comments and comment resolutions)
- Final Document (as approved)
- Concurrence/Approval Records

Audit Records Packages

- Notification Letter
- Audit Plan
- Audit Report

ATTACHMENT II
QA RECORD TRANSMITTAL CHECKLIST

1. QRP number has been established ☐

2. "QA" entered on first page ☐

3. Authenticated (signed and dated) ☐

4. Complete ☐
   - all pages present
   - all attachments and enclosures included
   - all blocks, signatures filled in or marked "NA"

5. Legible and reproducible ☐
   - clear, distinct
   - easily readable
   - black ink

6. No "white out" or correction tape ☐

7. No scratched out information or extraneous markings ☐

8. No text obliterated by stamps, etc. ☐

9. Marked "DRAFT," if applicable ☐

10 DOE System 80 records marked "PRIVILEGED" ☐

11. Transmittal complete ☐
    - Title, date, page count, QRP number

12. Special instructions provided
    - one-of-a-kind, special-process records ☐
    - System 80 records ☐

ATTACHMENT III
QA RECORD TRANSMITTAL (Example)

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

PAGE____ OF____
QA

QA RECORD TRANSMITTAL

TO: OCRWM QUALITY RECORDS CENTER (QRC)	DATE:
FROM: * _____ / Name/Signature	ORGANIZATION:

* *I HAVE REVIEWED AND ACCEPTED THE FOLLOWING RECORDS IN ACCORDANCE WITH QAAP 17.1. THEY ARE BEING TRANSMITTED FOR QRC PROCESSING.*

RECORD NUMBER	RECORD TITLE/SUBJECT	RECORD DATE	PAGE COUNT	QRP NUMBER

SPECIAL INSTRUCTIONS:

QRC RECEIPT ACKNOWLEDGEMENT (RETURN SIGNED COPY TO RECORD ORIGINATOR AS INFORMATION COPY)

_____ _____
QRC PERSONNEL SIGNATURE DATE

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ATTACHMENT III (Continued)
QA RECORD TRANSMITTAL

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

PAGE_____OF_____
QA

QA RECORD TRANSMITTAL

RECORD NUMBER	RECORD TITLE/SUBJECT	RECORD DATE	PAGE COUNT	QRP NUMBER

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ATTACHMENT IV
QA RECORDS PACKAGE REVIEW CHECKLIST

1. Records are arranged in logical sequence ☐
2. Exact duplicates, incomplete records, removed from the record package ☐
3. One-of-a-kind and special-process records are identified and the location is indicated on the Table of Contents ☐
4. Each record is properly marked, authenticated, complete and reproducible ☐
5. Corrections to records are in accordance with requirements ☐
6. Slip sheets identify missing records and are listed on Table of Contents ☐
7. Privileged records are properly identified and special instructions provided on Table of Contents ☐
8. Table of Contents shows correct QRP number and revision number ☐
9. All records are listed on the final Table of Contents ☐
10. The Table of Contents is signed and dated ☐

ATTACHMENT V
QA RECORDS PACKAGE TABLE OF CONTENTS (Example)

PAGE_____ OF_____

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

QA RECORDS PACKAGE:
I.D. NO.: _____
REVISION NO.: _____
QA

QA RECORDS PACKAGE TABLE OF CONTENTS

RECORD PACKAGE TITLE/DESCRIPTION: _____

NUMBER	RECORD TITLE/SUBJECT	DATE	NO. OF PAGES

NOTES:

VALIDATED BY: _____ _____
DATE

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ATTACHMENT V
QA RECORDS PACKAGE TABLE OF CONTENTS (Example)

PAGE_____ OF_____

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WASHINGTON, D.C.

QA RECORDS PACKAGE:
I.D. NO.: _____
REVISION NO.: _____
QA

QA RECORDS PACKAGE TABLE OF CONTENTS
(Continuation Sheet)

NUMBER	RECORD TITLE/SUBJECT	DATE	NO. OF PAGES

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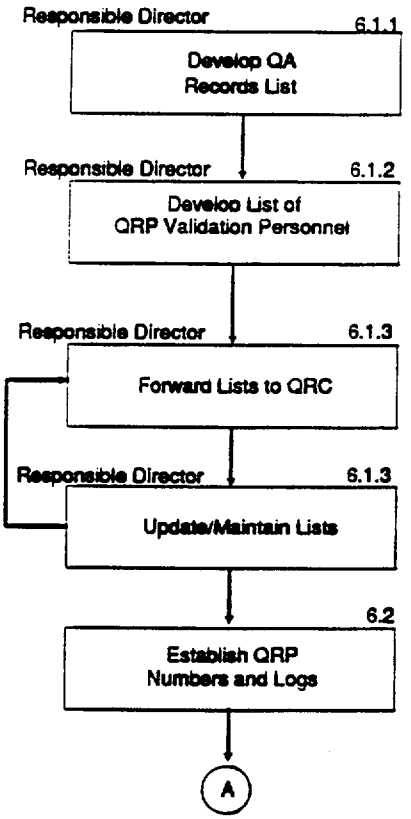
ATTACHMENT VI
QAAP 17.1 FLOWCHART



ATTACHMENT VI
QAAP 17.1 FLOWCHART (Continued)