



Office of Environmental Management

Administrative Procedure

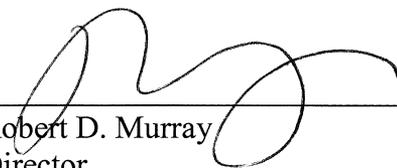
Quality Assurance Records

AP-17.1Q, Revision 1

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1.0 PURPOSE

This procedure describes the process and responsibilities for Quality Assurance (QA) Records that relate to the High-Level Waste (HLW) and Used Nuclear Fuel (UNF) Oversight Program.

2.0 SCOPE

The scope of this procedure is to describe the process for managing QA Records associated with the HLW and UNF Oversight Program.

3.0 APPLICABILITY

This procedure applies to Environmental Management (EM) personnel and contractors that participate in activities associated with the HLW and UNF Oversight Program.

4.0 REQUIREMENTS and REFERENCES

4.1 Requirements

4.1.1 DOE/RW-0333P, Revision 20, *Quality Assurance Requirements and Description (QARD)*

4.1.2 EM-QA-002, *Quality Assurance Program Plan (QAPP)*

4.1.3 Title 44 of the United States Code (44 U.S.C.)

4.2 References

N/A

5.0 DEFINITIONS

5.1 Federal Records – As stated in 44 U.S.C. 3301, a Federal record is defined as, “all books, papers, maps, photographs, machine readable materials, or other documentary materials, regardless of physical form or characteristics, made or received by an agency of the United States Government under Federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the Government or because of the informational value of data in them. Library and museum material made or acquired and preserved solely for reference or exhibition purposes, extra copies of documents preserved only for convenience of reference, and stocks of publications and of processed documents are not included.”

- 5.2 Lifetime QA Records – Federal Records that meet one or more of the following criteria:
- Those that would be of significant value in demonstrating capability for safe operation;
 - Those that would be of significant value in maintaining, reworking, repairing, replacing, or modifying an item;
 - Those that would be of significant value in determining the cause of an accident or malfunction of an item;
 - Those which provide required baseline data for in-service inspection.
- 5.3 Nonpermanent QA Records – Federal Records are those required to show evidence that an activity was performed in accordance with the applicable requirements but need not meet the criteria for lifetime QA records.

6.0 GENERAL RESPONSIBILITIES

6.1 Record Source

- 6.1.1 Creates, temporarily stores and submits QA records to EM Consolidated Business Center (CBC) Coordinator, Office of Technical Support and Asset Management

6.2 QA Lead for the HLW and UNF Oversight Program

- 6.2.1 Corrects QA Records in the absence of the Record Source

6.3 EMCBC Coordinator, Office of Technical Support and Asset Management

- 6.3.1 Receives, maintains, stores, protects, retrieves QA records.

7.0 GENERAL INFORMATION

- 7.1 Implementing procedures shall identify those documents that shall become QA records and those individuals responsible for submitting to the EMCBC Coordinator. Individuals responsible for the creation of QA records shall ensure that they are legible, accurate, complete, appropriate to the work accomplished, and traceable to the item(s) or activity(s) to which they apply. QA records may be originals or copies.
- 7.2 QA Documents shall be considered valid records when stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated. This authentication may take the form of a statement by the reporting individual or organization. If the nature of the record (e.g., magnetic or optical media) precludes stamping, initialing, or signing, then other means of identifying the record as complete by authorized personnel are permitted.

8.0 PROCEDURE

8.1 Identification and Creation of QA Records

8.1.1 When a new activity begins, the Record Source shall coordinate with the EMCBC Coordinator personnel to open a records package that shall be comprised of QA records associated with that specific activity. This allows these QA records to be processed while the activity is on-going, and for them to be duplicated and maintained in the dual storage, if required.

8.2 Submitting QA Records

8.2.1 The Record Source shall protect in-process records from damage or loss from the time of creation of the document until the document is ready for submittal. In-process QA records shall be kept in a secure area when not in use, (e.g., a desk drawer or file cabinet). When a QA Record, or record package, has been completed and authenticated it shall be submitted to EMCBC Coordinator along with the completed Form 17.1-1 *Records Transmittal Form*.

8.2.2 When submitting records, the Record Source shall provide Form 17.1-1 *Records Transmittal Form* to ensure the EMCBC Coordinator can verify that the QA records received are in agreement with the transmittal document.

8.3 Receiving and Indexing Quality Assurance Records

8.3.1 EMCBC Coordinator shall perform the following steps when receiving QA Records:

8.3.1.1 Verify the QA record received.

8.3.1.2 Resolve discrepancies in QA records or QA record packages through direct interaction with the Record Source.

8.3.1.3 Verify that the QA record has been authenticated, is legible and complete.

8.3.1.4 Acknowledge receipt with signature and date on Form 17.1-1, *Records Transmittal*. The form shall be kept with its corresponding records package.

8.3.2 The EMCBC Coordinator shall index QA records by updating Form 17.1-2, *Record Indexing Log*. The form shall contain the following information:

- The location of the QA records within the records management system.
- Identification of the item or related activity to which the QA records pertain.
- The record retention times.

8.3.3 On annual basis, the EMCBC Coordinator shall complete the Form 17.1-2, *Record Indexing Log* by signing and dating the form. The completed Form 17.1-2, *Record Indexing Log* shall be placed with the other QA records associated with the HLW and UNF Oversight Program.

8.4 Correcting QA Records

8.4.1 Corrections to QA records, including documents that will become QA records, shall include the initials or signature of the Record Source or the EMCBC Coordinator who made the correction and the date the correction was made.

8.4.2 Corrections to QA records shall be reviewed and approved by the Record Source. If the Record Source responsible for generating the record is no longer available, the QA Lead shall review and approve the corrected record(s). The review and approval shall be documented in writing (e.g., email, memorandum, twitter, etc.).

8.5 Storing, Retrieval, and Replacement of QA Records

8.5.1 The EMCBC Coordinator provides protection of the QA Records as follows:

8.5.1.1 QA records are protected from moisture, temperature, and pressure by regulating normal office environmental controls.

8.5.1.2 QA records shall be temporarily stored in a container or facility with a 1-hour fire rating, or dual storage shall be provided. Single storage, containers or facilities shall bear an Underwriters' Laboratories label (or equivalent) certifying 1-hour fire protection or be certified by a person competent in the technical field of fire protection.

8.5.1.3 QA records are protected from unauthorized access.

8.5.2 Retrieval of QA Records

8.5.2.1 Upon request, EMCBC Coordinator shall retrieve QA records using the indexing information in Form 17.1-2, *Record Indexing Log*.

8.5.2.2 The EMCBC Coordinator shall post a list designating personnel who are permitted to access QA Records in the area where the QA Records are stored. All entries to the area where QA records are stored shall be locked when records personnel are not present.

8.5.3 Replacement of QA Records

8.5.3.1 The QA Lead or EMCBC Coordinator shall replace, restore, or substitute a lost or damaged QA record by obtaining a copy, if available, from the Record Source.

8.5.3.2 If replacement or restoration is not practical (i.e., one-of-a-kind record), then EMCBC Coordinator shall request that the Record Source document the loss in accordance with AP-16.1Q, *Corrective Action*, as a noncompliance with either 8.2.1 or 8.5.1 of this procedure depending on the circumstances.

9.0 RECORDS MAINTENANCE

QA records shall be submitted to EMCBC Coordinator in accordance with this procedure as individual QA records or included in a QA records package, as specified.

9.1 QA Records

9.1.1 Lifetime Records

9.1.1.1 None

9.1.2 Nonpermanent Records

9.1.2.1 Form 17.1-1, *Records Transmittal*

9.1.2.2 Form 17.1-2, *Record Indexing Log* (Completed by Fiscal Year)

9.1.2.3 Written documentation from the QA Lead regarding review and approval of corrected records.

9.2 Non QA Records

9.2.1 None

10.0 FORMS USED

Form 17.1-1, *Records Transmittal*

Form 17.1-2, *Record Indexing Log*

11.0 ATTACHMENTS

N/A

Form 17.1-1, Records Transmittal

Record Package Title

Document Identifier

Document Revision

Record/Document Date

Record Package Page Count

Record Package Contents

Record Originator Print Name

Signature

Date

Record Receiver Print Name

Signature

Date

Form 17.1-1 – General Instructions

Based on the requirements of the procedure, document the following information on Form 17.1-1, Records Transmittal:

Record Package Title: Indicate the unique title of the record package (e.g., Audit Report 12-DOE-AU-005, High-Level Waste Quality Assurance Program Waste Treatment & Immobilization Plant)

Document Identifier: Indicate the unique identifier if any of the document (e.g., AP-18.1Q)

Document Revision: Indicate the revision of the document if any.

Record/Document Date: Indicate the Date that the record was authenticated (e.g., the date of the signature for approval of an audit report)

Record Package Page Count: Indicate the total number of pages of the record package.

Record Package contents: Summarize in sufficient detail of the contents of the record package such that they can be confirmed by the EM CBC Coordinator.

Form 17.1-2 – General Instructions

Based on the requirements of the procedure, document the following information on Form 17.1-1, Records Transmittal:

File Number: Indicate the file number of the record package that corresponds its location in the record management system.

File Category: Indicate the name of the file category of the record package that corresponds to the location in the record management system.

Record Package(s): Indicate the unique title of the record package (e.g., Audit Report 12-DOE-AU-005, High-Level Waste Quality Assurance Program Waste Treatment & Immobilization Plant)

Comments: State any relevant information about the record package including the identification of the item or related activity to which the record package pertains.

Retention Time: Indicate the total number of pages of the record package.

Hard Copy: Indicate the confirmation of the hard copy of the record package.

Digital Copy: Indicate if a digital copy of the record package is also available. If the hard copy was generated from the digital copy, confirm that the digital copy and hard copy are complete and match each other.

Form 5.1-1 – Record of Revision

DOCUMENT: AP-17.1Q, *Quality Assurance Records*

Revision Number	Description of Changes	Revision on Pages	Effective Date
0	Original	All	04/27/2011
1	General Revision	All	12/14/2012