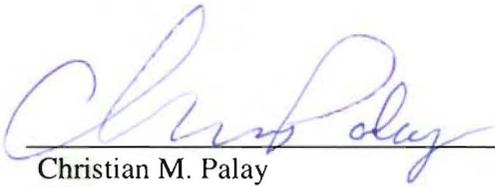


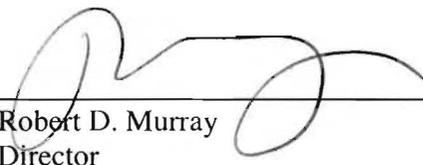


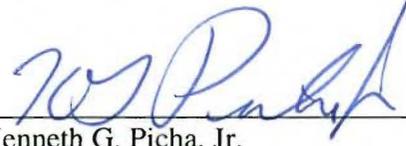
Office of Environmental Management (EM)

Subject: Quality Assurance Records

Administrative Procedure

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1.0 PURPOSE

- 1.1 This section establishes requirements to ensure that quality assurance (QA) records that furnish documentary evidence of quality are specified, prepared, and maintained. The records system shall be established by the organization responsible at the earliest practicable time consistent with the schedule for accomplishing activities affecting quality. These HLW and UNF programs are based on the Quality Assurance Requirements and Description (QARD, DOE/RW-0333P).

2.0 SCOPE

- 2.1 This procedure prescribes the process for identifying, creating, protecting, correcting, submitting, and retrieving QA records from the EMCBC Records Storage. It also specifies the responsibilities of each individual (the Record Source) who generates oversight audit or surveillance QA records for the HLW and UNF programs for submittal to EMCBC Records Storage.

3.0 APPLICABILITY

- 3.1 This procedure applies to QA records generated by personnel in support of work activities for the EM personnel and contractors who are directly or indirectly involved with the QARD oversight functions of programs related to HLW and UNF activities as conducted by the Office of Standards and Quality Assurance at EM Headquarters.

4.0 REQUIREMENTS and REFERENCES

- 4.1 Quality Assurance Requirements and Description (QARD), DOE/RW-0333P, Revision 20
- 4.2 EM-QA-002, Quality Assurance Program Plan (QAPP)
- 4.3 AP-1.1Q, High Level Waste (HLW) and Used Nuclear Fuel (UNF) Independent Oversight Program Description
- 4.4 AP-2.2Q, Surveillances
- 4.5 AP-16.1Q, Corrective Action
- 4.6 AP-18.1Q, Audits

- 4.7 44 U.S.C., Chapters 21, 29, 31, 33, and 35
- 4.8 36 CFR, Chapter 12, Subchapter B, “Records Management”
- 4.9 10 CFR 63.72, Construction Records
- 4.10 10 CFR 71.91, Records
- 4.11 10 CFR 71.135, Quality Assurance Records
- 4.12 10 CFR 72, Subpart D, Records, Reports, Inspections, and Enforcement
- 4.13 10 CFR 72.174, Quality Assurance Records
- 4.14 EMCBC Records Management Policy, PS-243-01
- 4.15 EMCBC Identifying, Filing and Maintaining Records, IP-243-03
- 4.16 EMCBC Destruction of Temporary Records, IP-243-06

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 the data in them.” Quality assurance records are those created and retained as prescribed under a quality assurance program that may require additional requirements for authenticity and protection.
- 5.2 Quality Assurance (QA) Record – A QA record is a completed document (or other medium) that furnishes evidence of the quality of items and/or activities affecting quality. A QA record must be maintained in accordance with the provisions of an approved program as well as Federal recordkeeping regulations/requirements.
- 5.3 Lifetime QA Records – Lifetime QA records are those that meet one or more of the following criteria:

- a) Those that would be of significant value in demonstrating capability for safe operation;
- b) Those that would be of significant value in maintaining, reworking, repairing, replacing, or modifying an item;
- c) Those that would be of significant value in determining the cause of an accident or malfunction of an item;
- d) Those which provide required baseline data for in-service inspection.

5.4 Nonpermanent QA Records – Nonpermanent QA 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 The record source shall be responsible for the creation, interim storage and final turnover of QA records to EMCBC Records Storage.

6.2 EMCBC Office of Logistics Management, Records Management

6.2.1 EMCBC Records Management personnel shall be responsible for the maintenance/use, storage, protection, retrieval and final disposition of QA records.

6.3 Each individual shall be responsible for the quality of his/her work. All individuals are responsible for identifying potential and existing conditions adverse to quality, and reporting them through the appropriate program outlined in AP-16-1Q, Corrective Action

7.0 GENERAL INFORMATION

This procedure addresses QA records generated during oversight activities performed on the HLW and UNF Programs to ensure compliance with Federal Records regulations and QA requirements.

8.0 PROCEDURE

8.1 Identification and Creation of QA Records

8.1.1 Implementing procedures shall identify those documents that shall become QA records. Individuals responsible for the creation of QA records shall ensure that they are legible, accurate, completed 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.

- 8.1.2 A QA record is not considered valid or complete until authenticated but is still considered a federal record and shall be managed as such. Authentication is the act of attesting that the information contained within a QA record is accurate, complete, legible, and appropriate to the work accomplished. Authorized personnel may accomplish authentication by any one of the following methods:
- Signature or initials and date;
 - Appropriate stamp and date; and
 - Memo with signature or initials and date.
- 8.1.3 Authentication should not be confused with any subsequent reviews of the content. All forms of authentication shall be accompanied with the appropriate authentication data.
- 8.1.4 When a new activity is started, the Record Source shall coordinate with the EMCBC Records Management 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.
- 8.1.5 The number of pages of a QA record must be indicated in some manner. The preferred method is to number each page as: “1 of 10, 2 of 10”, etc. An acceptable alternative is to number the first page as “1 of 10” and then continue with straight numbering. Paginating a quality record after it has been validated is not considered a change requiring revalidation of the QA record. Pagination or page numbering can be set up in the footer for QA records created on a computer.
- 8.1.6 The Record Source shall provide the following indexing information for submitted records to ensure traceability and retrieval:
- Date the QA record was created;
 - Author(s) name;
 - Recipient(s) name;
 - Full Title or subject (specific) to ensure traceability;
 - Numbers of pages; and
 - Accessibility (e.g., proprietary, privileged).
- 8.1.7 The additional listed information shall be provided, if applicable:
- Unique identifier (e.g., report number);
 - Attachments or enclosures;
 - Cross references; and

- References to QA Record Package (if applicable).

Note: Forms shall have all blanks filled in, or have “N/A” entered in the blank; unless instructions clearly state that an area does not need to be filled in.

8.2 Storing and Preserving Quality Assurance Records

8.2.1 The Record Source shall protect in-process documents from damage or loss from the time of creation of the document until the document is ready for submittal. Documents intended to be 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 Records Storage.

Note: All QA Records generated for scheduling, planning, performing, and documenting Quality Assurance (QA) oversight of the High-Level Radioactive Waste (HLW) and Used Nuclear Fuel (UNF) programs shall be classified as “Lifetime.”

8.2.2 QA Records shall not be destroyed without prior approval from EMCBC Records Management. EMCBC Records Management shall ensure the following conditions have been met:

- QA Regulatory requirements are satisfied;
- Operational status permits the disposal of QA records;
- Contractual requirements have been satisfied;
- DOE NARA-approved Records Disposition Schedule retention period has been met.; and
- EMCBC Records Disposition program requirements have been satisfied.

8.2.3 The EMCBC Records Management personnel provides protection of all QA Records as follows:

- EMCBC Records Storage is a Long Term Storage Facility located in Springdale, Ohio that can store all media types (e.g., paper, electronic) and can provide dual storage;
- Ensures QA records are protected from moisture, temperature, and pressure by regulating normal office environmental controls;
- QA records are filed in a container with a minimum of two-hour fire rating for single storage facility or a container with a minimum one-hour fire rating for dual storage. Records in a single storage facility are protected from excessive light, stacking, electromagnetic fields,

radiation, and accidental or deliberate alteration or erasure of information;

- EMCBC Records Storage is protected from unauthorized entry; and
- When required, uses a dual storage system.

8.3 Submitting QA Records and QA Record Packages

8.3.1 EMCBC Records Management personnel shall use the following steps when receiving QA Records:

- Verify the QA record received;
- Resolve discrepancies in QA records or QA record packages either through direct interaction with the Record Source or by formally rejecting the record;
- Verify that the QA record has been authenticated, is legible and complete;
- Verify electronic media to ensure appropriate metadata is included to meet NARA requirements;
- After acceptance, index the records into the Electronic Records Management System (ERMS) with appropriate identification (e.g., Privileged, Proprietary), the appropriate QA designation (lifetime), and scheduled in accordance with DOE NARA-approved Disposition Schedules (e.g., retention schedules).

Note: Editorial and/or review comments placed directly on draft documents, and prepared in lieu of Document Review Comment forms, are not considered to be corrections. Rather, they are review comments for consideration by the author. Therefore, these markings do not require initials and dates as per the records correction process given in Section 8.3.5, *Supplementing, Changing, or Correcting Records*.

8.3.2 Non-Paper Media QA Records

8.3.2.1 Machine readable media submitted to EMCBC Records Storage shall have a detailed external label affixed describing the QA record content. If multiple QA records are submitted together, an index describing each shall be included. A signature by the Record Source serves as verification that the contents of the QA record on the media is complete and appropriate for the work performed.

8.3.2.2 The Record Source shall protect non-paper media (e.g., CD's DVD's, etc.) containing QA records from magnetic fields, heat, moisture, light, or anything that would cause deterioration of the media and the information it contains.

8.3.3 E-mail QA Records

8.3.3.1 E-mails generated or received that meet the definition of a federal record, whether they are designated a QA record or not but relate to the QA record or QA record package shall be forwarded via email to EMCBC Records Storage. To ensure authenticity a hard copy shall be printed to include envelope/header information and submitted to the EMCBC Records Storage.

8.3.4 Special Processed QA Records

8.3.4.1 QA records that cannot be duplicated, (e.g., unique one-of-a-kind records), shall be identified, as such, and shall be coordinated with EMCBC Records Management personnel.

8.3.5 Supplementing, Changing, or Correcting QA Records

8.3.5.1 Corrections to QA records shall include the initials or signature of the authorized person making the correction and the date the correction was made. Corrections to QA records should be made with a single line-through and should not obliterate the prior entry. QA records should not be corrected through the use of correction fluids or tapes. Corrections to QA records will be authorized by the originating organization. Additionally, QA records should not contain highlighter markings, since this information may be lost when the record is photocopied or imaged.

8.3.5.2 QA records that are incomplete or illegible may be corrected by transcribing, regenerating, or enhancing the illegible portion of the QA record, or by obtaining a new, complete, legible record. A memo of record shall be used to document the impact of the incomplete or illegible information.

8.3.5.3 Replace, restore, or substitute a lost or damaged QA record by obtaining a copy, if available, from the Record Source. If replacement or restoration is not practical (i.e., one-of-a-kind record), then EMCBC Records Management personnel shall request that the Record Source document the loss, in a memorandum to file, that has been signed by the Responsible Manager or QA Lead. This memorandum shall describe the impact of the loss of the work.

8.3.5.4 If an entire QA record needs to be changed, or numerous corrections must be made, a new QA record shall be submitted to supersede the old QA record.

8.3.6 Retrieval of QA Records

8.3.6.1 Upon request, EMCBC Records Management personnel shall retrieve QA records using the indexing information prescribed in Section 8.1, *Identification and Creation of Records*. EMCBC Records Management is responsible for development and maintenance of an Electronic Records Management System that meets the Federal recordkeeping requirements, as well as, providing the efficient management, retrieval and disposition of QA Records. QA records may be viewed in EMCBC Records Storage by a designated person and “Informational Copies” may be provided with proper approval.

8.3.6.2 Access to the EMCBC Records Storage shall be controlled and a list maintained designating personnel who are permitted to access QA Records, including viewing privileged and proprietary records. All entries shall be locked when records personnel are not present.

9.0 RECORDS MAINTENANCE

9.1 QA records generated while performing oversight functions for the HLW and UNF Programs shall be submitted to EMCBC Records Storage in accordance with this procedure as individual QA records or included in a QA records package, as specified. QA records shall be maintained and dispositioned in accordance with the requirements listed in Section 4.0, *Requirements and References*.

9.2 Lifetime QA records shall be retained and maintained until the license is amended for permanent closure.

9.3 Nonpermanent QA records shall be retained until the issuance of a license to receive and possess SNF/HLW. At a minimum, nonpermanent QA records shall be retained for 10 years or the life of the item if less than 10 years. For programmatic nonpermanent QA records, the retention period shall be considered to begin on completion of the activity. For product nonpermanent QA records, the retention period shall be considered to commence upon completion of delivery.

10.0 FORMS USED

Form 5.1-1, Record of Revision

11.0 ATTACHMENTS

N/A

RECORD OF REVISION

DOCUMENT: AP-17.1Q, Quality Assurance Records

If there are changes to the controlled document, the revision number increases by one. Indicate changes by one of the following:

- I Placing a vertical black line in the margin adjacent to sentence or paragraph that was revised.
- I Placing the words GENERAL REVISION at the beginning of the text.

Rev. No.	Description of Changes	Revision on Pages	Date
0	Original	All	04/27/2011