



Environmental Management Consolidated Business Center
Ash Fall Project

Quality Assurance Records

Procedure: AFP-AP-20
Revision 0, 04/21/16

Quality Assurance Records

Revision: 0

Effective Date is 3 days after the date of approval

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1.0 PURPOSE

The purpose of this procedure is to establish the process and responsibilities for Quality Assurance (QA) records that relate to the Department of Energy Environmental Management Consolidated Business Center (EMCBC) Ash Fall Project.

2.0 SCOPE

The scope of this procedure is to describe the process for managing QA Records in support of the Department of Energy EMCBC Ash Fall Project work activities.

3.0 APPLICABILITY

This procedure applies to Office of River Protection (ORP) personnel, EMCBC personnel and contractors that generate, maintain, use, store, and index records resulting from participation in activities associated with the Ash Fall Project supporting the ORP.

4.0 REQUIREMENTS and REFERENCES

4.1 Requirements

4.1.1 EM-QA-001, *EM Quality Assurance Program (QAP)*

4.1.2 ASME NQA-1-2008/2009a, *Quality Assurance Requirements for Nuclear Facility Applications*

4.2 References

4.2.1 AFP-QAPP-01, *Quality Assurance Project Plan (QAPP)*

4.2.2 AFP-AP-19, *Corrective Actions*

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.

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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 that are 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.
- 5.4 QA Record – A completed document or other medium that furnishes evidence of the quality of items, the capability for safe operation, and/or activities.

6.0 GENERAL RESPONSIBILITIES

- 6.1 Record Source (Ash Fall Project Staff)
- 6.1.1 Creates, temporarily stores and submits QA records to EMCBC Coordinator, Office of Technical Support and Asset Management
- 6.2 QA Lead
- 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, and 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 completed QA records to the EMCBC Coordinator.

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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 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.

8.1.2 The Record Source shall create records ensuring they are legible, accurate, complete, and traceable to the activity to which they apply.

8.1.3 The Record Source shall ensure electronic records are provided the appropriate level of security to ensure integrity of the data in electronic information systems (including electronic back-up files).

8.2 Maintaining 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).

8.2.2 The Record Source shall protect records according to the following:

8.2.2.1 Keep liquids away from the record to prevent damage from spills.

8.2.2.2 Keep smoking materials and other heat sources away from the record to prevent scorching or burning.

8.2.2.3 Keep magnetic media away from sources of magnetic fields to prevent loss of recorded information.

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8.2.2.4 Avoid stacking magnetic media near telephones, radios, compact disk players and loudspeaker systems.

8.3 Submitting QA Records

8.3.1 The Record Source shall compile the records in hardcopy or electronic copy, and verify the records are complete.

8.3.2 For electronic records, the Record Source shall provide:

8.3.2.1 A directory listing all files contained on the electronic media.

8.3.2.2 Information related to the associated activity (e.g., Data Tracking Number).

8.3.3 When submitting records, the Record Source shall provide Form 20-1 *Records Transmittal Form* to ensure the EMCBC Coordinator can verify that the QA records received are in agreement with the transmittal document.

8.4 Receiving and Indexing QA Records

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

8.4.1.1 Verify the following for QA records received.

- Record is legible
- Record is authenticated
- Changes/corrections are appropriately documented
- All attachments are included.

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

8.4.1.3 Acknowledge receipt with signature and date on Form 20-1, *Records Transmittal*. The form shall be kept with its corresponding records package.

8.4.2 The EMCBC Coordinator shall index QA records by updating Form 20-2, *Record Indexing Log*. The form shall contain the following information:

- File Number
- File Category

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- Record/Record Package(s)
- Record Location
- Retention Time
- Hard Copy
- Digital Copy.

8.4.3 On an annual basis, the EMCBC Coordinator shall complete the Form 20-2, *Record Indexing Log* by signing and dating the form. The completed Form 20-2, *Record Indexing Log* shall be placed with the other QA records associated with the Ash Fall Project.

8.5 Correcting QA Records

8.5.1 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.

8.5.2 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, etc.).

8.6 Storing, Retrieval, and Replacement of QA Records

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

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

8.6.1.2 QA records shall be 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.

8.6.1.3 QA records are protected from unauthorized access.

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8.6.2 Retrieval of QA Records

8.6.2.1 Upon request, the EMCBC Coordinator shall retrieve QA records using the indexing information in Form 20-2, *Record Indexing Log*.

8.6.2.2 The EMCBC Coordinator shall post a list of designated 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.

8.6.3 Replacement of QA Records

8.6.3.1 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.

8.6.3.2 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 AFP-AP-19, *Corrective Actions*, as a noncompliance with either 8.2.1 or 8.6.1 of this procedure depending on the circumstances.

9.0 RECORDS

QA records shall be submitted to the 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 20-1, *Records Transmittal*

9.1.2.2 Form 20-2, *Record Indexing Log* (Completed by Fiscal Year)

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

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9.2 Non QA Records

9.2.1 None.

10.0 FORMS USED

Form 20-1 – Records Transmittal
Form 20-2 – Record Indexing Log

11.0 ATTACHMENTS

None.

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Ash Fall Project AFP-AP-20, Form 20-1, Records Transmittal		
Record Package Title		
Document Identifier		
Document Revision/Version Date		
Record/Record Package Page Count		
Record Package Contents		
_____	_____	_____
Record Source Print Name	Signature	Date
_____	_____	_____
EMCBC Coordinator Print Name	Signature	Date

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Form 20-1 – General Instructions

Based on the requirements of the procedure, document the following information on Form 20-1, Records Transmittal:

Record Package Title: Indicate the unique title of the record package (e.g., Supplier Report 16-DOE-EA-001, Audit of xyz company).

Document Identifier: Indicate the unique identifier, if any, of the document (e.g., AFP-AP-18)

Document Revision/Version Date: Indicate the revision/version date of the document, if any.

Record/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 EMCBC Coordinator.

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Form 20-2 – General Instructions

Based on the requirements of the procedure, document the following information on Form 20-2, Records Indexing Log:

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/Record Package(s): Indicate the unique title of the record package (e.g., Supplier Report 16-DOE-EA-001, Audit of xyz company) and total number of pages of the record package.

Record Location: State any relevant information about the record package including the identification of the item or related activity to which the record package pertains including any special storage information (e.g., IP Address, Room Number, etc.).

Retention Time: Indicate the amount of time the record has to be maintained. (This will be designated by the EMCBC Records Coordinator).

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.

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Form 12-1 – Record of Revision

DOCUMENT: AFP-AP-20, *Quality Assurance Records*

Revision Number	Description of Changes	Revision on Pages	Effective Date
0	Initial Issue	All	04/21/2016