

June 18, 2012



Environmental Management Consolidated Business Center (EMCBC)

Subject: Quality Assurance Records

IMPLEMENTING PROCEDURE APPROVED: (Signature on File)

EMCBC Director

ISSUED BY: Office of Technical Support and Asset Management

1.0 PURPOSE

This procedure describes the roles, responsibilities, and processes to be used for identification and maintenance of Environmental Management Consolidated Business Center (EMCBC) /Service Level Agreement (SLA) Quality Assurance (QA) Records. This procedure describes special requirements for QA records but does not negate any applicable Federal records requirements as implemented through IP-243-03, EMCBC Identifying, Filing and Maintaining Records.

Nothing in the issuance of this document alters the legal obligation to comply with Federal Law or Department of Energy (DOE) Directives, in particular those regarding Federal records. In the event there is a conflict between this procedure and a Federal Law or DOE Directive, the Federal Law or DOE Directive takes precedence.

2.0 SCOPE

This procedure describes the processes used by the EMCBC and participating SLA sites to identify and maintain QA records.

3.0 APPLICABILITY

The requirements contained within this document apply to all EMCBC and participating SLA site Federal or support contractor personnel and activities.

4.0 REQUIREMENTS and REFERENCES

4.1 Requirements

- 4.1.1 DOE O 414.1D, Quality Assurance
- 4.1.2 EM-QA-001, EM Quality Assurance Program (QAP)
- 4.1.3 American Society of Mechanical Engineers (ASME) NQA-1-2008, Quality Assurance Requirements for Nuclear Facility Applications (with addenda through 2009)

4.2 References

- 4.2.1 IP-243-03, Identifying, Filing and Maintaining Records
- 4.2.2 Title 36, Code of Federal Regulations (CFR), Part 1220, Federal Records

- 4.2.3 National Archives and Records Administration (NARA) – approved DOE Records Disposition Schedules
- 4.2.4 EMCBC Master File Plan

5.0 DEFINITIONS and ACRONYMS

- 5.1 Lifetime 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 that provide required baseline data for in service inspections.

Lifetime records are required to be maintained for the life of the particular item while it is installed in the plant or stored for future use. (ASME NQA-1-2008)

▲ Note: Lifetime as noted above refers to the period of time that records must be maintained and stored in accordance with NQA-1. Once the lifetime has been met, the record is maintained and retained in accordance with the DOE Records Disposition Schedule and NARA storage requirements.

- 5.2 Nonpermanent Records – are those required to show evidence that an activity was performed in accordance with the applicable requirements but need not be retained for the life of the item because they do not meet the criteria for lifetime records. Nonpermanent records shall be maintained for the identified retention period. (ASME NQA-1-2008)

▲ Note: Identified retention period as noted above refers to a defined period of time that active records must be maintained and stored in accordance with NQA-1. Once the record is cutoff and considered inactive, the record is maintained and retained in accordance with the DOE Records Disposition Schedule and NARA storage requirements.

- 5.3 Quality Assurance (QA) – All those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service. (ASME NQA-1-2008)
- 5.4 Quality Assurance Record – A completed document that furnishes evidence of the quality of items and/or activities affecting quality. Types of record media may include paper, electronic (magnetic or optical), or specially processed media such as radiographs, photographs, negatives, and microforms. The term *record*, as used throughout the Standard, is to be interpreted as quality assurance record. (ASME NQA-1-2008)

6.0 RESPONSIBILITIES

6.1 EMCBC Director or SLA Site Senior DOE Official

6.1.1 Ensures that appropriate processes are in place to identify and maintain QA records.

6.2 Assistant Director, Office of Technical Support and Asset Management or SLA Site Quality Assurance Manager

6.2.1 Appoints a QA Records Coordinator to ensure QA records are identified, classified, generated, authenticated, and maintained, in accordance with this procedure.

6.3 QA Records Coordinator

6.3.1 Reviews and classifies identified QA records.

6.3.2 Works with the applicable Records Management staff to ensure that QA records are properly filed and stored and that records storage facilities meet all appropriate requirements.

6.3.3 Works with Quality Assurance personnel to ensure that QA records are properly generated and authenticated.

6.4 Records Management Staff

6.4.1 Work with the QA Records Coordinator to ensure QA records have the correct schedule/retention assigned, they are properly maintained, stored and turned over when the lifetime has been met (lifetime QA records) or at cutoff (nonpermanent QA records).

6.5 Quality Assurance Personnel

6.5.1 Ensure that QA records are properly generated, authenticated, and filed in a timely manner.

7.0 GENERAL INFORMATION

Not applicable

8.0 PROCEDURE

8.1 The QA Records Coordinator shall ensure QA records are identified and specified through implementing procedures or appropriate documents to furnish documentary evidence that items or activities meet specified quality requirements. (NQA-1, Part I, Requirement 17, Section 100 and 200) Attachment A provides an example of QA records identification documentation.

- 8.2 The QA Records Coordinator shall review and classify QA records as lifetime or nonpermanent. (NQA-1, Part I, Requirement 17, Section 400, Paragraphs 401 and 402) Attachment B provides an example of QA records classification documentation.
- 8.3 The Records Management staff shall ensure retention is applied to QA records (NQA-1, Part I, Requirement 17, Section 700 and 36 CFR 1220.36) per IP-243-03, Identifying, Filing and Maintaining Records.
- Note: Classifications shall be noted in the EMCBC Master File Plan, if it is not noted, notify the Records Management staff (Office of Technical Support and Asset Management) to ensure the EMCBC Master File Plan is updated accordingly.
- 8.4 QA personnel shall ensure QA records are generated, authenticated, and completed per the applicable implementing procedure or document. Completed QA records shall be turned over to the QA Records Coordinator for filing in a timely manner.
- 8.5 The QA Records Coordinator shall document receipt of QA records. Incoming QA records shall be inspected for correct generation and authentication. QA records found deficient shall be returned for correction.
- 8.6 The QA Records Coordinator shall maintain and protect lifetime QA records for ease of access and storage until the particular item is no longer being used or is retired from service (lifetime has been met) per NQA-1, Part I, Requirement 17, Section 600 and 800. Ensure records are filed (arranged) by *item* to ensure traceability per NQA-1, Part I, Requirement 17, Section 200, Paragraph (b).
- 8.7 The QA Records Coordinator shall turnover lifetime QA records to the Records Management staff once the particular item is no longer being used or is retired from service (lifetime has been met); after which the records become inactive and are stored under NARA requirements (per IP-243-03, Identifying, Filing and Maintaining Records).
- 8.8 The QA Records Coordinator shall maintain and protect nonpermanent QA records for ease of access and storage until cutoff, as defined in the EMCBC Master File Plan, per NQA-1, Part I, Requirement 17, Section 600 and 800. Ensure records are filed (arranged) by *activity* to ensure traceability per NQA-1, Part I, Requirement 17, Section 200, Paragraph (b).
- Note: If the nonpermanent QA record must remain *active* longer than what is noted in the EMCBC Master File Plan, contact the EMCBC Records Management staff to make the necessary revisions to the file plan.
- 8.9 The QA Records Coordinator shall turnover nonpermanent QA records to the Records Management staff at cutoff; after which the records become inactive and are stored under NARA requirements (per IP-243-03, Identifying, Filing and Maintaining Records).

9.0 RECORDS MAINTENANCE

No new records are generated as a result of implementing this procedure; however, this procedure details the identification and filing for QA records generated/received at the EMCBC. QA records generated/received are noted in the EMCBC Master File Plan.

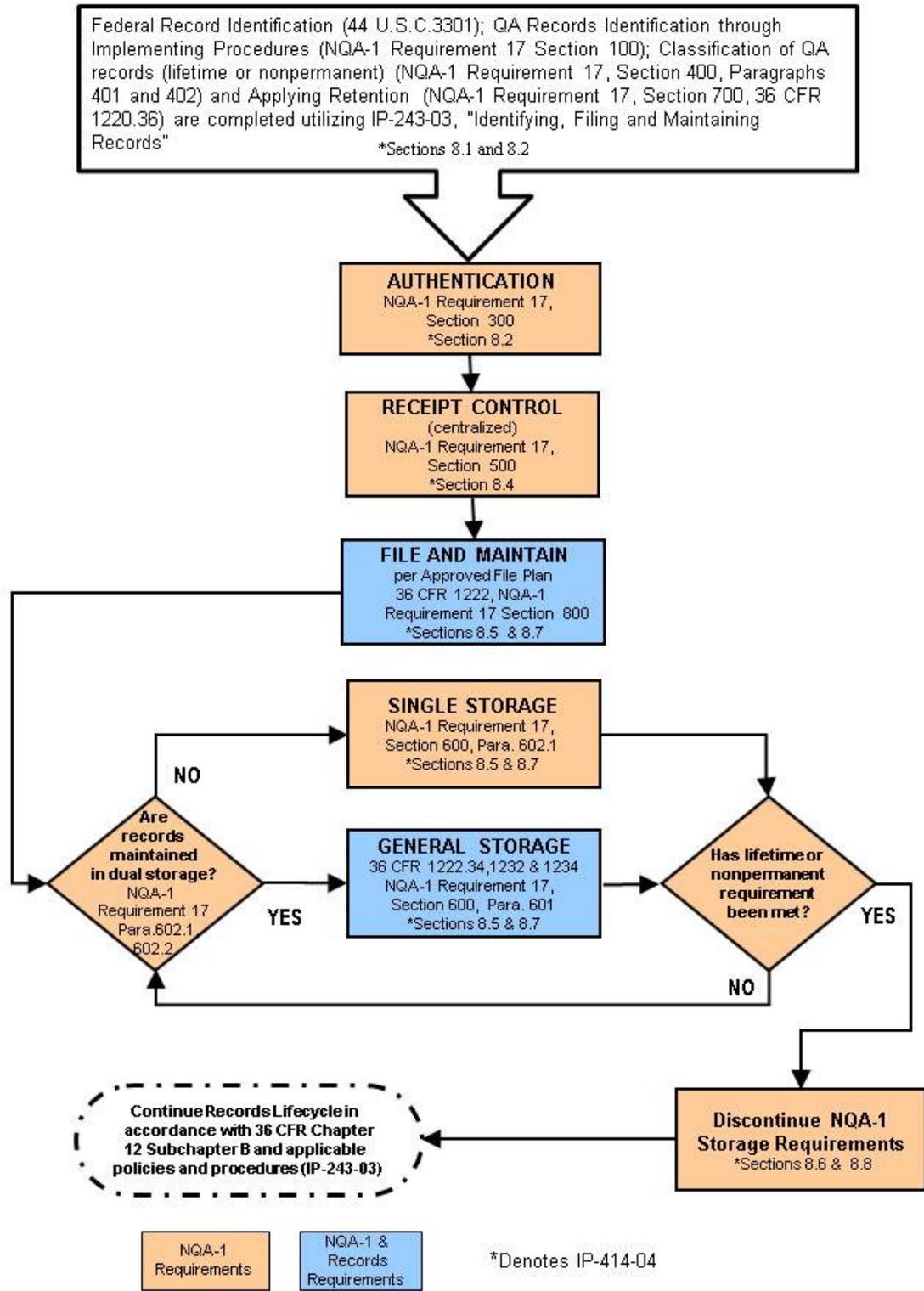
10.0 FORMS USED – Not Applicable

11.0 ATTACHMENTS

Attachment A – Sample EMCBC QA Records Identification Matrix

Attachment B – Sample EMCBC QA Records Classification Matrix

12.0 FLOWCHART



ATTACHMENT A

SAMPLE EMCBC QA RECORDS IDENTIFICATION MATRIX

NQA-1 Requirements and Applicable QA Records	Procedure
Requirement 1 – Organization	
Requirement 2 – Quality Assurance Program	
<p>500 Records</p> <p>Records of the implementation for indoctrination and training may take the form of attendance sheets, training logs, or personnel training records. Records of indoctrination and training shall include one or more of the following:</p> <p>(a) attendance sheets (b) training logs (c) personnel training records</p> <p>The employer shall establish and maintain records for indoctrination and training; Auditor and Lead Auditor qualification and requalification; and inspection and test personnel qualification and requalification.</p>	
Quality Assurance Program QAP/QIP and Implementing Procedures Qualification of Quality Assurance Assessment Personnel	PL-414-01 IP-414-02
Requirement 3 – Design Control	
<p>900 Documentation and Records</p> <p>Design documentation and records shall include not only final design documents, such as drawings and specifications, and revisions to those documents, but also documentation that identifies the important steps in the design process, including sources of design inputs that support the final design.</p>	
Not Applicable	
Requirement 4 – Procurement Document Control	
Requirement 5 – Instructions, Procedures, and Drawings	
Requirement 6 – Document Control	
Requirement 7 – Control of Purchased Items and Services	
<p>800 Records</p> <p>Records shall be established and maintained to indicate the performance of the following functions:</p> <p>(a) supplier evaluation and selection (b) acceptance of items or services (c) supplier nonconformances to procurement document requirements, including their evaluation and disposition (d) utilization and acceptance of commercial grade items</p>	
Review, Approval, and Assessment of QAPs/QIPs	IP-414-10

ATTACHMENT A (Cont'd)

NQA-1 Requirements and Applicable QA Records	Procedure
Requirement 8 – Identification and Control of Items	
Requirement 9 – Control of Special Processes	
<p>400 Records Records shall be maintained as appropriate for the currently qualified personnel, processes, and equipment of each special process.</p>	
Not Applicable	
Requirement 10 – Inspection	
<p>800 Records Appropriate records shall be established, maintained, and, as a minimum, identify the following: (a) item inspected (b) date of inspection (c) inspector (d) type of observation (e) results or acceptability (f) reference to information on action taken in connection with nonconformances</p>	
Not Applicable	
Requirement 11 – Test Control	
<p>600 Test Records Test records shall be established and maintained to indicate the ability of the item or computer program to satisfactorily perform its intended function or to meet its documented requirements. Test records vary depending on the test type, purpose, and application, but shall contain the following information, as a minimum, for the specified application identified in paras. 601 and 602.</p> <p>601 Test Records (a) item tested (b) date of test (c) tester or data recorder (d) type of observation (e) results and acceptability (f) action taken in connection with any deviations (g) person evaluating test results</p> <p>602 Computer Program Test Records (a) <i>Verification Test Records</i> (1) computer program tested (2) computer hardware tested (3) test equipment and calibrations, where applicable (4) date of test (5) tester or data recorder (6) simulation models used, where applicable</p>	

ATTACHMENT A

NQA-1 Requirements and Applicable QA Records	Procedure
<p>(7) test problems (8) results and applicability (9) action taken in connection with any deviations noted (10) person evaluating test results (b) <i>In-Use Test Records</i> (1) computer program tested (2) computer hardware tested (3) test equipment and calibrations, where applicable (4) date of test (5) tester or data recorder (6) acceptability</p>	
Not Applicable	
Requirement 12 – Control of Measuring and Test Equipment	
<p>400 Records 401 General Records shall be established and maintained to indicate calibration status and the capability of measuring and test equipment to satisfactorily perform its intended function. 402 Reports and Certificates Calibration reports and certificates reporting the results of calibrations shall include the information and data necessary for interpretation of the calibration results and verification of conformance to applicable requirements.</p>	
Not Applicable	
Requirement 13 – Handling, Storage, and Shipping	
Requirement 14 – Inspection, Test, and Operating Status	
Requirement 15 – Control of Nonconforming Items	
Requirement 16 – Corrective Action	
Requirement 17 – Quality Assurance Records	
Requirement 18 – Audits	
<p>800 Records Audit records shall include audit plans, audit reports, written replies, and the record of completion of corrective action.</p>	
<p>Quality Assurance Program Management Reviews Quality Assurance Program Assessments Quality Assurance Program Corrective and Preventive Action</p>	<p>IP-414-09 IP-414-10 IP-414-03</p>

ATTACHMENT B

SAMPLE EMCBC QA RECORDS CLASSIFICATION MATRIX

QA Records Listing	Procedure	File Plan	Classification
Requirement 2 – Quality Assurance Program			
Quality Assurance Program QAP/QIP QAP/QIP Implementing Procedures Quality Assurance Review and Approval	PL-414-01	ADM 18.36.1	Nonpermanent
Qualification of QA Assessment Personnel Qualification Objective Evidence	IP-414-02	ADM 18.35.a	Nonpermanent
Requirement 7 – Control of Purchased Items and Services			
Review, Approval, Assessment of QAPs/QIPs Review Reports Assessment Reports QAP/QIP	IP-414-10	ADM 22.2.b1	Nonpermanent
Requirement 18 – Audits			
Quality Assurance Program Reviews Review Plans Review Reports Review Checklists Attendance Sheets Objective Evidence	IP-414-09	ADM 22.2.b1	Nonpermanent
Quality Assurance Program Assessments Assessment Plans Assessment Reports Assessment Checklists Attendance Sheets Objective Evidence	IP-414-10	ADM 22.2.b1	Nonpermanent
Quality Assurance Program Corrective and Preventive Action Corrective Action Plans Preventive Action Plans Causal Analysis Reports Objective Evidence	IP-414-03	ADM 22.2.b.1	Nonpermanent

See the EMCBC Master File Plan for specifics on file arrangement, cutoff, and retention.

EMCBC RECORD OF REVISION

DOCUMENT: IP-414-04, EMCBC 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	Initial Procedure	All	06/18/12