

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-012

Revision 3 Chg 2

Page 1 of 8

Title

QAP-012 QUALITY ASSURANCE RECORDS CONTROL

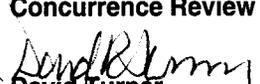
EFFECTIVITY AND APPROVAL

Revision 3 of this procedure became effective on 04/23/01. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
1	2	06/10/04
2	0	04/23/01
3	2	06/10/04
4-7	0	04/23/01
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Supersedes Procedure No. QAP-012, Rev. 3, Chg 0 dated 04/23/01.

Approvals

Written By  Robert Brient	Date 6/10/04	Concurrence Review  David Turner	Date 06/10/2004
Quality Assurance  Mark Ehnstrom	Date 6/10/04	Cognizant Director  Budhi Sagar	Date 6/10/04

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-012

Revision 2 Chg 0

Page 2 of 8

QAP-012 QUALITY ASSURANCE RECORDS CONTROL

1. PURPOSE

The purpose of this procedure is to describe the methods of collecting, validating, processing, storing, and retrieving Quality Assurance (QA) Records. This procedure implements the requirement of the CNWRA Quality Assurance Manual (CQAM) Section 17, and provides retention times for categories of records.

2. RESPONSIBILITIES

2.1 The Director of QA is responsible for implementing this procedure.

2.2 The Director of QA and each Element Manager (EM) are responsible for collecting, validating, and presenting records for processing in accordance with this procedure.

3. PROCEDURE

3.1 QA Records Categories

QA Records consist of Technical QA Records and QA Programmatic Records, and shall be captured and retained in accordance with this procedure.

3.1.1 Technical QA Records include deliverable products and the supporting documentation associated with the development of each product, such as:

- Technical reports
- Papers, abstracts, and presentation materials
- Guidance documents
- Technical data; experimental and test results, material analyses, and Scientific Notebooks (including computer files) which provide results or directly support conclusions
- Data analyses and existing data qualification documentation
- Software documentation
- Technical and Peer Review documentation

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

Proc. QAP-012

Revision 2 Chg 2

Page 3 of 8

QUALITY ASSURANCE PROCEDURE

3.1.2 QA Programmatic Records include those associated with the functioning of the QA program, such as:

- Professional Personnel Qualifications, QA Indoctrination, and training documentation
- Calibration reports and procedures
- Document control records
- Nonconformance, corrective action, surveillance, and audit documentation
- Controlled documents

3.2 Control of In-Process Records

3.2.1 Documents, files, reports, data, electronic files, and other items which become records shall be controlled to prevent loss and destruction. Reasonable precautions shall be taken while gathering and analyzing data—during interim storage before records processing—to preclude loss from fire, water or chemicals, unauthorized access and alteration, and damage or loss of computer files. When harsh environmental conditions are anticipated (e.g., collecting field data) data previously collected shall be copied or otherwise protected to prevent inadvertent loss or damage.

3.2.2 While project work is being conducted, scientific notebooks (whether maintained in hard copy or electronic) shall be considered as records-in-process. The Principal Investigator or person making entries shall suitably store and protect records-in-process from loss or damage. Scientific Notebooks shall be scanned for processing into the Licensing Support Network annually.

3.2.3 To minimize loss of CNWRA work in progress on behalf of its clients, scientific and engineering software, databases, and results of analyses to be used in CNWRA products shall be scanned for processing into the Licensing Support Network annually.

3.2.4 QA Programmatic Records in-process shall be stored in working files by QA staff in the QA Records Room, and completed records shall be processed and validated for permanent storage on an annual basis.

3.3 Records Corrections

3.3.1 Corrections to QA Records and records in-process shall be made by a single line through the incorrect data and inserting the correct data. Corrections may be made only by the individual making the original entry, the cognizant Principal Investigator (PI) or EM. Corrections shall be initialed and dated by the individual making the correction.

3.3.2 Typewriter correction fluid (white-out) or correction tape is not permitted. However, a corrected document may be photocopied and an original signature affixed for acceptance as a QA Record.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

Proc. QAP-012

Revision 2 Chg 0

Page 4 of 8

QUALITY ASSURANCE PROCEDURE

3.4 Records Collection and Validation

3.4.1 QA Records associated with technical activities shall be collected and submitted to QA staff for processing within one month after completion of the activities. The product(s) of such activities and supporting documentation may be consolidated into one record package, or may require separate record packages but must be identified by one accession number.

3.4.2 Similar QA Programmatic Records (i.e., audit reports, nonconformance reports, etc.) shall be assembled into records packages and the pages of each document within the package shall be sequentially numbered. Review documentation for controlled documents shall be processed as individual packages and the original document and acknowledgment records may be kept in a separate file in the document control section of the QA Records Room.

3.4.3 A QA Records Processing Worksheet, CNWRA Form QAP-16 (figure 1), shall be used for each records package, and shall include the following information:

- Record Title
- Record Date (month/year product was completed)
- Author
- Subject Code as shown in table 1
- Project Number
- Retain Until—All Technical QA Records shall be identified as “Permanent” and shall be retained indefinitely; QA Programmatic Records shall be retained as outlined in table 1, which has retention times listed.
- Record Package Contents—List of the documents comprising the package and the number of pages within each document.

3.4.4 The cognizant EM or Director, as applicable, shall attest that the records package is accurate and complete by signing and dating the QA Records Processing Worksheet.

3.5 Records Processing

3.5.1 Records received by QA for processing shall be examined to verify that the appropriate signature appears on the QA Records Processing Worksheet, the records package is complete, and individual records are legible before they are considered validated. Any discrepancies shall be identified to the responsible EM and resolved.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

Proc. QAP-012

Revision 2 Chg 0

Page 5 of 8

QUALITY ASSURANCE PROCEDURE

3.5.2 The information found on the upper portion of the QA Records Processing Worksheet shall be entered into the QA Records Database and an accession number assigned. The accession number, individual entering the information, and date of entry shall be recorded on the QA Records Processing Worksheet.

3.6 Records Storage

3.6.1 Permanent storage of records shall be provided by a dedicated vault located in SwRI Building 189 or SwRI Building 139 with a (minimum) two hour fire rating.

3.6.2 Only designated personnel shall be permitted access to the CNWRA QA Records Room, although others can be escorted.

3.6.3 Some in-process records are maintained in the CNWRA QA Records Room in folders identified as such. Following completion of activities, a complete QA records packet is assembled and verified by the Element Manager to be filed in permanent records.

3.6.4 Records may be checked out from the QA Records Room through QA staff during normal business hours. All records shall be returned daily before the close of business. Check-out cards shall document the record checked out, by whom, and date checked out.

3.6.5 CNWRA QA stores permanent and nonpermanent records. Records are designated for permanent retention if they meet any of the following criteria: (i) provide objective evidence of fulfillment of the particular requirements of the CQAM or Quality Assurance Procedures that implement the CQAM (e.g., audits, QA reviews, training, etc.); (ii) provide objective evidence of the fulfillment of the particular requirements of Technical Operating Procedures (e.g., calibration, regulatory analysis reviews, etc.); (iii) are needed to substantiate the results or basis for licensing and prelicensing reviews; (iv) support regulatory decisions; or (v) would be needed by an independent third party to reconstruct the work that was conducted or results that were obtained. Nonpermanent records are those required to show evidence that an activity was performed in accordance to applicable requirements but need not be retained for the life of the item or activity because they do not meet the criteria for permanent records. Nonpermanent records are kept for a minimum six year period.

3.6.6 Retention times are shown in table 1 for both permanent and nonpermanent record categories. These retention times supersede those referenced in other documents.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

Proc. QAP-012

Revision 2 Chg 0

Page 6 of 8

QUALITY ASSURANCE PROCEDURE

3.7 Records Retrieval

Records may be retrieved by electronic search of the QA Records Database or manual search of the files. QA Records are checked out to individuals and must be returned before the end of the work day. If there is a need for longer review, copies will be made and the original returned to QA Records.

4. RECORDS

The QA Records Processing Worksheet shall remain with the package it describes for as long as the package is retained.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-012

Revision 2 Chg 0

Page 7 of 8

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

QA RECORDS PROCESSING WORKSHEET

Record Title:

Record Date:

Author:

Subject Code:

Project Number:

Retain Until:

Record Package Contents

Number of Pages

Review Documentation

Transmittal Letter

Document

No. of Disk(s)

VALIDATION — I attest that this record package is accurate and complete.

Element Manager:

Date:

RECORDS PROCESSING

Assigned Accession Number:

Processed By:

Date:

CNWRA Form QAP 16

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

Proc. QAP-012

Revision 3 Chg 1

Page 8 of 8

QUALITY ASSURANCE PROCEDURE

Table 1. QA Records Subject Codes

QA RECORDS SUBJECT CODES		
Subject Code	Record	Category
QA Programmatic Records		
100	SwRI Audit Review	Permanent
101	Allegations of Inadequate Quality Documentation	Permanent
102	Delegation of Authority Documentation	Nonpermanent
150	Nonconformance Documentation	Nonpermanent
160	Corrective Action Documentation	Nonpermanent
161	CNWSA Quality Trends	Nonpermanent
170	Records Control Documentation	Nonpermanent
180	Audit Documentation	Permanent
181	Surveillance Reports	Nonpermanent
201	QA Indoctrination Documentation	Permanent
202	Training Documentation	Permanent
203	Personnel Qualification Documentation	Permanent
204	Periodic QA Status Review & QA Requirements Matrix	Nonpermanent
205	SwRI QA Committee Documentation	Nonpermanent
206	Quality Planning Documentation	Permanent
207	QA Memos	Permanent
208	Organizational COI	Permanent
500	QA Program Document Records Copies (APs, QAPs, and TOPs)	Permanent
601	Document Control Documentation	Nonpermanent
602	QA Program Document Review Documentation (Operations Plans and Project Plans)	Permanent
701	Procurement Documents (Receipt Travelers)	Permanent
702	Supplier Qualification Documentation (including Confirmatory Analysis Logbook)	Permanent
703	Supplier Documentation (SwRI QVL and ASL)	Permanent
704	Drawings/Sketches	Permanent
Technical QA Records		
120	Calibration Documentation (if not included as supporting documentation)	Permanent
301	Technical Reports	Permanent
302	Papers and Presentations (including abstracts)	Permanent
303	Regulatory Analysis Documentation	Permanent
304	Existing Data Qualification Documentation	Permanent
305	Software Control Documentation	Permanent
306	Technical Report/Presentation Review Documentation	Permanent
307	Regulatory Analysis Review Documentation	Permanent
308	Technical Activity Supporting Documentation: Experimental Data, Data Reduction and Analysis Documentation, Scientific Notebooks, Computer Files	Permanent
800	Sample Control Documentation	Permanent
900	Procedure Qualification Documentation (if not included as supporting documentation)	Permanent
901	Company Sensitive Documentation	Permanent