

**CENTER FOR NUCLEAR WASTE  
REGULATORY ANALYSES**

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**QUALITY ASSURANCE PROCEDURE**

Title

QAP-012 QUALITY ASSURANCE RECORDS CONTROL

EFFECTIVITY AND APPROVAL

Revision 3 of this procedure became effective on 4/23/2001. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
ALL	3	8/9/2004

Change 3 incorporates editorial changes and uses the term Manager instead of Element Manager.

Supersedes Procedure No. QAP-012, Rev. 3, Chg 2 dated 6/10/04.

Approvals

Written By	Date	Concurrence Review	Date
/s/Robert Brient	8/6/2004	/s/Patrick Mackin	8/6/2004
Quality Assurance	Date	Cognizant Director	Date
/s/Mark Ehnstrom	8/6/2004	/s/Budhi Sagar	8/6/2004

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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 managers 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 which 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. Table 1 lists categories of QA records that are to be retained. Specific contract requirements and 10 CFR Part 2, Subpart J, should be consulted for more detailed definition of records to be retained.

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

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### 3.2 Control of In-Process Records

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.

### 3.3 Records Corrections

3.3.1 Corrections to QA Records and records in-process shall be made by making 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 manager. 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.

### 3.4 Records Process

3.4.1 QA Records associated with technical activities shall be collected and submitted to QA staff for processing promptly to meet programmatic time limits. The product(s) of such activities and supporting documentation may be consolidated into one record package or in separate record packages.

3.4.2 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.

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

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- 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 documents comprising the package and number of pages within each document
- 3.4.4 Records received 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 these records are considered validated. Any discrepancies shall be identified to the responsible manager and resolved.
- 3.4.5 The information found on the upper portion of the Electronic Library Facility (ELF) Records Processing Worksheet shall be entered into the ELF 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.
- 3.4.6 The cognizant manager shall attest the records package is accurate and completed by signing and dating the QA Records Processing Worksheet.
- 3.5 Records Storage
- 3.5.1 Permanent storage of records shall be provided by dedicated vaults located in SwRI Building 189 or 139 with (minimum) 2-hour fire ratings.
- 3.5.2 Only designated personnel shall be permitted access to the CNWRA QA Records Room, although others may be escorted.
- 3.5.3 Some in-process records may be maintained in the CNWRA QA Records Room in folders identified as such. Following completion of activities, a complete QA records packet shall be processed in accordance with sections 3.4 and 3.5.
- 3.5.4 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. If there is need a for longer review, copies will be produced so the original can be returned to QA Records Room.

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3.5.5 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 Operations Plans, CQAM, QA Procedures, or Administrative 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) substantiate the results or basis for licensing and precicensing reviews; (iv) support regulatory decisions; or (v) satisfy potential requirement 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) 6-year period.

3.5.6 Table 1 identifies records categories, subject codes, and classifications as permanent or nonpermanent.

### 3.6 Records Retrieval

Records may be retrieved by electronic search of the ELF Records Database or manual search of the files.

## 4. RECORDS

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



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**Table 1. QA Records Subject Codes**

<b>QA RECORDS SUBJECT CODES</b>		
Subject Code	Record	Category
<b>QA Programmatic Records</b>		
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	CNWRA 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 Advisory Committee on Quality and Environmental Improvement	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 (Proposals, 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
705	Customer Satisfaction	Permanent
<b>Technical QA Records</b>		
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