GEOSCIENCES AND ENGINEERING DIVISION ADMINISTRATIVE PROCEDURE	Proc. QAP–012 Revision 4 Chg 1 Page 1 of 5

Title: **QUALITY ASSURANCE RECORDS CONTROL**

EFFECTIVITY AND APPROVAL

Revision 1 of this procedure became effective on 01/27/2010. This procedure consists of the pages and changes listed below.

Page No.	Change	Date Effective
1	1	01/27/2010
2-3	0	08/18/2005
4	1	01/27/2010
5	0	08/18/2005

Change 1 adds records storage in Building 57.

Supersedes Procedure No. Revision 4, Chg 0 dated 08/18/2005

Prepared by	Date	Approved by	Date
Robert Bunl	1/14/2010	[illegible]	1/14/2010

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 Geosciences and Engineering Division (Division) Quality Assurance Manual (QAM), Section 17.

2. RESPONSIBILITIES

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

2.2 Records originators are responsible for submitting records for processing and storage promptly after the records are completed.

2.3 Division managers are responsible for validating records in accordance with this procedure.

3. PROCEDURE

3.1 QA Records Categories

3.1.1 Technical QA records include deliverable products and the supporting documentation associated with the development of products. Supporting documentation includes document review packages, scientific notebooks, software documentation, test and field data, and equipment calibration records.

3.1.2 QA programmatic records include those items needed to document implementation of the basic quality assurance elements. These include personnel qualifications, QA indoctrination training documentation, document control records, nonconformances, corrective actions, surveillance and audit documentation, and controlled documents.

3.1.3 Table 1 lists categories of technical and programmatic QA records that shall be retained. AP–019, Records Management, specific contract requirements, and 10 CFR Part 2, Subpart J, should be consulted for more detailed information on records to be retained.

3.2 Control of In-Process Records

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

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 information and inserting the correct information. Corrections shall be initialed and dated by the individual making the correction. Corrections may be made only by the individual making the original entry, the cognizant principal investigator (PI), or manager.

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 Processing and Validation

3.4.1 Records originators (i.e., authors or their support staff) shall collect and submit QA records promptly (usually within one week of completion) to Division record control for processing.

3.4.2 Records control personnel shall complete a QA Records Processing Worksheet, form QAP–16, for each record or records package, which includes the following information

- Record title
- Record date
- Author(s)
- Subject code (see Table 1)
- Project number
- Retention period (see Table 1)
- Records package content and page count

3.4.3 Table 1 identifies records categories, subject codes, and classifications as permanent, or nonpermanent. Nonpermanent record shall be retained for a minimum of 6 years.

3.4.4 Records shall be examined by the cognizant manager for completeness, legibility, and accuracy. Any necessary corrections shall be made before the record is validated by the manager's signature on the QAP–16 form.

3.4.5 Record information from the QAP–16 form shall be entered into the electronic library facility (ELF) database, and a unique accession number shall be assigned. The accession number, individual entering the information, and date of entry shall be recorded on the QAP–16 form.

3.5 Records Storage

3.5.1 Validated records shall be stored in dedicated facilities located in Southwest Research Institute® Buildings 57, 189, or 139 having a (minimum) 2-hour fire rating.

3.5.2 Only designated personnel shall be permitted access to the records storage facilities, although others may be escorted into these areas.

3.5.3 In-process records may be stored in the records storage areas while the record packages are being accumulated. Once complete, the record packages shall be processed in accordance with Section 3.4.

3.5.4 Records may be checked out from the records storage area during normal business hours through authorized QA staff. Checked out records shall be returned before the close of business each day. Check-out cards shall document the record checked out, by whom, and date checked out. If longer access to the record is needed, a copy should be made so the original can be returned to the records storage area.

3.6 Records Retrieval

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

Table 1. QA Records Subject Code and Retention Periods

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	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	Nonpermanent
205	SwRI Advisory Committee on Quality and Environmental Improvement Documentation	Nonpermanent
206	Quality Planning Documentation	Permanent
207	QA Memos	Nonpermanent
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	Permanent
702	Supplier Qualification Documentation (including Confirmatory Analysis Logbook)	Permanent
703	Supplier Documentation (SwRI ASL)	Permanent
704	Drawings/Sketches	Permanent
705	Customer Satisfaction	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