| GEOSCIENCES AND ENGINEERING DIVISION<br>QUALITY ASSURANCE PROCEDURE | Proc. QAP–012<br>Revision 4 Chg 0<br>Page 1 of 5 |
|---|---|

Title: **QAP–012 QUALITY ASSURANCE RECORDS CONTROL**

EFFECTIVITY AND APPROVAL

Revision 0 of this procedure became effective on August 18, 2005. This procedure consists of the pages and changes listed below.

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Supersedes Procedure No. QAP–012, Rev. 3, Chg 3 dated 8/9/2004

| Prepared by | Date | Approved by | Date |
|---|---|---|---|
| Robert Smith | 8/17/2005 | [illegible] | 8/17/2005 |

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 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 six 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 areas located in Southwest Research Institute® Buildings 189 or 139 having a (minimum) 2-hour fire rating.

3.5.2 Only designated personnel shall be permitted access to the records storage areas, 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 |