

GEOSCIENCES AND ENGINEERING DIVISION
QUALITY ASSURANCE PROCEDURE

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Revision 3 Chg 0
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Title: **QAP-011 AUDITS**

EFFECTIVITY AND APPROVAL

Revision 3 of this procedure became effective on August 18, 2005. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
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Prepared by

Richard Brice

Date

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Approved by

Wesley A. Smith

Date

8/17/2005

QAP-011 AUDITS**1. PURPOSE**

The purpose of this procedure is to describe the Geosciences and Engineering Division (Division) methods of scheduling, preparing for, performing, reporting, and following up internal audits.

2. RESPONSIBILITIES

2.1 The Director of Quality Assurance (QA) is responsible for implementing this procedure.

2.2 Audit personnel are responsible for performing their tasks in accordance with this procedure.

3. PROCEDURE**3.1 Scheduled Audits**

3.1.1 An internal audit shall be scheduled, at a minimum, each calendar year by the Director of QA. The timing of this audit will take into consideration program status, as well as QA and technical activities being conducted. The annual audit should assess the full scope of the Division QA program; however, if several audits are scheduled, the full scope of the QA program shall be assessed by the combination of audits.

3.1.2 Technical areas to be audited shall be selected based on level and importance of ongoing activities and the time since last audit. Tasks should be audited at least every three years.

3.1.3 Supplemental audits shall be conducted as necessary to (i) verify corrective actions taken for a previous audit finding and (ii) assess activities that could not be evaluated because of the timing of the previous audit.

3.2 Audit Preparation

3.2.1 The audit team leader shall be appointed by the Director of QA. The audit team leader shall have the following duties.

- Issuing an audit notification letter or memorandum
- Coordinating the audit plan and checklist preparation
- Selecting and preparing the audit team prior to the start of the audit
- Organizing and directing the audit
- Conducting pre- and post-audit conferences

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- Coordinating preparation of the audit report
- Evaluating responses to audit-generated Corrective Action Requests

3.2.2 An audit plan shall be prepared for each audit, including the following, as a minimum.

- Audit scope (e.g., activities, products, projects, and quality elements to be audited)
- Organization to be audited
- Audit team and the team leader
- Applicable documents providing the source of requirements to be audited
- Tentative schedule of audit activities
- Audit checklist or reference to this audit procedure

3.2.3 An audit notification memorandum or letter shall be prepared and distributed approximately two weeks prior to the start of the audit. The notification shall include a copy of the audit plan. Copies of the notification shall be distributed to the Division management and affected principal investigators.

3.3 Audit Personnel

Sufficient audit personnel shall be assigned to effectively perform the audit within the scheduled time. Audit personnel shall not have direct responsibility for or have participated in the activities being audited.

- 3.3.1 Lead auditors and auditors shall be qualified in accordance with the Southwest Research Institute® Quality System Procedures, which meet the requirements of American National Standard Institute/American Society of Mechanical Engineers NQA-1.
- 3.3.2 Technical specialists not certified as auditors or lead auditors may be utilized as audit team members. Their qualifications as technical specialists shall be determined by the Director of QA in consultation with the director(s) of the audited department(s) and shall be documented.
- 3.3.3 Audit team members shall be selected based on their knowledge of the quality elements and/or technical areas relevant to the activity being audited.
- ### 3.4 Performance
- 3.4.1 Audits shall be performed using checklists prepared prior to the audit and approved by the audit team leader.
- 3.4.2 Audit checklist questions shall be based on QA requirements and technical reports applicable to the activity being audited.

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3.4.3 Checklists shall be revised during the audit as necessary, deleting items not applicable and adding items based on the audit observations or other findings.

3.4.4 Auditors shall evaluate the implementation of the quality elements and performance of technical activities based on evaluation of records, discussion with audited personnel, and direct observation of activities.

3.4.5 During the audit, the auditor shall document the findings and include or refer to the extent and type of observations and records reviewed.

3.5 Unsatisfactory Findings

Unsatisfactory audit findings shall be classified as:

- Major nonconformances that indicate that implementation is ineffective, there is a significant breakdown in the quality system, or the conditions are likely to lead to delivery of materially nonconforming products. Major nonconformances shall be addressed in accordance with QAP-010, Corrective Action.
- Minor nonconformances that do not indicate a significant breakdown in the quality system or are not likely to lead to delivery of materially nonconforming products. Minor nonconformances shall be addressed in accordance with QAP-009, Nonconformance Control.

3.6 Audit Conferences

3.6.1 Pre-audit conferences shall be conducted with the audit team and management of the audited organization to review the scope and purpose of the audit, introduce the audit team, and coordinate audit activities.

3.6.2 Daily audit status meetings should be held during the audit to review, potential findings, to coordinate audit activities, and to allow resolution of findings whenever possible.

3.6.3 Post-audit conferences shall be conducted with management of the audited organization to identify findings and to identify the individuals responsible for corrective action of the findings.

3.7 Audit Reports

3.7.1 Within 30 days of the completion of the audit, the audit team leader shall complete the audit report. The audit report shall be approved by the audit team and the Director of QA, and distributed to the Division management. Distribution of the report should also include each individual responsible for corrective action.

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3.7.2 The audit report shall consist of the following.

- Introduction, identifying
 - Audit number
 - Audit dates
 - Scope of the audit
 - Applicable requirements documents
 - Audit team leader and team members
 - Persons contacted during the audit
 - Audit conferences held
- Summary of findings, describing
 - Evidence reviewed and results of the quality elements and activities examined
 - Unsatisfactory conditions
 - Opportunities for improvement of the quality system
- A statement of adequacy and effectiveness of the quality system and its implementation.
- Approval signatures of the audit team and Director of Quality Assurance.

3.8 Follow-Up

In accordance with QAP-010, Corrective Action, the implementation and effectiveness of corrective actions shall be evaluated through follow-up activities by Division QA staff. If necessary to determine the effectiveness of corrective actions, follow-up audits shall be conducted.

4. RECORDS

The following audit-related documents shall be maintained and retained as QA records in accordance with QAP-012, Quality Assurance Records Control.

- Audit plans
- Auditor and technical specialist qualifications
- Completed checklists
- Meeting attendance rosters
- Audit reports