

GEOSCIENCES AND ENGINEERING DIVISION
QUALITY ASSURANCE PROCEDURE

Proc. QAP-011
Revision 4 Chg 1
Page 1 of 5

Title: **QAP-011 INTERNAL AUDITS**

EFFECTIVITY AND APPROVAL

Revision 4 of this procedure became effective on 12/15/2006. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
1	1	8/10/2007
2-4	0	12/15/2006
5	1	8/10/2007

Change 1: Revises audit reports approval requirements.

Supersedes Procedure No. QAP-011, Revision 4, Change 0, dated 12/15/06

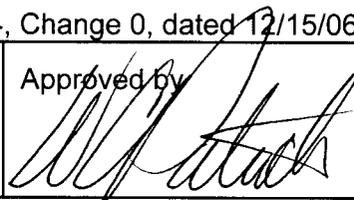
Prepared by



Date

8/11/2007

Approved by



Date

8/21/2007

QAP-011 INTERNAL 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. Internal audits are those conducted of the Division organization and activities by or on the behalf of the Division. This procedure addresses applicable portions of NQA-1-1986, Supplement 18-S-1 and Appendix 18A-1.

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.

2.3 Management and staff being audited are responsible for actively participating in audits and providing corrective action when necessary.

3. PROCEDURE

3.1 Scheduled Audits

3.1.1 One or more internal audits shall be scheduled each calendar year by the Director of QA. The timing of audits shall take into consideration program status, as well as QA and technical activities being conducted. Collectively, the audits shall assess the full scope of the Division QA program.

3.1.2 To the extent possible, audits shall be performance-based (i.e., activities and controls will be evaluated on the basis of their effect on performance). Technical areas to be audited shall be selected based on factors such as the level and importance of ongoing activities and the time since their last audit. Individual activities of long duration should be audited at least once every 3 years.

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

3.2 Audit Preparation

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

- Coordinating the audit plan and checklist preparation
- Selecting, preparing, and training (when necessary) the audit team
- Organizing and leading the audit
- Conducting pre- and post-audit conferences
- Coordinating preparation of the audit report

3.2.2 An audit plan shall be prepared for each audit. The plan shall identify 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

3.2.3 An audit notification memorandum or letter shall be prepared and distributed sufficiently in advance of the audit to allow for adequate preparation by the audit team and organization being audited. The notification shall include a copy of the audit plan. Copies of the notification shall be distributed to 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 frame. 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 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 Audit team members shall be selected based on their knowledge of the quality elements and/or technical areas relevant to the activity being audited.

3.3.3 Technical specialists not otherwise certified as auditors or lead auditors may be audit team members. Their qualifications as technical specialists shall be determined by the Director of QA in consultation with the management of the audited department(s) and shall be documented. Technical specialists shall be trained in audit techniques.

3.4 Performance

3.4.1 Audits shall be performed using checklists prepared prior to the audit.

- 3.4.2 Audit checklists shall be based on QA requirements and technical documentation applicable to the activity being audited. Checklists may be revised during the audit, and auditors may deviate from checklists as necessary to meet the objectives of the audit.
- 3.4.3 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, as appropriate.
- 3.4.4 During the audit, auditors shall document objective evidence of the results of their investigations.
- 3.5 Findings
- 3.5.1 Unsatisfactory audit findings shall be classified as follows:
- Major nonconformances are those that indicate that implementation is ineffective, there is a significant breakdown in the quality system, or 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 are those 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.
- 3.5.2 Regardless of whether corrected during the audit, findings shall be documented in accordance with Section 3.5.1 of this procedure.
- 3.5.3 As appropriate, auditors may identify opportunities for improvement, offer recommendations, and identify good practices.
- 3.6 Audit Conferences
- 3.6.1 A pre-audit conference shall be conducted between 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, coordinate audit activities, and allow resolution of potential findings whenever possible.
- 3.6.3 A post-audit conference shall be conducted with management of the audited organization to report findings and identify the individuals responsible for corrective action of the findings.

3.7 Audit Reporting

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

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 about the overall adequacy and effectiveness of the quality system and its implementation

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 (see Section 3.1.3).

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
- Checklists
- Meeting attendance rosters
- Audit reports