

GEOSCIENCES AND ENGINEERING DIVISION

QUALITY ASSURANCE PROCEDURE

Proc. QAP-004

Rev. 5 Chg 2

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Title: **QAP-004 SURVEILLANCE CONTROL**

EFFECTIVITY AND APPROVAL

Revision 5 of this procedure became effective on 08/08/2005. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
1-2	2	5/12/2010
3	1	7/6/2009
4-5	2	5/12/2010

Change 1: Change from paper-based report to Quality Reporting System (QRS).

Change 2: Reflects QA title change

Supersedes Procedure No. QAP-004, Rev. 5, Chg 1, dated 7/6/2009

Prepared by



Date

4/28/2010

Approved by



Date

4/28/2010

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QAP-004 SURVEILLANCE CONTROL

1. PURPOSE

The purpose of this procedure is to describe the methods of planning and scheduling, conducting, and documenting surveillance activities. This procedure implements the requirements of the Geosciences and Engineering Division (Division) Quality Assurance Manual Section 18, Audits.

2. RESPONSIBILITY

- 2.1 The quality assurance (QA) staff are responsible for implementing this procedure.
- 2.2 Personnel performing surveillance activities are responsible for conducting those activities in accordance with this procedure.

3. PROCEDURE

3.1 Introduction

Surveillance is conducted to determine whether an activity is being performed in accordance with specified requirements. Surveillance typically involves direct observation of activities and is an effective quality verification method for software development, experiments, tests, and similar activities. Surveillance supplements the internal audit program through real time observation and verification that is more frequent than audits and can be performed on short notice. It facilitates timely actions to (i) identify and correct problems and (ii) identify and reinforce good practices while the work is in process.

3.2 Planning and Scheduling Surveillance

- 3.2.1 A surveillance schedule shall be developed annually by the director of QA to ensure activities are periodically evaluated. Surveillance may be scheduled according to the organizations conducting activities or according to the activities conducted.
- 3.2.2 Unscheduled surveillance may be performed as determined necessary by the QA staff. Any member of the Division management team may request that surveillance be conducted.
- 3.2.3 The surveillance schedule shall be revised as necessary to reflect changes in planned activities and to incorporate new tasks.
- 3.2.4 Surveillance schedules and revisions shall be posted on the GED Electronic Library Facility (ELF).

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3.3 Conducting Surveillance

3.3.1 Personnel performing surveillance activities shall be trained in the use of this procedure and shall be independent of the activities being evaluated.

3.3.2 The surveillance scope should be consistent with Table 1 as appropriate to the work being performed. Surveillance should focus on activities being conducted at the time of the surveillance. Emphasis should be placed on verifying compliance with requirements most directly affecting performance and product quality.

3.3.3 Surveillance shall be based on applicable procedural or other requirements. Checklists based on applicable requirements should be used to assure thorough evaluations.

3.4 Processing a Surveillance Report

Surveillance activities shall be documented and approved using the SwRI Quality Reporting System (QRS) tool.

3.4.1 Accessing the Quality Reporting System

QRS is accessed at <https://iqsweb.itc.swri.edu/qrs/qrs-login.pl>.

Account Name: First initial and last name, all lower case, no spaces.

Password: Use your BAMS password, which can be obtained from Information Management System staff. Upon entry to QRS, click on *Report Menu*.

3.4.2 Initiating a Surveillance Report

The individual performing the surveillance activity shall initiate a Surveillance Report (SR) in QRS by clicking on the *Initiate Report* tab, then *Submit SR*. The initiator shall provide the following information.

Division: Click the box on the right and select *20-Geosciences and Engineering*. Below the Division, click the box on the right and select the Department/Section associated with the activity evaluated. When multiple organizations are involved, select the next higher organizational level that encompasses all affected organizations.

Project No: Using the system icon on the right, enter the project number (partial or full) or select *Division 20* to obtain a list of all projects, then select the project number most closely associated with the surveillance activity.

Quality Program: Select *GED (20) QAM*, then *Add Program*.

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Associated Report (Optional): Identify any Nonconformance Report or Corrective Action Report listed in QRS associated with the surveillance activity.

Surveillance Scope: Briefly describe the scope of surveillance activities.

References: Procedures, reports, or other documents pertinent to the surveillance activity should be referenced.

Starting and Ending Dates: Identify the period of the surveillance activities.

Person(s) Conducting Test/Exam/Procedure: Identify persons contacted or observed during the surveillance.

Satisfactory Findings: Satisfactory findings are activities determined to be acceptable. The satisfactory findings may be directly related to specific procedural requirements or may be good practices. Satisfactory findings shall identify the verifications performed and should identify the records or activities observed to determine the finding as being satisfactory.

Unsatisfactory Findings: Unsatisfactory findings shall be fully described (i.e., the requirement not complied with and condition contrary to the requirement). In general, nonconformances identified during surveillance will be formally reported (i.e., QAP-009, Nonconformance Control or QAP-010, Corrective Action, as appropriate). Exceptions shall be justified. The identifying numbers of Nonconformance Reports or Corrective Action Requests shall be entered in the Associated Reports field.

Recommendations/Actions: Recommendations may be provided on the surveillance report, including areas to improve performance, improved methods of recording and storing data, and recommended changes to procedures.

Equipment Calibration: Identify measuring and test equipment reviewed during the surveillance, as appropriate.

SwRI cc: Standard distribution of surveillance report includes the report initiator, the manager of the organization subject to the surveillance, and QA staff. Add any additional distribution using the pull down menu.

3.4.3 Approvals

After the report is submitted, QRS notifies the manager of the organization subject to the surveillance that approval action is required. The manager shall request clarification and revision of the draft report as necessary.

After the manager approves the report, QRS notifies QA staff for evaluation of the draft report. QA staff shall request clarification and revision of the draft report as necessary.

4.0 RECORDS

Surveillance reports shall be maintained as quality assurance records in accordance with QAP-012, Quality Assurance Records Control.

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Table 1

Activity Type	Surveillance Scope	Procedure Reference
General	Verify that a quality requirements application matrix has been completed for the activity.	QAP-013
	Verify that personnel performing activities are properly qualified.	QAP-007
	Verify that scientific notebooks are used when appropriate and entries are properly made.	QAP-001
	Verify that deliverables have required reviews performed and comments resolved. Verify editorial reviews.	QAP-002
Laboratory Activities	Verify that measuring and test equipment is calibrated and is appropriate for the intended use.	QAP-019
	Verify that samples are appropriately identified and controlled.	TOP-012
	Verify that chemicals are properly labeled, controlled, and stored.	TOP-012, AP-010
	Verify that TOPs applicable to specific activities are being implemented effectively.	As indicated in QRAM
Field Activities	Verify that measuring and test equipment is calibrated and is appropriate for the intended use.	QAP-019
	Verify that samples are appropriately identified and controlled.	TOP-012
	Verify that preparations have been made before departure to remote sites.	AP-013
	Verify that TOPs applicable to specific activities are being implemented effectively.	As indicated in QRAM
Modeling and Analysis	Verify that software development and use are properly controlled.	TOP-018
	Verify that calculations are documented and checks have been performed during document reviews when required.	QAP-014
Regulatory Analyses and Technical Support	Verify that APs and TOPs applicable to specific activities are being implemented effectively. Verify that current versions of regulations, statutes, licensee submittals, and the like are being used.	As indicated in QRAM

AP = Administrative procedure

QAP = Quality assurance procedure

GRAM = Quality requirements application matrix

TOP = Technical operating procedure