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Title

QAP–004 SURVEILLANCE CONTROL

EFFECTIVITY AND APPROVAL

Revision 4 of this procedure became effective on 01/08/2004. This procedure consists of the pages and changes listed below.

Page No.	Change	Date Effective
All	0	01/08/2004

Supersedes Procedure No. QAP–004, Rev. 3, Chg. 2, dated 07/09/2003

Approvals

Written By R. Brient	Date 1/8/2004	Concurrence Review P. Mackin	Date 1/8/2004
Quality Assurance M. Ehnstrom	Date 1/9/04	Cognizant Director B. Sagar	Date 1/8/2004

QAP–004 SURVEILLANCE CONTROL

1. PURPOSE

The purpose of this procedure is to describe the methods of planning, scheduling, conducting and documenting surveillance activities. This procedure implements the requirements of Center for Nuclear Waste Regulatory Analyses (CNWRA) Quality Assurance Manual Section 18, Audits.

2. RESPONSIBILITY

2.1 The CNWRA Director of Quality Assurance is responsible for implementing this procedure.

2.2 Personnel performing surveillance activities are responsible for conducting those activities in accordance with this procedure.

2.3 The cognizant Principal Investigator or Element Manager is responsible for identifying activities that would benefit from surveillance and for identifying upcoming hold or witness points to the Director of Quality Assurance.

3. PROCEDURE

3.1 Introduction

Surveillance determines whether an activity is being performed in accordance with specified requirements. Surveillance typically involves direct observation of activities or review of records 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.

3.2 Surveillance Planning

3.2.1 A surveillance schedule shall be developed annually by the Director of Quality Assurance to ensure activities are periodically evaluated. In general, the activities for which surveillance is an appropriate verification method include

- Laboratory and field activities
- Activities documented in scientific notebooks
- Document review
- Software development and use
- Calculation verification

3.2.2 Staff members are encouraged to request surveillance of specific activities at times other than those scheduled.

3.2.3 The surveillance schedule shall be revised as necessary to reflect changes in technical and programmatic activities.

3.2.4 Surveillance schedules and revisions shall be posted on the CNWRA Quality Assurance webpage <http://tuti/qa>.

3.3 Surveillance Conduct

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 Surveillance should be consistent with the scope of Table 1, as appropriate to the work being evaluated.

3.3.3 If a nonconformance is identified while conducting surveillance, a Nonconformance Report or Corrective Action Request shall be initiated in accordance with QAP–009 or QAP–010, as appropriate.

3.4 Surveillance Documentation

Surveillance activities shall be documented on CNWRA Form QAP–8, Quality Assurance Surveillance Report, Attachment 1. The form shall be completed as follows:

3.4.1 A surveillance number shall be obtained from CNWRA Quality Assurance or document control personnel. This number shall be the next sequential number in the surveillance log maintained by Quality Assurance. The surveillance scope shall also be identified in the log.

3.4.2 At the top of the form, the project number; surveillance report number; surveillance scope; reference documents; starting and ending date; identity of the person or personnel performing the surveillance; and the persons contacted during the surveillance shall be identified.

3.4.3 Satisfactory findings are activities determined to be acceptable and should be recorded in the appropriate section of the form. The satisfactory findings may be directly related to a specific procedural requirement 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.

3.4.4 Unsatisfactory findings are activities determined to be unacceptable and should be recorded in the appropriate section of the form. The unsatisfactory finding may be in direct violation of a procedural requirement or may be an unacceptable practice. Unsatisfactory findings shall be fully described (i.e., the requirement not complied with and condition contrary to the requirement). If initiated, the identifying numbers of the Nonconformance Report or Corrective Action Request should be listed in the appropriate field. If the unsatisfactory finding is relatively minor and was easily corrected during the surveillance, a Nonconformance Report or Corrective Action Report may not be necessary, but the condition and correction of the condition shall be fully explained and justified.

3.4.5 Attachments may be provided as objective evidence of surveillance findings.

3.4.6 Recommendations may be listed on the surveillance report, including areas to improve job performance, improved methods of recording and storing data, and possible changes to procedures to describe current job practices.

4. RECORDS

Surveillance Reports and Surveillance Report Logs shall be maintained as Quality Assurance records and retained for the length of time specified in the CNWRA Quality Assurance Manual Section 17.

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
General	Verify that deliverables have had required reviews performed and comments resolved. Verify editorial reviews.	QAP–002
	Verify that calculation checks have been performed during document reviews when required.	QAP–014
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 prior to 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
Regulatory Analyses and Support	Verify that APs and TOPs applicable to specific activities are being implemented effectively.	As indicated in QRAM

AP = Administrative procedure
QAP = Quality assurance procedure
QRAM = Quality requirements application matrix
TOP = Technical operating procedure

ATTACHMENT 1

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES QUALITY ASSURANCE SURVEILLANCE REPORT

PROJECT NO.:	REPORT NO.:	PAGE 1 OF 1

SURVEILLANCE SCOPE:

REFERENCE DOCUMENTS:

STARTING DATE: ENDING DATE:

QA REPRESENTATIVE:

PERSONS CONDUCTING TEST/EXAM/ACTIVITY:

SATISFACTORY FINDINGS:

UNSATISFACTORY FINDINGS:

NONCONFORMANCE REPORT NO.:
CORRECTIVE ACTION REQUEST NO.:

ATTACHMENTS:

RECOMMENDATIONS/ACTIONS:

APPROVED: _____
CENTER DIRECTOR OF QUALITY ASSURANCE

DATE: _____

DISTRIBUTION:
ORIGINAL - QA Records
CNWRA QA DIRECTOR
ORIGINATOR
PRINCIPAL INVESTIGATOR
ELEMENT MANAGER

_____

CNWRA FORM QAP-8 (7/03)