

IMPORTANT NOTICE: The current official version of this document is available via the Sandia National Laboratories OSTI On-line Documents web site. A printed copy of this document may not be the version currently in effect

**SANDIA NATIONAL LABORATORIES
QUALITY ASSURANCE PROGRAM
for the
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT**

QAP 16-1

CORRECTIVE ACTION

Revision 1

Effective Date: 05/20/2004

Author: Original Signed by Jose A. Archuleta

Date: 05/18/2004

Concurrence: Original Signed by Martha J. Mitchell
QA Reviewer

Date: 05/18/2004

Approval: Original Signed by S. Andrew Orrell
SNL OSTI Project Lead

Date: 05/20/2004

CHANGE HISTORY

Revision	Description	Effective Date
0	This is the initial version of this document.	05/13/2004
1	Administrative changes resulting from Audit OQA –FS-04-07	05/20/2004

TABLE OF CONTENTS

	<u>Page</u>
1.0 PURPOSE AND SCOPE	4
2.0 IMPLEMENTATION ACTIONS	4
2.1 GENERAL	4
2.2 PROCESSING NONCONFORMING REPORTS	4
2.3 PROCESSING CONDITIONS ADVERSE TO QUALITY	5
2.3.1 INITIATION OF A CORRECTIVE ACTION REQUEST	6
2.3.2 CORRECTIVE ACTION PLAN: RESPONSE AND RESPONSE EVALUATION TO A CORRECTIVE ACTION	6
2.3.3 FOLLOW-UP VERIFICATION AND CLOSURE OF CORRECTIVE ACTION REQUEST	7
2.3.4 PARTIAL VERIFICATION OF CORRECTIVE ACTION	7
2.4 STOP WORK ORDER (SWO)	7
2.5 RECURRING CONDITIONS ADVERSE TO QUALITY	8
2.6 TREND ANALYSIS	8
3.0 RECORDS	9
4.0 APPENDICES	9
APPENDIX A: NONCONFORMANCE REPORT FORM QAP 16-1-1.....	10
APPENDIX B: NONCONFORMANCE TAG EXAMPLES	11
APPENDIX C: CORRECTIVE ACTION REQUEST	12
APPENDIX D: CORRECTIVE ACTION PLAN	13
APPENDIX E: CORRECTIVE ACTION VERIFICATION	14
APPENDIX F: CAUSAL CODES	15

1.0 Purpose and Scope

This procedure prescribes the Sandia National Laboratories (SNL) Office of science and Technology (OSTI) process for identifying, documenting, evaluating, preventing, controlling, and correcting conditions adverse to quality, and for ensuring continuous improvement.

All SNL OSTI personnel are responsible for detecting and preventing conditions adverse to quality, and for promoting continuous improvement of processes and activities. Management is responsible for developing and fostering an environment in which continuous improvement is a fundamental and integral part of the SNL OSTI's mission and daily conduct. Management at all levels shall foster a "no fault" attitude to encourage the identification of conditions adverse to quality.

The Nonconformance Reporting (NCR) portion of this procedure applies to all items on this project since it provides the mechanisms for reworking items and accepting data collected under nonconforming conditions. Unless systematic and repetitive conditions are identified, the Corrective Action Reporting process shall not be applicable to non-Q items or activities.

Acronyms and definitions for terms used in this procedure may be found in the OSTI Glossary.

2.0 Implementation Actions

2.1 General

Conditions adverse to quality (CAQ) are categorized based on the effect the CAQ has on compliance with regulatory requirements for safety, operability, licensing, and the effective implementation of the Quality Assurance Program Plan (QAPP).

A CAQ is a deviation from a requirement, a deficiency, or some other condition that adversely impacts the quality of a process or product including failures, malfunctions and technical inadequacies.

A significant condition adverse to quality (SCAQ) is a condition that, if uncorrected, could have a serious impact on safety, operability, waste isolation, regulatory compliance demonstration or effective implementation of the SNL OSTI quality assurance program.

2.2 Processing Nonconforming Reports (NCRs) on Items Not Meeting Requirements

General items and samples:

QA shall be notified when a deficiency in a characteristic or record that renders the quality of an item or sample potentially unacceptable or indeterminate, and a Nonconformance Report (NCR), Appendix A, shall be generated. An NCR number shall be assigned by QA. The item or sample shall be tagged with a "Hold Tag" to identify its condition as required by QAP 16-1, Corrective Action. The tag shall be completed when investigation indicates there are restrictions to use or disposition has been determined. Example tags are shown in Appendix B of QAP 16-1.

M&TE Nonconformance

The following conditions shall be identified, by the user of the M&TE, and resolved via the Nonconformance system included in the Corrective Action System.

- M&TE found to be out-of-tolerance during a calibration check, regardless of whether the device was or could be adjusted into tolerance.
- M&TE that produces results known to be in error.
- When M&TE Calibration or Accuracy is in question or any of the conditions listed below are noted, the user shall tag, segregate, or otherwise control the M&TE item to prevent its use until it has been calibrated:
 - The item has exceeded its calibration due date (see also section 2.2.5).
 - The accuracy of the item is suspect because of mishandling, misuse, or unusual results.
 - The item has broken calibration seals.
 - The item has been modified or repaired, had components replaced, or operating software updated.

General Nonconformance

The user shall ensure that the QA contact is notified in such cases, in a documented manner (e.g., memo, e-mail, copy of the calibration report).

These conditions shall result in the following QA actions:

- Immediate remedial action to tag, segregate, or otherwise control the device to prevent the further use of M&TE that could not be adjusted into tolerance during calibration,
- Notification to any other users of the equipment, and
- Investigative action to identify all of the uses of the subject M&TE item since its last calibration, and to evaluate the impact of the out-of-tolerance condition with regard to the validity of previous inspection, test, or data-collection efforts, including the acceptability of items, data collected, processes monitored, or conclusions reached.

Note: If any M&TE is consistently found to be out-of-tolerance during calibration, the user shall have it replaced or repaired, unless a reduced calibration interval is expected to correct the situation. Calibration range or tolerances may be decreased if this does not impact the intended use of the information gathered.

2.3 Processing Conditions Adverse to Quality and Significant Conditions Adverse to Quality

CAQ and SCAQ are documented, reported to the appropriate level of management responsible for the condition and tracked through the Corrective Action Request (CAR) process. QA Lead or alternate is responsible for maintaining the SNL OSTI Corrective Action tracking system database for CARs. QA will make final distribution of all completed and verified CARs. Distribution of the completed CAR will include appropriate management, responsible individuals, and the SNL Records Center. Phases of the CAR process are documented using the following forms:

<u>CAR Phase</u>	<u>CAR Form Number</u>
Initiation	QAP16-1-2 (Corrective Action Request)
Response	QAP16-1-3 (Corrective Action Plan)
Verification	QAP16-1-4 (Corrective Action Verification)

2.3.1 Initiation of a Corrective Action Request

All individuals working on SNL OSTI activities are responsible for identifying and reporting conditions that could adversely affect quality. Documentation of CAQ shall identify and describe the deviation in detail, spelling out how the deviation fails to conform to SNL OSTI Procedures, Test Plans, etc. Any individual working on OSTI activities may initiate a CAR. The CAR process should be initiated as soon as practical once a deviation is identified.

The initiator of the CAR should consult an OSTI QA staff member if the adverse condition appears serious enough to consider categorizing it as a SCAQ. Final determination that a condition will be categorized as a SCAQ shall be made by the QA Team Lead or by the Audit Team Leader during a QA audit. Determination of whether or not the SCAQ warrants issuance of a Stop Work Order (SWO) shall be made in accordance with the process described in Section 2.4 below.

Note: CARs resulting from normal work activities associated with the OSTI project shall have a W designation in the CAR number. CARs resulting from internal or external audits or surveillances will be sequentially numbered using the individual audit/surveillance number. The CAR number will be the audit or surveillance number followed by CAR-A/S-04-XX, and for other work, CAR-W-04-XX.

2.3.2 Corrective Action Plan: Response and Response Evaluation to a Corrective Action Request

The SNL OSTI delegate (CAP Author) responsible for the work activity shall prepare and submit a Form QAP16-1-3, Corrective Action Plan (CAP) to an SNL OSTI QA staff member. The CAP (block 2) shall address the following items for each category:

CAQ	SCAQ (plus items identified in a CAQ)
Name of individual responsible for the action; Estimated completion date; Remedial Action; Investigative Action; Causal code; and Actions to preclude recurrence (optional).	Identification of the root cause of the condition, documentation and results of the root cause determination; and Actions to Preclude Recurrence.

CAPs for CAQs should be submitted to an SNL OSTI QA staff member normally within 30 calendar days of issuance of the CAR. SCAQ CAPs should be submitted within 10 calendar days of issuance of a CAR documenting a SCAQ. For a SCAQ CAP, include documentation and results of the root cause determination. If the CAP can not be provided within the timeframe (30 days CAQ or 10 days SCAQ), then an extension request shall be requested and granted by an SNL OSTI QA staff on or before the due date of the CAP.

A SNL OSTI QA staff member shall review and evaluate the proposed corrective actions described on the CAP, and if acceptable, indicate concurrence in block 3, and returns the approved CAP to its author. The author and initiator then sign concurrence of the proposed corrective action(s) in block 4. The original CAP Form is then forwarded to the QA to enter into the Corrective Action Tracking System.

If any of the proposed corrective actions listed on the CAP are unacceptable to the SNL OSTI QA staff member, then the responsible delegate will submit a new CAP addressing the

corrective actions determined to be unacceptable (if still within the 30 day or 10 day timeframe). If the new CAP cannot be submitted within the timeframe, an extension request shall be submitted for approval on or before the due date.

The CAP author has overall responsibility for coordinating activities to ensure timely completion of the corrective actions listed on the CAP. For CARs with multiple deficiencies, this may require coordination with several individuals from different organizations.

If additional information in the response reveals that a Stop Work Order (SWO) is necessary, the stop work process described in Section 2.3 shall be implemented.

Substantive revisions to the text of a CAR or CAP shall have the same level of approval as the original document. Due date extensions may be granted by the QA organization members and noted on the document original.

2.3.3 Follow-up Verification and Closure of a Corrective Action Request

When all approved corrective actions have been completed, the CAP author shall notify the QATSC. The QATSC shall notify a SNL OSTI QA staff member that corrective action verification is needed.

The SNL OSTI QA staff member selected shall evaluate and verify completion and effective implementation of all corrective actions for the CAR, document this verification on Form QAP 16-1-4, and notify the QATSC that verification is completed. If results of the verification are unsatisfactory, the SNL OSTI responsible manager or delegate shall be notified by QA so that a request for an extension to complete required corrective actions committed to in the approved CAP can be processed. Once corrective actions are complete a re-verification will be performed.

2.3.4 Partial Verification of Corrective Actions

If only partial verification can be performed, document the corrective actions verified, check the "Some" box in Section 4 of Appendix E, sign and date the Corrective Action Verification Form in Section 4. Provide all required detail to indicate corrective actions completed and what actions still remain to be verified. When verification of the remaining actions are subsequently completed, another Form QAP16-1-4 will be completed with details of the verification and traceability to the original verification form, the CAR and CAP.

The SNL OSTI QA staff member will forward the original and any subsequent Form QAP16-1-4, and all supporting documentation to the QATSC. The QATSC will assemble all forms and supporting documentation to make a comprehensive QA record of the closed CAR for distribution to the responsible manager/individual(s) and the SNL Records Center.

2.4 Stop Work Order (SWO)

Any person may identify a situation or condition (typically a SCAQ) for which a SWO is necessary. The potential stop work situation or condition shall be brought to the immediate attention and evaluated by the SNL QA Lead or delegate, the individual responsible for the activity, and the Responsible manager. When Environment Safety and Health (ES&H) is an issue (contact the SNL ES&H Coordinator), all personnel have the authority to stop work. If the work involves a contractor, work stoppage shall be communicated to the contractor through the appropriate Sandia Contracting Representative.

If time is critical (to prevent personnel injury or prevent risk of major noncompliance) the individual responsible for the activity may verbally direct that work be stopped. This shall be followed-up as soon as possible by initiating the CAR process including a letter or memo documenting the Stop Work directive. The recipient of the SWO shall take immediate action to terminate the subject activity and develop corrective actions to correct the deficiency or condition that caused the work stoppage. Investigation, evaluation, remediation, verification, and documentation of the deficiency or condition shall be done in a CAR, letter or memo detailing all the actions required to lift the SWO. The lifting of a SWO shall be documented by a memo attached to the CAR and other documentation.

The SNL QA Team Lead or delegate and the Manager responsible for the activity have the ultimate approval to stop work (in part or total). The SNL OSTI responsible manager and SNL QA Team Lead have the authority to rescind the SWO. The lifting of a SWO shall be documented by use of the Corrective Action Verification Form, letter or memo. Documentation shall state the conditions that justify the lifting of the SWO. The QA shall concur that proper QA controls are in place before the Responsible Manager releases the Stop Work.

QA and responsible individual(s) shall be notified and provided the results of the Stop Work evaluation through formal communications and distribution of Stop Work documentation generated during initiation, investigation, remediation, verification and resolution of the SWO.

2.5 Recurring Conditions Adverse to Quality

For recurring conditions (e.g., same process deviation, activity deviation occurring three times or more) adverse to quality, the CAR Process as described in Section 2.3 shall be followed. The following additional items shall be addressed in Block 2 of the CAP including a determination of the events that led to the deviation(s);

- Development of an understanding to the technical and work activities associated with the recurring condition;
- Determine the extent to which similar quality problems, or precursors to the deviation, have been recognized, and the impact of completed work;
- Consider suspending work (if SCAQ) associated with the applicable activity;
- Identify any generic implications and impacts on completed work;
- Suggest actions that can be taken by the responsible organization to preclude recurrence; and
- Determine the effectiveness of any corrective actions taken.

2.6 Trend Analysis

The trend analysis process provides a method to collect information from program participants (e.g., SNL OSTI program, customer, contractor) to analyze reported deficiencies and Corrected During the Audit/Corrected During the Surveillance (CDA/CDS), and to identify recurring conditions, and causes and root causes that are adverse to quality. Nonconforming conditions are not trended except by number of occurrences and time to disposition.

This analysis uses quality performance data identified, collected and routinely analyzed to assist in the improvement of activities and processes subject to the QA Program. The analysis shall take into account CARs and CDAs/CDSs issued both internally to the SNL OSTI program and from external program participants. CARs and CDAs/CDSs will be evaluated to identify adverse trends, cause/root cause and shall not be limited to one type of work or organization. The trend analysis should focus in areas reported by causal codes (Appendix F), timely completion of

corrective actions, and other quality affecting activities identified during the trend period. The trend analyses are conducted periodically to provide prompt identification of trends adverse to quality.

The QA staff shall gather information and prepare a Trend Analysis Report. Information in the Trend Analysis Report shall be reported to responsible SNL OSTI management, and customer for corrective action as applicable.

3.0 Records

The following QA records, generated as a result of this procedure, shall be prepared and submitted to OCRWM and a copy to the SNL Records Center in accordance with QAP 17-1 (Records):

QA Record

Form QAP 16-1-1
Form QAP16-1-2
Form QAP 16-1-3
Form QAP16-1-4
CAR/CAP changes
Extension Request, as applicable
Supporting documentation
Recurring Condition Evaluation

Trend Analysis Report

4.0 Appendices

Appendix A: Nonconformance Report, Form QAP 16-1-1
Appendix B: Nonconformance Tag Examples
Appendix C: Corrective Action Request, Form QAP16-1-2
Appendix D: Corrective Action Plan, Form QAP16-1-3
Appendix E: Corrective Action Verification, Form QAP16-1-4
Appendix F: Causal Codes



Appendix A

	OSTI Nonconformance Report (NCR)	Form Number: QAP 16-1-1 Page 1 of 1
1. NCR No. _____		
2. Initiator Name _____ Organization _____ Date _____ <small>Print Name Initials</small>		
3. Brief Description of Nonconformance (Use Continuation Page if necessary)		
4. Working Controlling Document No. _____	Number of Tags Applied: _____ Number of Holdings Removed: _____ DATE: _____	
6. NCR EVALUATION <input type="checkbox"/> Q <input type="checkbox"/> Non <input type="checkbox"/> Invalid <input type="checkbox"/> Valid _____ Date _____ <small>Print Name Initials</small>	7. Impacts Waste Isolation, Safety, Licensing, or Data <input type="checkbox"/> Yes <input type="checkbox"/> No	
8. NCR DISPOSITION Corrective Action Required: <input type="checkbox"/> Yes <input type="checkbox"/> No Corrective Action No. _____ QA _____ <small>Print Name Initials</small> Date _____	9. Disposition <input type="checkbox"/> Rework ^{1,2} <input type="checkbox"/> Repair ^{1,2} <input type="checkbox"/> Use-As-Is <input type="checkbox"/> Limited Use ^{1,2} <input type="checkbox"/> Discard/Reject/Scrap Conditional Release ² : <input type="checkbox"/> Yes <input type="checkbox"/> No <small>¹Requires re-examination requirements and acceptance criteria. ²Attach justification if Yes</small>	
10. Disposition Approval Approved by QA _____ <small>Signature Organization Date</small>		
11. Completion of Disposition Action _____ Date _____ Performing Organization _____ Organization: _____ Date _____ <small>Signature</small>		

Appendix B Nonconformance Tag Examples

HOLD TAG

**DO NOT REMOVE
THIS TAG
WITHOUT
AUTHORIZATION**

NCR # _____
Date _____

ITEM# AND
DESCRIPTION

REASON FOR HOLD

FRONT

TAG COMPLETION

**CONDITIONAL
RELEASE or
RESTRICTIONS FOR
LIMITED USE**

FINAL DISPOSTION

DISPOSITION DATE

TAG REMOVED DATE

Return removed tag to
QA

BACK

DO NOT USE

**SEGREGATE ITEM
FROM
WORKING EQUIPMENT**

NCR# _____

Appendix C

	OSTI Corrective Action Request (CAR)	Form Number: QAP 16-1-2 Page ___ of ___
1. Corrective Action Request Number: _____		
Initiator: _____ <small>Printed Name</small>		Date: _____
2. Significant Condition Adverse to Quality (SCAQ)? <input type="checkbox"/> Yes <input type="checkbox"/> No Stop Work? <input type="checkbox"/> Yes <input type="checkbox"/> No		
Date: _____		
SNL QA Team Lead or Audit Team Leader's Printed Name and Signature (ONLY required if SCAQ or Stop Work) _____		
SNL OSTI Responsible Manager's Printed Name and Signature (ONLY required if Stop Work) _____		
3. Deviation identified during Audit/Surveillance No: _____ Supplier (if applicab. _____		
Other: _____ Fact No. _____		
LEAVE THIS BLOCK BLANK IF NOT APPLICABLE		
4. Procedure Reference: _____ (Site procedure & section, document, form, etc. with a brief description)		
5. Description (Provide sufficient detail to allow determination of appropriate corrective actions. Include attachments as necessary)		
6. Proposed Corrective Action: Complete Form QAP 16-1-3, Corrective Action Plan (CAP, Appendix D)		
CAP Response Due Date: _____ (Normally 30 calendar days for CAQ or 10 calendar days for SCAQ)		
Individual(s) Responsible for Submitting CAP (Point of contact for tracking system):		
_____	_____	Date: _____
<small>Printed Name of Delegate</small>	<small>Signature</small>	
_____	_____	Date: _____
<small>Printed Name of Delegate</small>	<small>Signature</small>	
7. Concurrence:		
_____	_____	_____
<small>Printed Name of QA Staff</small>	<small>Signature</small>	<small>Date</small>
_____	_____	_____
<small>Printed Name of Responsible Manager</small>	<small>Signature</small>	<small>Date</small>
Forward Copy to Manager/Responsible Individual(s) & Send Original To QATSC		

Appendix D

	OSTI Corrective Action Plan (CAP)	Form Number: QAP 16-1-3 Page ___ of ___
1. CAR No: _____		
2. CAP Proposed Corrective Actions: (Include attachments as needed)		
Sample Form		
Each CAQ proposed corrective action must include the following: <ul style="list-style-type: none"> Name of individual responsible for the action; Estimated completion date; Remedial actions; Investigative actions (extent of deviation and impact on quality); Causal Code(s); and Actions to Preclude Recurrence (optional). 	SCAQs require the following: <ul style="list-style-type: none"> Items required for CAQ; Identification of the root cause of the condition; Documentation and results of the root cause determination; and Actions to Preclude Recurrence. 	
3. QA Approval of Proposed Corrective Actions: _____		
Print	Signature	Date
4. CAP Author/SNL OSTI Manager Responsible for Corrective Actions:		
	Signature	Date: _____
	Signature	Date: _____
Forward Copy to Manager/Responsible Individual(s) & Send Original To QA		

Appendix F Causal Codes

1. Equipment/Material Problem
 - a. defective or failed part
 - b. defective or inadequate material
 - c. defective weld, braze, or soldered joint
 - d. error by manufacturer in shipping or marking
 - e. electrical or instrument noise
 - f. contamination
 - g. calibration
2. Procedure Problem
 - a. defective or inadequate procedure
 - b. lack of procedure
 - c. failure to use procedure
3. Personnel
 - a. inadequate work environment
 - b. inattention to detail
 - c. violation of requirement or procedure
 - d. verbal communication problem
 - e. other human error
4. Design Problem
 - a. inadequate man-machine interface
 - b. inadequate or defective design
 - c. error in equipment or material selection
 - d. drawing specification, or data errors
5. Training Deficiency
 - a. no training provided
 - b. insufficient practice or hands-on experience
 - c. inadequate content
 - d. insufficient refresher training
 - e. inadequate presentation or materials
6. Administrative Control
 - a. inadequate administrative control
 - b. work organization/planning deficiency
 - c. inadequate supervision
 - d. improper resource allocation
 - e. policy not adequately defined/disseminated/enforced
 - f. other management problem
7. External Phenomena
 - a. weather or ambient condition
 - b. power failure or transient
 - c. external fire or explosion
 - d. theft, tampering, sabotage, vandalism
8. Other