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

QAP 5-1

IMPLEMENTING PROCEDURES

Revision 1

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Date: 05/18/2004

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Date: 05/18/2004

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SNL OSTI Project Lead

Date: 05/20/2004

CHANGE HISTORY

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

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1.0 Purpose and Scope

This procedure prescribes the process to be followed for preparing, reviewing, approving, and maintaining Quality Assurance (QA) implementing procedures (QAPs) and Experimental Implementing Procedures (EIPs) for the Sandia National Laboratories (SNL) Office of Science and Technology and International (OSTI) Program.

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

To include after completion of the review process for the procedure/revision, the Responsible Managers for the work activities are responsible for ensuring individuals under their supervision are properly trained to perform assigned tasks.

2.0 Implementation Actions

2.1 General Requirements

2.1.1 Incorporating Upper Tier Requirements

QAPs shall be developed to provide QA requirements for activities conducted for the OSTI Program. EIPs shall be developed to provide requirements and guidance for technical activities that are repetitive and are more effective if uniform process information is available these procedures shall provide for adequate implementation of QA requirements, and shall be written in sufficient detail to provide for consistent implementation by personnel qualified to work on OSTI projects. Implementation actions shall be specified in either the text of the procedure, or in process flow charts contained within the procedure.

Procedures shall provide control over internal interfaces within an organization, and external interfaces between organizations. An interface exists when one participant prescribes an activity or requirement to, or shares an activity or requirement with, another participant. Interfaces shall be defined, documented, and controlled within relative procedures.

When upper-tier requirement documents are revised, the procedures shall be reviewed, and changes incorporated, as appropriate, to ensure that applicable QA requirements are addressed.

2.1.2 OSTI Glossary

Acronyms and definitions for terms used in QAPs, which are not in common English usage, may be included in the OSTI Glossary. They also may be defined within the QAP as necessary for clarity.

2.2 Format and Content Elements of Implementing Procedures

2.2.1 Types of Implementing Procedures

An OSTI procedure which contains requirements that apply to the entire OSTI Program shall be published as a QAP. Technical or experimental activities containing requirements shall be published in an EIP.

2.2.2 Procedure Format

All QAPs and EIPs procedures shall contain the following Sections:

- 1.0 Purpose and Scope
- 2.0 Implementation Actions
- 3.0 Records
- 4.0 Appendix(ces) or Attachment(s)

If a Section does not apply to a particular procedure, the words “Not Applicable” shall be entered after the Section title. This shall be followed by a brief explanation of why the Section is not applicable. EIPs shall include needed Health and Safety information and precautions in Section 2.0. More extensive Health and safety information or Technical references such as vendor materials may be included in attached materials as described in Appendix A of this QAP. Health and Safety Warnings shall precede the description of the activity to which they apply.

Subsections shall be numbered sequentially. For example:

- 2.1
- 2.1.1
- 2.1.2
- 2.1.3
- 2.1.3.1
- 2.2
- 2.2.1

2.2.3 Page Format

Document Control shall assign procedure numbers and revision numbers. New procedures shall be designated “Revision 0”. Subsequent revisions shall be sequentially numbered, i.e., the first revision shall be numbered “Revision 1.”

Normally, the first number of a QAP shall correspond to an NQA-1 basic element, for example, QAP 5-1 contains requirements related to NQA-1 basic element 5 “Instructions, Procedures, and Drawings.” EIPs shall be numbered sequentially. Numbers shall be obtained from Document Control.

Each QAP page, including pages that contain forms and flow charts, shall contain the following document control header in the upper-right corner of the page:

<u>Example</u>	<u>Explanation</u>
QAP 5-1 or EIP-009	Procedure Number
Revision 0	Revision number
Page 4 of 13	Page x of y
[QA: QA or QA: NQ]	Quality Level

The procedure’s title shall be included in the upper-left portion of all pages except the first page.

Note: The pagination for procedure forms shall appear within the body of the form, and the page of the procedure that contains the form shall include the normal document control header at the top of the page.

A warning to the reader, such as the example given below, shall be placed near the top of the first page of procedures:

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2.3 Preparation, Review, and Approval of Implementing Procedures and Revisions

Implementing documents shall include the following information as appropriate to the nature, scope, and circumstances of the work being performed:

- Responsibilities and organizational interfaces of organizations affected by the document;
- Technical and regulatory requirements
- A sequential description of the work to be performed, including controls for altering the sequence of required operations;
- Quantitative or qualitative acceptance criteria sufficient for determining that activities were satisfactorily accomplished. This may be the review cycle for documents;
- Prerequisites, limits, precautions process parameters and environmental conditions’
- Quality verification points and hold points;
- Methods for determining that the work was performed as required;
- Identification of QA records generated by the document;
- Identification of associated items and activities.

2.3.1 Review and Approval

The review described below shall be documented on Form QAP 6-1-1, Document Review and Comment. The author may obtain additional approval signatures to meet customer requirements, or to provide support.

<u>Roles and Responsibilities</u>	<u>QAP Required Approval</u>	<u>EIP Required Approval</u>
Author (OSTI staff member) ensures that the procedure/revision is complete, ready for review, approval, and issuance.	X	X
QA Reviewer (independent OSTI QA staff member) verifies through review that appropriate quality requirements and controls are included, and any resultant comments have been adequately addressed in the procedure/revision.	X	X
OSTI QA Manager (or delegate) confirms that the procedure/revision is consistent with Project/Program QA policies and requirements.	X	
OSTI Manager (or delegate) confirms that the procedure/revision is consistent with Project/Program direction.	X	
Technical Reviewer (review may be performed by the Principal Investigator if that individual is not the author) verifies that the procedure/revision is technically adequate, correct, and complete. This person must be independent and technically competent to review the procedure (see definitions of “independence” and “technical reviewer” in the OSTI Glossary).		X
SNL ES&H Coordinator confirms that the procedure/revision addresses SNL safety concerns applicable to the activity.		X

2.3.2 Implementing Procedure Review and Approval Process

Procedures shall be reviewed in accordance with QAP 6-1 (Document Review Process). Unless otherwise identified in the procedure, Document Control or QA shall submit Records to the SNL Records Center.

2.4 Changes to Implementing Procedures

2.4.1 Process for Changing OSTI Procedures

Changes to procedures shall be prepared by the author, and reviewed in accordance with QAP 6-1. The author shall ensure that revisions to a procedure are clearly indicated with vertical change bars in the margin of the revised procedure.

Note: Change bars will indicate changes for the current revision only.

2.4.2 History of Changes

Changes to procedures and the reasons for those changes, shall be documented in the Change History of the procedure.

2.5 Issuance and Recall of Quality Assurance Procedures

Once all required signatures are obtained (see Section 2.3.1 above), the new/revised procedure is approved for issuance by the author. This individual's signature is added to the first page of the procedure. The author shall submit the procedure to Document Control.

When an implementing procedure is no longer needed or used it should be recalled and removed from the web distribution.

2.6 Compliance with Quality Assurance Procedures

Individuals performing work shall comply with applicable procedures QAPs. When work cannot be accomplished as described in the implementing procedure, or when it would result in an undesirable situation, a condition adverse to quality, or a safety risk, the work shall be suspended. If there is no safety risk, work may be resumed as soon as a Corrective Action Request (CAR) is written in accordance with QAP 16-1 (Corrective Action). If there is a safety concern, ES&H and management must be consulted before work is resumed.

3.0 Records

The following QA records, generated through implementation 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

- Final approved procedure/revision
- DRC forms

4.0 Appendices

Appendix A: Procedure Cover Page Template

Appendix A
PROCEDURE COVER PAGE TEMPLATE

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QAP XXX

PROCEDURE TITLE

Revision XX

Effective Date: _____

Author: _____

Date: _____

Concurrence: _____

Date: _____

QA Reviewer

Date: _____

Technical Reviewer*

*If document requires Technical Review

Approval: _____

Date: _____

SNL OSTI Project Lead