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**SANDIA NATIONAL LABORATORIES
CIVILIAN RADIOACTIVE WASTE MANAGEMENT
QUALITY ASSURANCE IMPLEMENTING PROCEDURE (QAIP)**

QAIP 20-1

TECHNICAL PROCEDURES

Revision 10

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Author: Original Signed by Jose A. Archuleta

Date: 07/13/2004

Concurrence: Original Signed by James F. Graff
QA Reviewer

Date: 07/14/2004

Approval: Original Signed by Peter N. Swift
SNL CRWM Lab Lead

Date: 07/14/2004

REVISION HISTORY

Revision	Summary
00	Initial Issue.
01	Note 1 was added to Section 4.2 to explain what editorial corrections consist of, how they could be made, and what reviews were required. This implemented details from the QARD.
02	Sections 4.4 and 6.0 and Appendix A were modified to clarify the review and approval process for TPs, incorporate a new requirement concerning responsibility for data reduction and transfer, and to update titles in the "References" section.
03	Modifications were made to sections 4.1, 4.2, 5.0, and Appendix A to clarify how to document modifications to the process specified in a nationally-recognized standard, and to include a "Rationale for Revision" for each TP change.
04	Body of procedure put in playscript format; Revision History incorporated replacing "Rationale for Revision" form; and other modifications necessary to incorporate changes in requirements (QARD Revision 5). Corrective action resulting from Deficiency Report YMQAD-96-034 implemented to clarify records status of review comments.
05	Changes to section 4.2, 5.0, and Appendix A in response to Deficiency Reports YM-96-D080 and YM-96-D088. Concerning expedited changes, clarified that the PI is the authorizing "level of management", specified a time limit for completion of a formal change subsequent to an expedited change, specified a methodology for evaluation of the effect of a formal change differing from an expedited change, and specified that a memo or an e-mail is to be the mechanism for notifying concerned parties about expedited changes. Requires retention of mandatory comment records in section 4.1. Defines record retention period for records generated by this QAIP. Clarified in Appendix A that TPs must cite QAIP 17-1 for records submittal and that records resulting from activities governed by TPs are lifetime (QA:L) records.
06	Reformatted for consistency with other QAIPs, deletes reference to QAIP 2-5, and clarifies record processing.
07	Revised for consistency with Process Validation and Re-engineering procedure changes.
08	Revision to delete requirements to AP-2.14 Review of Technical Products, AP-6.1Q Controlled Documents, and to meet format criteria of QAIP 5-1.
09	Revision to clearly identify the individual who has responsibility for "approval" of TPs or revisions of TPs. Added a template (Appendix B) to the procedure to clarify the TP cover page requirements.
10	Revision to comply with QARD requirement 6.2.5C, control of the disposition of obsolete or superseded documents; editorial changes.

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1.0 PURPOSE AND SCOPE

The purpose of this Sandia National Laboratories (SNL) Civilian Radioactive Waste Management (CRWM) procedure is to define the process for preparing, revising, and approving Technical Procedures (TPs) used in scientific investigations.

This procedure details the requirements for preparation and use of TPs and applies to SNL CRWM staff and others who plan, prepare, conduct, and oversee scientific investigations.

In general, TPs are required for those portions of scientific investigations wherein personnel perform repetitive operations/activities (e.g., the operation of specific equipment or equipment systems used in scientific investigations, or data collection activities involving several replications).

2.0 DEFINITIONS

Technical Procedure (TP): Detailed implementing procedure consisting of a set of written instructions defining technical requirements; constraints; the type, range, and accuracy of measuring devices; and the procedural steps to accomplish a particular task.

3.0 PROCEDURE

3.1 Preparation, Review, Approval, and Issuance of TPs

- 3.1.1 The Author shall prepare a TP to address all appropriate content topics shown in Appendix A and the TP cover sheet shall adhere to the format of Appendix B. The TP number shall be an Arabic numeral that provides a unique identification and shall be obtained from the SNL YMP Document Control staff. Each page of a TP shall bear the following header, located in the upper right-hand side of the page:

TP Number
Revision Number
Page (Number) of (Total number)
QA Designator (QA:QA)

The TP shall include a Revision History immediately following the cover page that provides a description of the changes made to the TP, clearly indicating the source of the changes (procedure improvement, resolution of a deficiency, planning document change, etc.).

- 3.1.2 The author shall obtain reviews from the following individuals as a minimum: a technical reviewer, a QA reviewer, and the Principal Investigator (PI) for the work activity.
- 3.1.3 The reviewers shall clearly and legibly write all comments on the procedure or revision or indicate that there are no comments. Mandatory comments shall be indicated with an asterisk. The reviewer's signatures on the TP cover sheet indicate that the document was reviewed and that review comments were satisfactorily resolved and incorporated.
- 3.1.4 The Technical Reviewer shall review the procedure to ensure technical adequacy, correctness, and completeness. (The technical review may be performed by the PI, if the PI is not the author.)

- 3.1.5 The Quality Assurance (QA) Reviewer shall review the procedure to assure that appropriate quality requirements and controls are included.
- 3.1.6 For each review, the Author shall resolve comments and incorporate the applicable responses in the procedure or revision.
- 3.1.7 The PI is the “level of management” authorized to approve TPs or revisions, shall review to ensure that the TP addresses planning objectives, shall sign the procedure or revision for approval, and shall enter the effective date. The PI then forwards the approved procedure or revision, a copy of the procedure in an acceptable word processing format, and all review documentation to Document Control.
- 3.1.8 SNL Document Control shall ensure that an official version of the procedure or revision is placed on the Sandia National Laboratories Yucca Mountain Project Online Documents web site, and that QA records are submitted to the Records Processing Center (RPC).

3.2 Changes to Procedures

- 3.2.1 Upon identifying the need for a procedural change, the Author shall draft the procedure change(s) and revise the procedure. The Revision History shall be reviewed and updated each time a revision is proposed, to ensure that commitments are not inadvertently deleted.
- 3.2.2 Editorial corrections can be made to documents without being subject to review requirements, and shall be approved by the PI. The following items are examples of editorial corrections:
 - a) Correcting grammar or spelling,
 - b) Renumbering sections or attachments in a way that does not affect the sequence of work,
 - c) Changing the title or number of the document, and
 - d) Updating organizational titles (not responsibilities).
- 3.2.3 If a user of the procedure determines an activity cannot be performed as listed and the change process would cause unreasonable delays, then an EXPEDITED CHANGE may be requested by performing the following steps:
 - a) The user shall contact the responsible PI (who is the “level of management” authorized to approve expedited changes).
 - b) The PI shall review the nature of the change required and either authorize an expedited change or shall stop work until the procedure is revised.
 - c) If an expedited change is authorized, the procedure shall be changed at the work location by taking the following steps:
 - 1) On a copy of the current controlled version of the procedure, draw a single line through the text to be changed.
 - 2) Insert the corrected text above or adjacent to the text being changed.
 - 3) Initial and date the change.
 - 4) Notify the PI of the change completion.
 - d) In a timely manner, the user notifies other affected personnel, as necessary, of the expedited changes via memorandum or e-mail.
- 3.2.4 An EXPEDITED CHANGE shall be processed through the formal revision process within 30 working days of the approval of the expedited change. If the formal revision process results in a change that is different from the expedited change, the results of the work

activities performed under the expedited change shall be evaluated by comparing those results with the projected results had the activities been performed as the formal revision specifies. The results of the evaluation shall be documented and included with the approved revision and review documentation and forwarded for processing by Document Control.

3.3 Distribution and Use of Documents

- 3.3.1 Documents, either in hardcopy or electronic media, used to perform work shall be distributed to, or made available to, and used at the work location.
- 3.3.2 Effective dates shall be established for approved implementing documents.
- 3.3.3 The disposition of obsolete or superseded documents shall be controlled by SNL Document Control to ensure that they are not used to perform work.

4.0 RECORDS

The following QA records and record packages generated as a result of implementing this procedure, including corrections and changes thereto, shall be prepared and submitted as project records in accordance with AP-17.1Q by Document Control staff upon issuance as a controlled document. Individuals creating records shall ensure that the QA records are legible and accurate. QA records shall be protected from damage or loss until submitted to the RPC. Records shall be considered QA records when stamped, initialed, or signed and dated as complete. QA records may be originals or copies. These QA records include:

The approved procedure or revision

Copies of the procedure or revision containing reviewer's comments

Documentation of the evaluation resulting from differing expedited and formal revisions to a TP

5.0 REFERENCES

AP-17.1Q, Records Management

6.0 APPENDICES

Appendix A Technical Procedure Content
Appendix B TP Cover Page Template

TECHNICAL PROCEDURE CONTENT

Appendix A

The topics listed below shall be included in Technical Procedures (TPs), as appropriate. Many of the requirements listed below for a scientific investigation may already be addressed in planning documents and need not be repeated in the TP. Conversely, some of these topics may already be addressed in planning documents, but in a less-detailed manner than is needed in a TP. In such cases, the author shall include as much detail as deemed necessary in the TP.

1. Objectives and the primary tasks involved (including sequencing, if appropriate).
2. Acceptance criteria sufficient for determining that activities were satisfactorily accomplished.
3. Responsibilities of personnel.
4. Reference to any applicable nationally-recognized standards and criteria (e.g., ASTM or ISRM Standards).
5. Reference to other appropriate implementing documents and to appropriate planning documents. Also, identification of associated investigative activities.
6. A description of the laboratory and/or field testing equipment.
7. The identification of computer software.
8. The necessary prerequisites (e.g., calibrated instrumentation, personnel familiarization), special controls, precautions, environmental conditions, process parameters, and/or skills.
9. Methods of identifying, recording, and documenting data to provide traceability, indicate usability, document validation status, and any applicable Project Data Archive Data-Set identification number.
10. Identify methods on how data reduction and transfer shall be controlled to permit independent reproducibility by another qualified individual. Data shall be identified in a manner that facilitates traceability to associated documentation and to its qualification status.
11. Instructions for addressing accuracy, precision, and representativeness of the results (or a detailed reference to appropriate study plan that discusses this issue).
12. A sequential description of the actions to be taken (scientific approach or technical methods used) including the quality assurance program verifications and hold points to overview the work.
13. Controls for altering the sequence of required operations.
14. The required records generated by the TP and method for the recording of objective evidence of the results of the work performed, for example, data collection forms specified by the TP, data acquisition system printouts, sample control documentation (e.g. chain of custody forms), instrumentation calibration/calibration check records, etc. Also included shall be documentation of the evaluation of the results of activities governed by the TP if there is a difference between an expedited change to a TP and the subsequent resulting "formal" revision. This section shall require that records be submitted in accordance with AP-17.1Q and/or AP-SIII.3Q and that they be designated QA:QA.

TP COVER PAGE TEMPLATE
Appendix B

TP-XXX
Revision XX
Page X of Y
QA:QA

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**SANDIA NATIONAL LABORATORIES
CIVILIAN RADIOACTIVE WASTE MANAGEMENT
TECHNICAL PROCEDURE (TP)**

TP-XXX

PROCEDURE TITLE

Revision XX

Effective Date: _____

Author

Date

Technical Review

Date

Quality Assurance Review

Date

Approval

Date

(Reviewer signatures above serve to document the review and resolution of comments)