

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-013

Revision 6 Change 1

Page 1 of 6

Title

QAP-013 QUALITY PLANNING

EFFECTIVITY AND APPROVAL

Revision 6 of this procedure became effective on 8/29/2003. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
ALL	1	7/19/2004

Change 1 incorporates editorial changes and uses the term Manager instead of Element Manager.

Supersedes Procedure No. QAP-013, Rev. 6, Chg 0, dated 8/29/2003

Approvals

Written By	Date	Concurrence Review	Date
/s/Robert Brient	7/19/2004	/s/Patrick Mackin	7/20/2004
Quality Assurance	Date	Cognizant Director	Date
/s/Mark Ehnstrom	7/21/2004	/s/Budhi Sagar	7/20/2004

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES
QUALITY ASSURANCE PROCEDURE**

Proc. QAP-013

Revision 6 Change 1

Page 2 of 6

QAP-013 QUALITY PLANNING

1. PURPOSE

The purpose of this procedure is to identify methods for applying the Center for Nuclear Waste Regulatory Analyses (CNWRA) Center Quality Assurance Manual (CQAM) and implementing procedures for specific CNWRA activities. This procedure implements the requirements of CQAM Sections 2, 3, and 18.

2. RESPONSIBILITY

2.1 The Director of Quality Assurance (QA) is responsible for implementing this procedure.

2.2 Managers and principal investigators (PIs) are responsible for identifying QA requirements applicable to all CNWRA accepted and proposed work.

3. PROCEDURE

3.1 Initial quality planning shall be accomplished through the preparation of Quality Requirements Application Matrices (QRAM), CNWRA Form (Form QAP-17, Fig. 1). The QRAM will identify the extent to which the quality program will be applied. Additional quality measures to be applied to a specific project because of client requirements or regulations shall be documented on the QRAM. Quality planning shall be performed prior to initiation of work activities.

3.1.1 For each element of the work breakdown structure (e.g., Key Technical Issue, Integrated Subissue, project) for CNWRA accepted and proposed work, a QRAM shall be prepared by the cognizant manager and PI, and then shall be approved by the Technical and QA Directors.

3.1.2 The QRAM shall include a brief description of the scope of work and shall identify procedures or actions that are applicable to the activity. The basis for applicability shall be (i) the nature of the activity (e.g., the type of work to be performed), and (ii) the ultimate use of the CNWRA products. Products, such as data and analysis methods (including software), that are expected to be used directly in safety-related applications are of the highest importance, and more stringent requirements apply. Otherwise, and in the absence of specific implementing procedures, good scientific and engineering practices apply to all CNWRA technical activities.

3.1.3 The QRAM shall reference the project or proposal number and current revision of the statement of work for which the QRAM was written.

3.1.4 The QRAM shall indicate if implementing procedures need to be developed to provide adequate controls.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES
QUALITY ASSURANCE PROCEDURE**

Proc. QAP-013

Revision 6 Change 1

Page 3 of 6

3.1.5 The QRAM and QRAM revisions shall be approved by the cognizant manager, Director of QA and the Technical Director in Block 3 of the QRAM form and shall be distributed to CNWRA management and the cognizant PI.

3.1.6 Whenever a CNWRA approved or proposed work plan is changed, the QRAM should be reevaluated and revised, if needed. The basis for revision shall include (i) new tasks, (ii) substantially revised tasks, or (iii) a change in the importance of products with respect to their potential use. Revisions shall be made through markup of the existing QRAM forms, and shall be initialed and dated by the Manager. The QRAM shall be circulated along with changed plans or proposals and shall be re-approved (see Section 3.1.5) whether or not the QRAM was revised.

4. RECORDS

The QRAM and revisions shall be controlled as QA Records in accordance with CQAM Section 17 and shall be permanently retained.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES
QUALITY ASSURANCE PROCEDURE**

Proc. QAP-013

Revision 6 Change 1

Page 4 of 6

CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES
QUALITY REQUIREMENTS APPLICATION MATRIX

OPS Plan or Proposal Title and Client Name: _____

Revision & Change: _____ Date: _____

Project/Proposal No: (if available) _____ Manager: _____

Principal Investigator: _____

Task/Subtask Description:

1. Project/Task Specific Quality Requirements:

AP-005	Obtaining Subcontract Services	<input type="checkbox"/> Yes	<input type="checkbox"/> No
AP-006	Obtaining Consultant Services	<input type="checkbox"/> Yes	<input type="checkbox"/> No
QAP-001	Scientific Notebook Control - Determined by the Manager	<input type="checkbox"/> Yes	<input type="checkbox"/> No
QAP-016	Procurement - will there be any quality-affecting procurement to support this work?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
QAP-017	Drawing Control - are there going to be any drawings?	<input type="checkbox"/> Yes	<input type="checkbox"/> No

2. Quality Requirements Applicable to specific Activities:

2.1: Laboratory and Field Investigations:

TOP-012	Identification, Control, Storage, Handling, Shipping, and Archiving of Samples	<input type="checkbox"/> Yes	<input type="checkbox"/> No
CQAM Ch.12	Control of Measuring and Test Equipment	<input type="checkbox"/> Yes	<input type="checkbox"/> No

2.2 Development and Use of Scientific and Engineering Software:

TOP-018	Development and Control of Scientific and Engineering Software	<input type="checkbox"/> Yes	<input type="checkbox"/> No
---------	--	------------------------------	-----------------------------

List of software subject to these requirements and approximate schedule for implementation:

Figure 1

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES
QUALITY ASSURANCE PROCEDURE**

Proc. QAP-013

Revision 6 Change 1

Page 5 of 6

CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES

QUALITY REQUIREMENTS APPLICATION MATRIX

Software Name:	Software to be Developed/Modified	Software to be Used	Anticipated Validation Dates	Proposed Surveillance Dates
	<input type="checkbox"/>	<input type="checkbox"/>		
	<input type="checkbox"/>	<input type="checkbox"/>		
	<input type="checkbox"/>	<input type="checkbox"/>		
	<input type="checkbox"/>	<input type="checkbox"/>		
	<input type="checkbox"/>	<input type="checkbox"/>		
	<input type="checkbox"/>	<input type="checkbox"/>		

If non-controlled scientific and engineering software will be used, a copy of the software itself and input/output files for specific applications in a deliverable will be maintained as a QA Record.

If controlled software will be used in this task, all input files and appropriate sample output files will be provided to the QA Records folder and retained as a QA Record.

Additional Comments:

2.3 Data and Data Analyses:

QAP-014, Documentation and Verification of Scientific & Engineering Calculations Yes No

QAP-015, Qualification of Existing Data. Yes No

Are existing data used in this activity anticipated to be used to challenge (potential) licensee positions or data?

Describe plans for existing data qualification.

TOP-025, Preparation of NRC Assessment Reports Yes No

If NRC staff contribute, obtain scientific notebook copies prior to document reviews. Yes No

3.0 Approval:

Manager Date

Technical Director Date QA Director Date

Figure 1

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES
QUALITY ASSURANCE PROCEDURE**

Proc. QAP-013
Revision 6 Change 1
Page 6 of 6

CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES
QUALITY REQUIREMENTS APPLICATION MATRIX

Plan/Proposal Revision _____ Change _____ Date _____
 No QRAM changes were necessary QRAM changed as marked

 Manager Date

 Technical Director Date QA Director Date

Plan/Proposal Revision _____ Change _____ Date _____
 No QRAM changes were necessary QRAM changed as marked

 Manager Date

 Technical Director Date QA Director Date

Plan/Proposal Revision _____ Change _____ Date _____
 No QRAM changes were necessary QRAM changed as marked

 Manager Date

 Technical Director Date QA Director Date

Figure 1