

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-013

Revision 0

Page 1 of 4

Title

Quality Planning

EFFECTIVITY AND APPROVAL

Revision 0 of this procedure became effective on 02/14/91. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
All	0	02/14/91

SUPERSEDED

by Revision 1 - 7/15/92

Supersedes Procedure No. None

Approvals

Written By <i>Robert Burt</i>	Date <i>1/29/91</i>	Technical Review <i>J.C. Schmitt</i>	Date <i>2/6/91</i>
Quality Assurance <i>James Mahulo</i>	Date <i>2/13/91</i>	Cognizant Director <i>[Signature]</i>	Date <i>2/17/91</i>

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

Proc. QAP-013
Revision 0
Page 2 of 4

QAP-013 - Quality Planning

1. PURPOSE

The purpose of this procedure is to identify the methods of applying the CQAM and Operating Procedures to specific Center activities, and to provide for scheduling of quality verification. This procedure implements the requirements of CQAM Sections 2, 3, and 18.

2. RESPONSIBILITIES

2.1 The Director of QA is responsible for implementation of this procedure.

2.2 The Element Managers, Principal Investigators, and task leaders, as applicable, are responsible for identifying CQAM requirements applicable to Research Project Plan and Operations Plan tasks as specified by this procedure.

3. PROCEDURE

3.1 Center Operations Plans and Research Project Plans shall include Quality Assurance Sections which indicate that activities shall be controlled in accordance with the CQAM, and shall identify, in general, the portions of the CQAM applicable. This preliminary quality planning shall be as accurate and as detailed as possible considering the general nature of these plans. Concurrence with the Quality Assurance Section (and the balance of the Plan) by the Technical Director and Director of QA shall be documented by their signature approval of these documents as required by CQAM Section 6.

3.2 Initial quality planning shall be accomplished through the preparation of a Quality Requirements Application Matrix.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-013

Revision 0

Page 3 of 4

- 3.2.1 The Quality Requirements Application Matrix shall be prepared by the QA Staff with the input of the Technical Director and Director, SE&I.
- 3.2.2 The Quality Requirements Application Matrix shall list the portions (sections or paragraphs) of the CQAM applicable to individual Operations Plans and Research Project Plans tasks and subtasks, as indicated in the respective Plans. In addition, Operating Procedures implementing the applicable CQAM paragraphs shall be identified.
- 3.2.3 The Quality Requirements Application Matrix shall indicate Operating Procedures needing to be developed when no existing controls are in effect for activities affecting quality.
- 3.2.4 The Quality Requirements Application Matrix shall be reviewed quarterly, and revised as necessary to provide initial planning for new Plans or tasks, to revise planning based on new information concerning tasks, and as new Operating Procedures are issued implementing the applicable portions of the CQAM.
- 3.2.5 The Quality Requirements Application Matrix and its revisions shall be approved by the Director of QA and the Technical Director, and shall be distributed as an attachment to the Monthly QA Status Reports as specified in 3.3.4.
- 3.3 Monthly QA Status Reports shall be prepared by the QA Staff to provide quality planning based on the schedule of activities affecting quality. Due to the uncertain nature of experimental and developmental tasks, many activities may not be anticipated far in advance, necessitating this method of short term quality planning.
- 3.3.1 Monthly QA Status Reports shall be developed through interviews with task leaders and Principal Investigators to determine when activities affecting quality are to be conducted, and to apply the CQAM portions and Operating Procedures

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-013

Revision 0

Page 4 of 4

identified in the Quality Requirements Application Matrix to specific activities within tasks and subtasks on a timely basis.

3.3.2 For procedures identified in the Quality Requirements Application Matrix as needing to be developed, the Monthly QA Status Report shall identify that need on a timely basis. The subject of the procedure, the responsible Element, and due date for issuance shall be identified and entered into the Center Commitment Control System for tracking. QA shall establish hold points on affected activities to assure that procedures are issued prior to the initiation of the affected activities.

3.3.3 In addition to providing the status of individual tasks and a schedule of upcoming activities, the Monthly QA Status Report shall provide for planning for QA verification of activities by identifying other hold points, notification points and witness points for surveillance.

3.3.4 Monthly QA Status Reports shall be distributed to the Center President, Directors, Element Managers, Principal Investigators, and task leaders, as a minimum.

4. RECORDS

The Quality Requirements Application Matrix and revisions, and Monthly QA Status Reports shall be controlled as QA records in accordance with CQAM Section 17, and permanently retained.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

Proc. QAP-013

Revision 1

QUALITY ASSURANCE PROCEDURE

Page 1 of 4

Title

QAP-013 – Quality Planning

EFFECTIVITY AND APPROVAL

Revision 1 of this procedure became effective on 7/14/92 . This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
All	0	7/14/92

SUPERSEDED

*Superseded by QAP-013, Revision 2, Changed,
3/06/95*

Supersedes Procedure No. QAP-013, Rev. 0

Approvals

Written By <i>Robert Smith</i>	Date <i>7/15/92</i>	Technical Review <i>Samuel Malabro</i>	Date <i>7/15/92</i>
Quality Assurance <i>Samuel Malabro</i>	Date <i>7/15/92</i>	Cognizant Director <i>Samuel Malabro</i>	Date <i>7/15/92</i>

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-013

Revision 1

Page 2 of 4

QAP-013 - Quality Planning

1. PURPOSE

The purpose of this procedure is to identify the methods of applying the CQAM and Operating Procedures to specific Center activities, and to provide for scheduling of quality verification. This procedure implements the requirements of CQAM Sections 2, 3, and 18.

2. RESPONSIBILITIES

2.1 The Director of QA is responsible for implementation of this procedure.

2.2 The Element Managers, Principal Investigators, and task leaders, as applicable, are responsible for identifying CQAM requirements applicable to Research Project Plan and Operations Plan tasks as specified by this procedure.

3. PROCEDURE

3.1 Initial quality planning shall be accomplished through the preparation of a Quality Requirements Application Matrix.

3.1.1 The Quality Requirements Application Matrix shall be prepared by the QA Staff with the input of the Technical Director.

3.1.2 The Quality Requirements Application Matrix shall list the portions (sections or paragraphs) of the CQAM applicable to individual Operations Plans and Research Project Plans tasks and subtasks, as indicated in the respective Plans. In addition, Operating Procedures implementing the applicable CQAM paragraphs shall be identified.

3.1.3 The Quality Requirements Application Matrix shall indicate Operating Procedures needing to be developed when no existing controls are in effect for activities affecting quality.

3.1.4 The Quality Requirements Application Matrix shall be reviewed quarterly, and revised as necessary to provide initial planning for new Plans or tasks, to revise

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-013

Revision 1

Page 3 of 4

planning based on new information concerning tasks, and as new Operating Procedures are issued implementing the applicable portions of the CQAM.

- 3.1.5 The Quality Requirements Application Matrix and its revisions shall be approved by the Director of QA and the Technical Director, and shall be distributed as an attachment to the Monthly QA Status Reports as specified in 3.2.4.
- 3.2 Monthly QA Status Reports shall be prepared by the QA Staff to provide quality planning based on the schedule of activities affecting quality. Due to the uncertain nature of experimental and developmental tasks, many activities may not be anticipated far in advance, necessitating this method of short term quality planning.
 - 3.2.1 Monthly QA Status Reports shall be developed through interviews with task leaders and Principal Investigators to determine when activities affecting quality are to be conducted, and to apply the CQAM portions and Operating Procedures identified in the Quality Requirements Application Matrix to specific activities within tasks and subtasks on a timely basis.
 - 3.2.2 For procedures identified in the Quality Requirements Application Matrix as needing to be developed, the Monthly QA Status Report shall reflect that need. The subject of the procedure, the responsible Element, and due date for issuance shall be identified and entered into the Center Commitment Control System for tracking. QA shall establish hold points on affected activities to assure that procedures are issued prior to the initiation of the affected activities.
 - 3.2.3 In addition to providing the status of individual tasks and a schedule of upcoming activities, the Monthly QA Status Report shall provide for planning for QA verification of activities by identifying other hold points, notification points and witness points for surveillance.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-013

Revision 1

Page 4 of 4

3.2.4 Monthly QA Status Reports shall be distributed to the Center President, Directors, Element Managers, Principal Investigators, and task leaders, as a minimum.

4. RECORDS

The Quality Requirements Application Matrix and revisions, and Monthly QA Status Reports shall be controlled as QA records in accordance with CQAM Section 17, and shall be retained for six years.

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

Proc. QAP-013
Revision 2
Page 1 of 5

Title
QAP-013 QUALITY PLANNING

EFFECTIVITY AND APPROVAL

Revision 2 of this procedure became effective on 3/06/95. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
All	0	3/06/95

SUPERSEDED

Supersedes Procedure No. QAP-013, Rev. 1

Approvals

Written By <i>Robert Brient</i> ROBERT BRIENT	Date <i>3/6/95</i> 3/6/95	Concurrence Review <i>Wesley Patrick</i> WESLEY PATRICK	Date <i>3/6/95</i> 3/6/95
Quality Assurance <i>Bruce Mabrito</i> BRUCE MABRITO	Date <i>3/6/95</i> 3/6/95	Cognizant Director <i>Henry Garcia</i> HENRY GARCIA	Date <i>3/6/95</i> 3/6/95

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-013

Revision 2

Page 2 of 5

QAP-013 QUALITY PLANNING

1. PURPOSE

The purpose of this procedure is to identify the methods of applying the Center for Nuclear Waste Regulatory Analyses (CNWRA) Quality Assurance Manual (CQAM) and Operating Procedures to specific CNWRA activities, and to provide for scheduling of quality verification. 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 implementation of this procedure.

2.2 The Element Managers (EMs) and Principal Investigators (PIs) are responsible for identifying QA requirements applicable to Research Project Plan and Operations Plan tasks as specified by this procedure.

3. PROCEDURE

3.1 Initial quality planning shall be accomplished through the preparation of Quality Requirements Application Matrices (QRAM), CNWRA Form Quality Assurance Procedure (QAP-17) (Figure 1).

3.1.1 For each task/subtask identified in Research Project Plans and Operations Plans, a QRAM shall be prepared during a joint meeting of the cognizant EM and PI, the Technical Director and QA Staff.

3.1.2 The QRAM shall provide a brief description of the activity, and shall identify specific CQAM Chapters and/or Operating Procedures that are applicable to the activity. The basis for applicability shall be: (i) the nature of the activity (i.e., the type of work to be performed and the products), and (ii) the use of the products (i.e., their importance to licensing). Products, such as data and analysis methods (including software) which are expected to be used directly in license application reviews are of the highest importance, and more stringent requirements apply. Otherwise, and in the absence of specific Operating Procedures, good scientific and engineering practices apply to all CNWRA technical activities.

3.1.3 The QRAM shall indicate Operating Procedures which need to be developed when no existing controls have been established.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-003

Revision 2

Page 3 of 5

QUALITY PLANNING

- 3.1.4 The QRAM shall be reviewed by the QA staff whenever Research Project Plans or Operations Plans are revised to determine if the QRAM should be re-evaluated as described in section 3.1.1. The basis for re-evaluation shall include: (i) new tasks, (ii) substantially revised tasks, (iii) changes in the importance of products with respect to their potential use, and (iv) new Operating Procedures affecting the types of activities included in the task.
- 3.1.5 The QRAM and its revisions shall be approved by the Director of QA and the Technical Director, and shall be distributed to CNWRA management and the cognizant PI.
- 3.2 Monthly QA Status Reports shall be prepared by the QA Staff to provide for QA verification activities based on the schedule of activities affecting quality and long term surveillance plans.
- 3.2.1 The Monthly QA Status Report shall identify hold points, notification points, and witness points for surveillance. In addition, this report shall document current Nonconformance Reports and Corrective Action Requests and the status of their resolution.
- 3.2.2 Monthly QA Status Reports shall be distributed to CNWRA management and PIs.

4. **RECORDS**

The QRAM and revisions, and Monthly QA Status Reports 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 2

Page 4 of 5

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES		Page 1 of _
QUALITY REQUIREMENTS APPLICATION MATRIX		
Task/Subtask Title: _____		
Project No.:	_____	Element Manager: _____
Principal Investigator: _____		
Task/Subtask Description: 		
1. Generally Applicable Quality Requirements:		
QAP-001 Scientific Notebook Control		
QAP-002 Review of CNWRA Documents, Reports, Papers, and Presentation Materials (QAPs that describe Quality Assurance department functions are also universally applicable)		
2. Quality Requirements Applicable to Specific Activities:		
2.1 Systematic Regulatory Analysis:		
TOP-001-07	Procedure for High-Level Waste Functional Analysis	_____
TOP-001-11	Development of Compliance Determination Strategies	_____
TOP-001-12	Development of Technical Review Components	_____
TOP-001-13	Development of Compliance Determination Methods	_____
TOP-001-15	PADB Loading, Version, and Change Control	_____
2.2 Laboratory and Field Investigations:		
TOP-012	Identification, Control, Storage, Handling, Shipping, and Archiving of Samples	_____
CQAM Ch.12	Control of Measuring and Test Equipment	_____

CNWRA FORM QAP-17

Sample

Figure 1

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-013

Revision 2

Page 5 of 5

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES		Page	of	
QUALITY REQUIREMENTS APPLICATION MATRIX				
2.3 Development and Use of Scientific and Engineering Software:				
For software that are expected to be used directly in license application reviews:				
TOP-018 Development and Control of Scientific and Engineering Software _____				
List of software subject to these requirements and approximate schedule for implementation:				
2.4 Data and Data Analyses:				
For data that are expected to be used directly in license application reviews				
QAP-015 Qualification of Existing Data _____				
QAP-014 Documentation and Verification of Routine Calculations _____				
List data subject to qualification and approximate schedule for implementation:				
3.0 Approval:				
_____	_____	_____	_____	_____
Technical Director	Date	Director QA	Date	

CNWR A FORM QAP-17

Sample

Figure 1 (Cont'd)

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-013

Revision 3

Page 1 of 5

Title

QAP-013 QUALITY PLANNING

EFFECTIVITY AND APPROVAL

Revision 3 of this procedure became effective on 7/27/99. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
All	0	7/27/99

SUPERSEDED

Supersedes Procedure No. QAP-013, Rev. 2

Approvals

Written By  MARK EHNSTROM	Date 7/30/99	Concurrence Review  BUDHI SAGAR	Date 7/30/99
Quality Assurance  BRUCE MABRITO	Date 7/30/99	Cognizant Director  HENRY GARCIA	Date 7/30/99

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-013

Revision 3 Chg 0

Page 2 of 5

QAP-013 QUALITY PLANNING

1. PURPOSE

The purpose of this procedure is to identify the methods of applying the Center for Nuclear Waste Regulatory Analyses (CNWRA) Quality Assurance Manual (CQAM) and Operating Procedures to specific CNWRA activities, and to provide for scheduling of quality verification. 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 implementation of this procedure.

2.2 The Element Managers (EMs) and Principal Investigators (PIs) are responsible for identifying QA requirements applicable to Operations Plans, Research Project Plans, accepted proposals and Internal Research and Development projects (IR&D) as specified by this procedure.

3. PROCEDURE

3.1 Initial quality planning shall be accomplished through the preparation of Quality Requirements Application Matrices (QRAM), CNWRA Form Quality Assurance Procedure (QAP-17) (Figure 1).

3.1.1 For each task identified in Operations Plans, Project Plans, IR&D projects and accepted proposals, a QRAM shall be jointly prepared by the cognizant EM and PI, the Technical Director and QA Staff.

3.1.2 The QRAM shall provide a brief description of the activity, and shall identify Operating Procedures or actions that are applicable to the activity. The basis for applicability shall be: (i) the nature of the activity (i.e., the type of work to be performed products), and (ii) the use of the products (i.e., their importance to licensing). Products, such as data and analysis methods (including software) which are expected to be used directly in license application reviews are of the highest importance, and more stringent requirements apply. Otherwise, and in the absence of specific Operating Procedures, good scientific and engineering practices apply to all CNWRA technical activities.

3.1.3 The QRAM shall reference the revision and change number of the Operations Plan, Project Plan, IR&D project or accepted proposal for which the QRAM was written.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

Proc. QAP-013

Revision 3 Chg 0

Page 3 of 5

QUALITY ASSURANCE PROCEDURE

3.1.4 The QRAM shall indicate Operating Procedures which need to be developed when no existing controls have been established.

3.1.5 Whenever Operations Plans, Project Plans, IR&D projects, and accepted proposals have been revised, it is the responsibility of the EM to determine if the corresponding QRAM should be re-evaluated as described in Section 3.1.1. The basis for re-evaluation shall include:(i) new tasks,(ii) substantially revised tasks, and (iii) change in the importance of products with respect to their potential use. If the re-evaluation determines that the existing QRAM is acceptable, this review will be documented by the EM, Technical Director and Director of QA.

3.1.6 The QRAM and QRAM revisions shall be approved by the Director of QA and the Technical Director, and shall be distributed to CNWRA management and the cognizant PI.

3.2 Quarterly QA Status Reports shall be prepared by the QA staff to provide for QA verification activities based on the schedule of activities affecting quality and long term surveillance plans.

3.2.1 The Quarterly QA Status Report shall identify hold points, notification points, and witness points for surveillance. In addition, this report shall document current Nonconformance Reports and Corrective Action Requests and the status of their resolution.

3.2.2 The Quarterly QA Status Reports shall be distributed to CNWRA management.

4. RECORDS

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

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

Proc. QAP-013

Revision 3 Chg 0

QUALITY ASSURANCE PROCEDURE

Page 4 of 5

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

Page 1 of 2

QUALITY REQUIREMENTS APPLICATION MATRIX

Task/Subtask Title: _____

OPS Plan/Proposal Title: _____

Revision & Change/Date: _____

Project No: 20-_____ Element Manager: _____

Principal Investigator: _____ Plan/Proposal Rev/Chg.: _____

Task/Subtask Description:

1. Generally Applicable Quality Requirements:

QAP-001 Scientific Notebook Control - Determined by EM or Project Manager

QAP-002 Review of CNWRA Documents, Reports, Papers, and Presentation Materials

Additional QAPs required:

- QAP-004 Surveillance Control
- QAP-005 Quality Indoctrination Training
- QAP-007 Professional Personnel Qualification
- QAP-008 Document Control
- QAP-009 Nonconformance Control
- QAP-010 Corrective Action
- QAP-012 QA Records Control
- QAP-013 Quality Planning

Other QAPs: _____

2. Quality Requirements Applicable to specific Activities:

2.1 Systematic Regulatory Analysis:

TOP-001-11	Development of Compliance Determination Strategies	<input type="checkbox"/> Yes	<input type="checkbox"/> No
TOP-001-13	Development of Compliance Determination Methods	<input type="checkbox"/> Yes	<input type="checkbox"/> No
TOP-001-15	PADB Loading, Version, and Change Control	<input type="checkbox"/> Yes	<input type="checkbox"/> No

2.2 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

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-013

Revision 3

Page 1 of 5

Title

QAP-013 QUALITY PLANNING

EFFECTIVITY AND APPROVAL

Revision 3 of this procedure became effective on 7/27/99. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
1	1	12/31/99
2	1	12/31/99
3	1	12/31/99
4-5	0	7/27/99

SUPERSEDED

Supersedes Procedure No. QAP-013, Rev. 3, Chg 0

Approvals

Written By

Bruce Mabrito
BRUCE MABRITO

Date

12/30/99

Concurrence Review

N. Srihar
NARASI SRIDHAR

Date

12/30/99

Quality Assurance

Randy Folck
RANDY FOLCK

Date

12/30/99

Cognizant Director

Henry Garcia
HENRY GARCIA

Date

12/30/99

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

Proc. QAP-013

Revision 3 Chg 1

QUALITY ASSURANCE PROCEDURE

Page 2 of 5

QAP-013 QUALITY PLANNING

1. **PURPOSE**

The purpose of this procedure is to identify the methods of applying the Center for Nuclear Waste Regulatory Analyses (CNWRA) Quality Assurance Manual (CQAM) and Operating Procedures to specific CNWRA activities, and to provide for scheduling of quality verification. 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 implementation of this procedure.

2.2 The Element Managers (EMs) and Principal Investigators (PIs) are responsible for identifying QA requirements applicable to Operations Plans, Research Project Plans, proposals and Internal Research and Development projects (IR&D) as specified by this procedure.

3. **PROCEDURE**

3.1 Initial quality planning shall be accomplished through the preparation of Quality Requirements Application Matrices (QRAM), CNWRA Form Quality Assurance Procedure (QAP-17) (Figure 1).

3.1.1 For each task identified in Operations Plans, Project Plans, IR&D projects and proposals, a QRAM shall be jointly prepared by the cognizant EM and PI, the Technical Director and QA Staff.

3.1.2 The QRAM shall provide a brief description of the activity, and shall identify Operating 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 use of the products (e.g., their importance to licensing). Products, such as data and analysis methods (including software) which are expected to be used directly in license application reviews are of the highest importance, and more stringent requirements apply. Otherwise, and in the absence of specific Operating Procedures, good scientific and engineering practices apply to all CNWRA technical activities.

3.1.3 The QRAM shall reference the revision and change number of the Operations Plan, Project Plan, IR&D project or proposal for which the QRAM was written.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

Proc. QAP-013

Revision 3 Chg 1

Page 3 of 5

QUALITY ASSURANCE PROCEDURE

- 3.1.4 The QRAM shall indicate Operating Procedures which need to be developed when no existing controls have been established.
- 3.1.5 Whenever Operations Plans, Project Plans, IR&D projects, and proposals have been revised, it is the responsibility of the EM to determine if the corresponding QRAM should be re-evaluated as described in Section 3.1.1. The basis for re-evaluation shall include: (i) new tasks, (ii) substantially revised tasks, and (iii) change in the importance of products with respect to their potential use. If the re-evaluation determines that the existing QRAM is acceptable, this review will be documented by the EM, Technical Director and Director of QA.
- 3.1.6 The QRAM and QRAM revisions shall be approved by the Director of QA and the Technical Director, and shall be distributed to CNWRA management and the cognizant PI.
- 3.2 Quarterly QA Status Reports shall be prepared by the QA staff to provide for QA verification activities based on the schedule of activities affecting quality and long term surveillance plans.
- 3.2.1 The Quarterly QA Status Report shall identify hold points, notification points, and witness points for surveillance. In addition, this report shall document current Nonconformance Reports and Corrective Action Requests and the status of their resolution.
- 3.2.2 The Quarterly QA Status Reports shall be distributed to CNWRA management.

4. RECORDS

The QRAM and revisions, and Quarterly QA Status Reports 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 4
Page 1 of 5

Title

QAP-013 QUALITY PLANNING

EFFECTIVITY AND APPROVAL

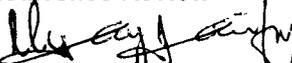
Revision 4 of this procedure became effective on 8/22/2000. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
All	0	8/22/2000

SUPERSEDED

Supersedes Procedure No. QAP-013, Rev. 3, Chg 1

Approvals

Written By  BRUCE MABRITO	Date 8/22/2000	Concurrence Review  N.S. NARASI SRIDHAR	Date 8/24/2000
Quality Assurance  MARK EHNSTROM	Date 8/22/2000	Cognizant Director  HENRY GARCIA	Date 8/22/00

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

Proc. QAP-013

Revision 4 Chg 0

Page 2 of 5

QUALITY ASSURANCE PROCEDURE

QAP-013 QUALITY PLANNING

1. PURPOSE

The purpose of this procedure is to identify the methods of applying the Center for Nuclear Waste Regulatory Analyses (CNWRA) Quality Assurance Manual (CQAM) and Operating Procedures to specific CNWRA activities, and to provide for scheduling of quality verification. 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 implementation of this procedure.

2.2 The Element Managers (EMs) and Principal Investigators (PIs) are responsible for identifying QA requirements applicable to Operations Plans, Research Project Plans, proposals and Internal Research and Development projects (IR&D) as specified by this procedure.

3. PROCEDURE

3.1 Initial quality planning shall be accomplished through the preparation of Quality Requirements Application Matrices (QRAM), CNWRA Form Quality Assurance Procedure (QAP-17) (Figure 1).

3.1.1 For each element of the work breakdown structure (Key Technical Issue, Integrated Subissue, project) identified in Operations Plans, Project Plans, projects and proposals, a QRAM shall be jointly prepared by the cognizant EM and PI, the Technical Director and QA Staff.

3.1.2 The QRAM shall provide 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 use of the products (e.g., their importance to licensing). Products, such as data and analysis methods (including software) which are expected to be used directly in license application reviews are of the highest importance, and more stringent requirements apply. Otherwise, and in the absence of specific Operating Procedures, good scientific and engineering practices apply to all CNWRA technical activities.

3.1.3 The QRAM shall reference the revision and change number of the Operations Plan, Project Plan, project or proposal for which the QRAM was written.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

Proc. QAP-013

Revision 4 Chg 0

Page 3 of 5

QUALITY ASSURANCE PROCEDURE

3.1.4 The QRAM shall indicate Operating Procedures which need to be developed when no existing controls have been established.

3.1.5 Whenever Operations Plans, Project Plans, and proposals have been revised, it is the responsibility of the EM to determine if the corresponding QRAM should be re-evaluated as described in Section 3.1.1. The basis for re-evaluation shall include: (i) new tasks, (ii) substantially revised tasks, and (iii) change in the importance of products with respect to their potential use. If the re-evaluation determines that the existing QRAM is acceptable, this review will be documented by the EM, Technical Director and Director of QA on the existing QRAM form.

3.1.6 The QRAM and QRAM revisions shall be approved by the Element Managers, Director of QA and the Technical Director, and shall be distributed to CNWRA management and the cognizant PI.

3.2 Quarterly QA Status Reports shall be prepared by the QA staff to provide for QA verification activities based on the schedule of activities affecting quality and long term surveillance plans.

3.2.1 The Quarterly QA Status Report shall identify hold points, notification points, and witness points for surveillance. In addition, this report shall document current Nonconformance Reports and Corrective Action Requests and the status of their resolution.

3.2.2 The Quarterly QA Status Reports shall be distributed to CNWRA management.

4. RECORDS

The QRAM and revisions, and Quarterly QA Status Reports 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 4 Chg 0

Page 4 of 5

Page 1 of 2

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

QUALITY REQUIREMENTS APPLICATION MATRIX

OPS Plan/Proposal Title: _____

Revision & Change: _____ Date: _____

Project/Proposal No: (if available) _____ Element 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 EM or Project Manager	<input type="checkbox"/> Yes <input type="checkbox"/> No
QAP-016	Procurement - will there be any quality-affecting procurement during 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

Additional QAPs required:

QAP-002 Review of CNWRA Documents, Reports, Papers, and Presentation Materials - All
QAP-004 Surveillance Control
QAP-005 Quality Indoctrination
QAP-007 Professional Personnel Qualification
QAP-008 Document Control
QAP-009 Nonconformance Control
QAP-010 Corrective Action
QAP-012 QA Records Control
QAP-013 Quality Planning

2. Quality Requirements Applicable to specific Activities:

2.1 Systematic Regulatory Analysis:

TOP-001-11	Development of Compliance Determination Strategies	<input type="checkbox"/> Yes <input type="checkbox"/> No
TOP-001-13	Development of Compliance Determination Methods	<input type="checkbox"/> Yes <input type="checkbox"/> No
TOP-001-15	PADB Loading, Version, and Change Control	<input type="checkbox"/> Yes <input type="checkbox"/> No

2.2 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

CNWRA FORM QAP-17 (8/2000)

**Sample
Figure 1**

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

Proc. QAP-013

Revision 4 Chg 0

Page 5 of 5

QUALITY ASSURANCE PROCEDURE

Page 2 of 2

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY REQUIREMENTS APPLICATION MATRIX

2.3 Development and Use of Scientific and Engineering Software:

For software that are expected to be used directly in regulatory reviews:

TOP-018 Development and Control of Scientific and Engineering Software

Yes No

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

If non-controlled Scientific and Engineering Software are 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 are 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.

2.4 Data and Data Analyses:

For data that are expected to be used directly in regulatory reviews:

QAP-015 Qualification of Existing Data

Yes No

QAP-014 Documentation and Verification of Scientific & Engineering Calculations

Yes No

List data subject to qualification and approximate schedule for implementation:

List data exempted from qualification in accordance with QAP-015, 5.3:

3.0 Approval:

Element Manager Date

Technical Director Date QA Director Date

4.0 Approval: Plan/Proposal Revision _____ Change _____ Date _____

Element Manager Date

Technical Director Date QA Director Date

5.0 Approval: Plan/Proposal Revision _____ Change _____ Date _____

Element Manager Date

Technical Director Date QA Director Date

CNWR FORM QAP-17 (8/2000)

**Sample
Figure 1 (Cont'd)**

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

Proc. QAP-013

Revision 5

QUALITY ASSURANCE PROCEDURE

Page 1 of 6

Title

QAP-013 QUALITY PLANNING

EFFECTIVITY AND APPROVAL

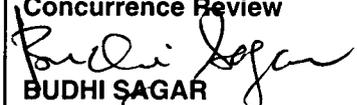
Revision 5 of this procedure became effective on 10/04/2001. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
All	0	10/04/2001

SUPERSEDED

Supersedes Procedure No. QAP-013, Rev. 4, Chg 0

Approvals

Written By  BRUCE MABRITO	Date 10/4/2001	Concurrence Review  BUDHI SAGAR	Date 10/5/2001
Quality Assurance  MARK EHNSTROM	Date 10/8/2001	Cognizant Director  HENRY GARCIA	Date 10/5/01

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

Proc. QAP-013

Revision 5 Chg 0

Page 2 of 6

QUALITY ASSURANCE PROCEDURE

QAP-013 QUALITY PLANNING

1. PURPOSE

The purpose of this procedure is to identify the methods of applying the Center for Nuclear Waste Regulatory Analyses (CNWRA) Quality Assurance Manual (CQAM) and implementing procedures to 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 implementation of this procedure.

2.2 The Element Managers (EMs) and Principal Investigators (PIs) are responsible for identifying QA requirements applicable to operations plans, research project plans, and commercial proposals as specified by this procedure. These QA requirements shall be agreed to prior to the formal initiation of the project.

3. PROCEDURE

3.1 Initial quality planning shall be accomplished through the preparation of Quality Requirements Application Matrices (QRAM), CNWRA Form Quality Assurance Procedure (QAP-17) (Figure 1). The QRAM will be used to identify the extent to which the quality program will be applied. If different quality requirements are to be applied to a specific project because of client desires or local or national laws, this will be documented on the appropriate QRAM.

3.1.1 For each element of the work breakdown structure (e.g., Key Technical Issue, Integrated Subissue, project) identified in an operations plan, project plan, or proposal, a QRAM shall be jointly prepared by the cognizant EM and PI, and then approved by the Technical and QA Director.

3.1.2 The QRAM shall document the plan or proposal and client, 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.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

Proc. QAP-013

Revision 5 Chg 0

Page 3 of 6

QUALITY ASSURANCE PROCEDURE

- 3.1.3 The QRAM shall reference the revision and change number of the operations plan, project plan, or commercial proposal for which the QRAM was written.
- 3.1.4 The QRAM shall indicate if implementing procedures need to be developed to provide adequate controls.
- 3.1.5 Whenever an operations plan, project plan, and commercial proposal is revised, it is the responsibility of the EM to determine if the corresponding QRAM should be re-evaluated and revised. The basis for re-evaluation shall include (i) new tasks, (ii) substantially revised tasks, and (iii) change in the importance of products with respect to their potential use. If the re-evaluation determines that the existing QRAM is acceptable, this review will be documented by the EM, Technical Director and Director of QA on the existing QRAM form.
- 3.1.6 The QRAM and QRAM revisions shall be approved by the cognizant EM, Director of QA and the Technical Director, and shall be distributed to CNWRA management and the cognizant PI.

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

Proc. QAP-013

Revision 5 Chg 0

Page 4 of 6

QUALITY ASSURANCE PROCEDURE

Page 1 of 3

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) _____ Element 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 EM or Project 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

Additional QAPs required:

QAP-002	Review of CNWRA Documents, Reports, Papers, and Presentation Materials - All	<input type="checkbox"/> Yes <input type="checkbox"/> No
QAP-004	Surveillance Control	<input type="checkbox"/> Yes <input type="checkbox"/> No
QAP-005	Quality Indoctrination	<input type="checkbox"/> Yes <input type="checkbox"/> No
QAP-007	Professional Personnel Qualification	<input type="checkbox"/> Yes <input type="checkbox"/> No
QAP-008	Document Control	<input type="checkbox"/> Yes <input type="checkbox"/> No
QAP-009	Nonconformance Control	<input type="checkbox"/> Yes <input type="checkbox"/> No
QAP-010	Corrective Action	<input type="checkbox"/> Yes <input type="checkbox"/> No
QAP-012	QA Records Control	<input type="checkbox"/> Yes <input type="checkbox"/> No
QAP-013	Quality Planning	<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

CNWRA FORM QAP-17 (9/2001)

**Sample (Page 1 of 3)
Figure 1**

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

Proc. QAP-013

Revision 5 Chg 0

Page 5 of 6

QUALITY ASSURANCE PROCEDURE

Page 2 of 3

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY REQUIREMENTS APPLICATION MATRIX

2.2 Development and Use of Scientific and Engineering Software:

Will scientific and engineering software be used or evaluated? Yes No

TOP-018 Development and Control of Scientific and Engineering Software Yes No

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

New Chart of QRAM

Software Name:	Proposed Surveillance Dates	Anticipated Validation Dates

If non-controlled scientific and engineering software are 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 are 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:

For data that are expected to be used directly in regulatory reviews safety-related or client directed applications:

QAP-015 Qualification of Existing Data Yes No

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

List data subject to qualification and approximate schedule for implementation:

List data exempted from qualification in accordance with QAP-015, 5.3:

**Sample (Page 2 of 3)
Figure 1 (Cont'd)**

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

Proc. QAP-013

Revision 5 Chg 0

Page 6 of 6

QUALITY ASSURANCE PROCEDURE

Page 3 of 3

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY REQUIREMENTS APPLICATION MATRIX

3.0 Approval:

Element Manager Date

Technical Director Date QA Director Date

4.0 Approval: Plan/Proposal Revision _____ Change _____ Date _____

Element Manager Date

Technical Director Date QA Director Date

5.0 Approval: Plan/Proposal Revision _____ Change _____ Date _____

Element Manager Date

Technical Director Date QA Director Date

6.0 Approval: Plan/Proposal Revision _____ Change _____ Date _____

Element Manager Date

Technical Director Date QA Director Date

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-013

Revision 6 Change 0

Page 1 of 3

Title

QUALITY PLANNING

EFFECTIVITY AND APPROVAL

Revision 6 of this procedure became effective on ^{8/29/03}~~09/29/2003~~. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
ALL	0	08/29/2003 ^{8/29/03}

Supersedes Procedure No. QAP-013, Rev. 5, Chg 0, 10/04/2001

Approvals

Written By <i>Robert Brient</i> Robert Brient	Date 8/29/03	Concurrence Review <i>Budhi Sagar</i> Budhi Sagar	Date 8/28/03
Quality Assurance <i>Mark R. Ehstrom</i> Mark Ehstrom	Date 8/28/03	Cognizant Director <i>Pat Mackin</i> Pat Mackin	Date 8/28/03

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

QUALITY ASSURANCE PROCEDURE

Proc. QAP-013

Revision 6 Change 0

Page 2 of 3

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) 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 The Element Managers (EMs) 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). The QRAM will identify the extent to which the quality program will be applied. Additional quality measurements 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) of CNWRA accepted and proposed work, a QRAM shall be prepared by the cognizant EM and PI, and then 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 revision and project or proposal number of the 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**

Proc. QAP-013

Revision 6 Change 0

Page 3 of 3

QUALITY ASSURANCE PROCEDURE

3.1.5 The QRAM and QRAM revisions shall be approved by the cognizant EM, 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, and (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 EM. The QRAM shall be circulated along with the changed plan or proposal 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 REQUIREMENTS APPLICATION MATRIX

OPS Plan or Proposal Title and Client Name: _____

Revision & Change: _____ Date: _____

Project/Proposal No: (if available) _____ Element 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 EM or Project 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

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

QUALITY REQUIREMENTS APPLICATION MATRIX

2.2 Development and Use of Scientific and Engineering Software:

TOP-018 Development and Control of Scientific and Engineering Software Yes No

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

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"/>		
	<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.

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

