

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

Proc. QAP-008
Revision 4 Change 1
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Title
QAP-008 DOCUMENT CONTROL

EFFECTIVITY AND APPROVAL

Revision 4 of this procedure became effective on 9/12/2003. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
All	1	7/23/2004

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

Supersedes Procedure No. QAP-008, Rev. 4, Chg 0 dated 9/12/2003.

Approvals

Written By	Date	Concurrence Review	Date
/s/Robert Brient	7/26/2004	/s/Patrick Mackin	7/21/2004
Quality Assurance	Date	Cognizant Director	Date
/s/Mark Ehnstrom	7/26/2004	/s/Budhi Sagar	7/22/2004

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QAP-008 DOCUMENT CONTROL

1. PURPOSE

The purpose of this procedure is to describe the methods of preparing, approving, and distributing, Center for Nuclear Waste Regulatory Analyses (CNWRA) controlled documents such as plans, manuals, procedures, and instructions. This procedure also provides controls for documents other than those prepared by the CNWRA but necessary to effectively perform work activities. This procedure implements the requirements of CNWRA Quality Assurance Manual (CQAM), Section 6.

2. RESPONSIBILITIES

2.1 The Director of Quality Assurance (QA) is responsible for the overall implementation of this procedure.

2.2 Managers are responsible for identifying recipients of controlled documents. |

2.3 Individuals performing CNWRA activities affecting quality are responsible for using the appropriate document and revision.

2.4 Controlled document recipients are responsible for acknowledging receipt for and understanding documents issued to them. |

3. PROCEDURE

3.1 Document Identification

3.1.1 The CQAM, operations plans, project plans, work plans, test plans, and procedures including those of external origin, shall be identified by unique titles reflecting their content and subject matter. Revisions and changes to these documents shall be identified by sequential numbers. Issuance of a revision shall reset the change number to zero. |

3.1.2 Quality Assurance Procedures (QAPs), Technical Operating Procedures (TOPs), and Administrative Procedures (APs), shall be identified by unique numbers assigned by Document Control and sequential revision and change numbers. The change number shall reset to zero upon revision of the document. The author shall contact Document Control during the preparation of a procedure to obtain the document and revision/change number. In general, the next sequential three digit number shall be assigned to new procedures, (e.g., TOP-00n). |

3.1.3 Scientific notebooks shall be assigned a unique number. A log of scientific notebook issuance shall be maintained by Document Control containing the number, date of issuance, the notebook subject, and the individual to whom the notebook was issued. |

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- 3.2 Document Format: CQAM, APs, QAPs, and TOPs
- 3.2.1 The CQAM shall consist of an Introduction and sufficient sections to describe the corresponding quality requirements of the CNWRA sponsor and clients. In general, individual CQAM Sections should include a Purpose, Responsibilities, and a Description of Requirements.
- 3.2.2 The CQAM shall include a policy statement signed by the President of the CNWRA, and an Effectivity and Approval page. The Effectivity and Approval page shall indicate the change status and date of the document. In addition, it shall contain the required approval signatures.
- 3.2.3 Each page of the CQAM shall identify the section number, revision and change number, and page number (e.g., page 1 of n).
- 3.2.4 Procedures shall include, as a minimum, sections describing the purpose, responsibilities, procedure, and records requirements. Procedures are the principal means for providing instructions for conducting CNWRA activities and shall have sufficient details and step-by-step descriptions of the methods to be used to be easily understood by the users.
- 3.2.5 Procedures shall include an Effectivity and Approval page that indicates the revision and change status of the procedure and each of its pages, and contains the required approval signatures.
- 3.2.6 Each page of procedures shall identify the procedure number, revision and change number, and page number (e.g., page 1 of n).
- 3.3 Document Approval and Effectivity
- 3.3.1 Original documents, changes, and revisions shall be reviewed as specified in QAP-002.
- 3.3.2 Documents may be changed on a page-by-page basis or revised in total. Changes to documents shall be identified in the adjacent right margin with a vertical bar.
- 3.3.3 Document Control shall maintain a list of the procedures contained on the CNWRA webpage (<http://tuti/qa>). The Master Document List shall include the following information:
- Document title
 - Document number, as applicable
 - Revision and change numbers
 - Document date or date of issue

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3.4 Distribution

3.4.1 Controlled documents may be distributed by means of electronic media (e.g., read-only information on computer networks), e-mail, or hard copies.

3.4.2 Documents shall be distributed so the procedures are available at the point of use. Individuals requiring documents shall be identified by managers in accordance with QAP-005. Document distribution to management shall include:

CQAM—CNWRA President, directors, managers, PIs, and SwRI QA Manager.

Operations Plans—President, directors, managers, and affected PIs.

APs QAPs, and TOPs—CNWRA President, directors, and managers.

3.4.3 Changes in document distribution shall be made as new staff are added or as assignments to different activities are made as required by QAP-005.

3.4.4 Whenever possible document distribution will be accomplished electronically.

(a) For CNWRA staff, procedures shall be displayed on the CNWRA website (<http://tuti/ga>). Acknowledgment for training purposes (QAP-005) shall be accomplished by using the "Verification notice for QA" feature.

(b) For SwRI staff, consultants, and subcontractors, distribution shall be accomplished by e-mail attachment or hard copy. Acknowledgment for training purposes (QAP-005) shall be accomplished by return e-mail or by returning the DC-1-2 form included with the hard copy. Distribution of hard copies of documents shall be by the use of the Controlled Document Transmittal, Training, and Acknowledgement Record, CNWRA Form DC-1-2.

3.4.5 Recipients shall incorporate the changes or revisions, destroy or mark as obsolete superseded documents, and acknowledge receipt of transmittal by signing and returning the Form DC-1-2 to Document Control.

3.4.6 As appropriate, uncontrolled copies may be distributed to clients and others; however, receipt acknowledgment is not required. Uncontrolled copies of documents shall be clearly identified as uncontrolled.

3.4.7 The Director of QA shall notify managers of those individuals not acknowledging receipt. The Director of QA and manager shall take action as necessary to obtain the acknowledgments.

3.4.8 Managers and PIs shall take action as necessary to provide current and correct procedures to the point of use and to prevent obsolete copies (controlled or uncontrolled) from being available for use in quality affecting activities.

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3.5 Documents of External Origin

3.5.1 Documents of external origin are documents of importance to the CNWRA operations and technical activities from sources other than the CNWRA. The CNWRA Library shall be the central location for the collection, issuance, and storage for documents of external origin. Documents shall be entered into the Electronic Library Facility (ELF) database.

3.5.2 The CNWRA staff members can search for a document from the CNWRA Library using the ELF database.

3.5.3 The individual CNWRA staff member is responsible for determining if the external origin document in the library is acceptable for project work. The CNWRA staff member also has the responsibility for assuring that distribution is made of the appropriate revision of the document. The CNWRA library staff should be consulted to identify the current revision.

3.5.4 If the CNWRA staff member obtains an external origin document that should be maintained in the CNWRA library, the staff member shall interface with CNWRA library staff. The external origin document shall be entered in the ELF database, given a control number, and placed in the CNWRA library.

3.5.5 Classified, proprietary, company sensitive, and other information not releaseable shall be controlled in accordance with the security level of the document.

3.5.6 Electronic media, databases, codes, maps, drawings, photos, and other nonprinted external origin text shall be maintained as shelved library documents and entered into the ELF database. Such documents of external origin shall be protected so the media/data are not compromised and shall be available to CNWRA staff members for their use in project work.

4. RECORDS

4.1 Controlled Document Transmittal, Training and Acknowledgement Record forms shall be maintained as QA Records in accordance with QAP-012.

4.2 Archive copies of the CQAM and procedures, including superceded versions, shall be maintained as QA Records in accordance with QAP-012.