

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-008

Revision 0

Page 1 of 15

Title Document Control

EFFECTIVITY AND APPROVAL

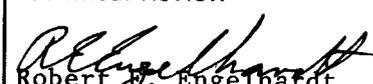
Revision 0 of this procedure became effective on 10/02/90. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
ALL	0	10/02/90

SUPERSEDED

Supersedes Procedure No. N/A

Approvals

Written By  Robert Brient	Date <u>9/24/90</u>	Technical Review  Robert E. Engelhardt	Date <u>9/27/90</u>
Quality Assurance  Bruce Habritto	Date <u>10/1/90</u>	Cognizant Director  Henry P. Garcia	Date <u>10/2/90</u>

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QAP-008 Document Control

1. PURPOSE

The purpose of this procedure is to describe the methods of preparing, approving, distributing and controlling Center plans, procedures, and instructions. This procedure implements the requirements of CQAM Section 6.

2. RESPONSIBILITIES

- 2.1 The Director of Administration is responsible for the overall implementation of this procedure and for the functions of Document Control identified in this procedure.
- 2.2 Element Managers are responsible for identifying recipients of controlled documents.
- 2.3 Controlled document recipients are responsible for acknowledging receipt of documents and incorporating revisions and changes.

3. PROCEDURE

3.1 Document Identification

- 3.1.1 The Center Quality Assurance Manual (CQAM), Operations Plans and Project Plans 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. During the development of the CQAM, Operations Plans and Project Plans and their revisions and changes, Document Control shall be notified by the author in order to update the Master Document List (see paragraph 3.2.4) by listing the document status as "in process."

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3.1.2 Operating Procedures (OPs), which include Quality Assurance Procedures (QAPs) and Technical Operating Procedures (TOPs), 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 new OPs to obtain the document number, and during preparation of revisions and changes, to update the Master Document List. In general, the next sequential three digit number shall be assigned to new OPs, such as TOP-00n. OPs of similar application may be assigned the same three digit base number with a two digit sub-number, such as TOP-001-02.

3.1.3 Unfilled Scientific Notebooks shall be assigned a unique number upon issuance. A log of Scientific Notebook issuance shall be maintained by Document Control containing its number, date of issuance, the Research Project, and the individual to whom the notebook was issued.

3.2 Document Format

3.2.1 As contractually specified documents, the format and content of Operations Plans is primarily guided by applicable contract requirements. These documents shall specify that activities shall be conducted in accordance with applicable portions of the CQAM. In addition, the applicable portions of the CQAM shall be identified to the extent possible.

3.2.2 The CQAM shall consist of an Introduction and 18 sections corresponding to the 18 criteria of 10CFR50, Appendix B. In general, CQAM Sections include a Purpose, Responsibilities, description of requirements, and Records.

3.2.3 The CQAM shall include a policy statement signed by the President of the Center, and an

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Effectivity and Approval page, CNWRA Form QAP-3 (Figure 1). The Effectivity and Approval page shall indicate the change status and date of the document and its individual pages. In addition, it shall contain the required approval signatures.

3.2.4 The body of the CQAM shall be printed on CNWRA Form QAP-4 (Figure 2), each page identifying in headings the Section number, revision and change number, and page number (page 1 of n).

3.2.5 OPs shall include, as a minimum, sections describing Purpose, Responsibilities, Procedure, and Records. OPs are the principal media of instructions for conducting Center activities and shall provide sufficient details and step-by-step descriptions of the methods to be used that may be easily understood by the intended user of the procedure.

3.2.6 OPs shall include an Effectivity and Approval page, CNWRA Forms TOP-1 (Figure 3) and QAP-1 (Figure 4), as applicable, indicating the revision and change status of the procedure and each page and shall contain the required approval signatures.

3.2.7 The body of OPs shall be printed on CNWRA Forms TOP-2 (Figure 5) and QAP-2 (Figure 6), as applicable, each page identifying in headings the Procedure number, revision and change number, and page number (page 1 of n).

3.3 Document Approval and Effectivity

3.3.1 Original documents, changes and revisions shall receive approvals as specified in the CQAM and QAP-002. Documents not requiring NRC acceptance shall become effective on the date of the latest approval signature. Documents requiring NRC acceptance shall be classified as "Approved Draft" and shall not become effective until NRC comments are resolved.

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3.3.2 Documents may be changed on a page by page basis or revised in total. For changes, an effectivity page with signatures approving the change and the changed pages (only) shall be distributed. Revisions shall include an effectivity page approving the changes and the entire document.

3.3.3 TOPs may be changed in the laboratory or in the field without the required approvals provided that the change is authorized by the Principal Investigator and that the change is documented in the appropriate Scientific Notebook. The required approvals shall be obtained by the Principal Investigator within a reasonable period, and may be documented by signatures in the Scientific Notebook. Field or laboratory changes are not permanent and apply only to the immediately affected activities. Permanent changes to TOPS require the usual review and approval process.

3.3.4 Document Control shall maintain a Master Document List on electronic media with continuous updating, and provide hardcopy distribution to Directors, Element Managers, and Principal Investigators bi-monthly. The Master Document List shall include the following information:

Document Title
Document Number, as applicable
Revision and Change numbers
Document Date (preparation date)
Effective Date
Status; "In Process", "Approved Draft", "In Effect" or "Superseded"
Master Document List Effective Date

Documents that have been revised, changed, or otherwise superseded shall be retained on the Master Document List with their superseded status so indicated.

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3.4 Distribution

3.4.1 Documents shall be distributed to those individuals performing activities so that the procedures are available at the point of use. Individuals requiring documents shall be identified on the Controlled Document Request, CNWRA Form AP-3 (Figure 7), by the Element Manager responsible for the activity controlled by the document. In addition to the affected technical staff, document distribution shall include:

CQAM - Center President, Directors, Element Managers, Principal Investigators, SwRI QA Manager, SwRI QAC Chairman.

TOPs, Operations Plans, Project Plans - Technical Director, Director of Systems Engineering and Integration, Director of QA, affected Element Managers.

QAPs - Center President, Directors, Element Managers, Principal Investigators.

Controlled distribution to the NRC shall made be as requested.

3.4.2 Additions to the Controlled Document Request, approved by the cognizant Element Manager, shall be made as necessary as new staff are added or as assignments to different activities are made.

3.4.3 On a quarterly basis, a list of Center staff and document distribution shall be provided to Element Managers in order to determine that procedures are available to those requiring them.

3.4.4 Controlled documents, revisions and changes shall be distributed to those listed on the Controlled Document Request by the use of the Controlled Document Transmittal and

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Acknowledgement Record, CNWRA Form DC-1 (Figure 8). The recipient is required to review the transmitted document, incorporate changes or revisions, destroy or mark as obsolete superseded items, and acknowledge receipt within one month of transmittal.

3.4.5 The Director of QA shall notify Element Managers of those individuals not acknowledging within the allotted time. The Director of QA and Element Managers shall take action as necessary to obtain the acknowledgements.

3.4.6 Uncontrolled copies of documents may be issued upon approval by the Element Manager. Uncontrolled copies shall be clearly identified as such.

3.4.7 Element Managers and Principal Investigators shall take actions as necessary to provide current and correct procedures to the point of use, and to prevent obsolete copies (controlled or uncontrolled) from being available.

4. RECORDS

4.1 Controlled Document Request and Controlled Document Transmittal and Acknowledgement Records forms shall be maintained as QA Records in accordance with CQAM Section 17 and retained for the period of use of the documents plus six years thereafter.

4.2 The Master Document List monthly hardcopy printouts shall be retained as QA Records for one year. Computer files should be adequately protected to prevent loss between the monthly printouts.

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CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES QUALITY ASSURANCE MANUAL		
EFFECTIVITY AND APPROVAL		
Revision _____ of this procedure became effective on _____. This procedure consists of the pages and changes listed below.		
<u>Section</u>	<u>Page No.</u>	<u>Change</u> <u>Date Effective</u>
Approvals		
Director of QA	Date	Center President Date

CNWRA Form QAP-3

Figure 1

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**CENTER FOR NUCLEAR WASTE
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QUALITY ASSURANCE MANUAL

CNWRA Form QAP-4

Figure 2

**CENTER FOR NUCLEAR WASTE
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TECHNICAL OPERATING PROCEDURE			
Title			
EFFECTIVITY AND APPROVAL			
Revision _____ of this procedure became effective on _____. This procedure consists of the pages and changes listed below.			
<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>	
Supersedes Procedure No.			
Approvals			
Written By	Date	Technical Review	Date
Quality Assurance	Date	Cognizant Director	Date

CNWRA Form TOP-1

Figure 3

**CENTER FOR NUCLEAR WASTE
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		Revision _____
		Page _____ of _____
Title _____		
EFFECTIVITY AND APPROVAL		
Revision _____ of this procedure became effective on _____. This procedure consists of the pages and changes listed below.		
<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
Supersedes Procedure No. _____		
Approvals		
Written By	Date	Technical Review
Quality Assurance	Date	Cognizant Director

CNWRA Form QAP-1

Figure 4

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TECHNICAL OPERATING PROCEDURE**

Proc. _____

Revision _____

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CNWRA Form TOP-2

Figure 5

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CNWRA Form QAP-2

Figure 6

CNWRA Form QAP-2

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**CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES
CONTROLLED DOCUMENT REQUEST**

PAGE _____ OF _____

_____ authorizes that Center Controlled
(Element Manager or Director)

Document(s) _____

be sent to the following individual(s)
Name

Address

ELEMENT MANAGER (SIGNATURE)

DATE

DIRECTOR (SIGNATURE)

DATE

CNWRA FORM AP-3

Figure 7

**CENTER FOR NUCLEAR WASTE
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**CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES
CONTROLLED DOCUMENT TRANSMITTAL AND ACKNOWLEDGEMENT RECORD**

TO :

FROM:

Center Document Control Office
Center for Nuclear Waste Regulatory Analyses
6220 Culebra Rd.
P. O. Drawer 28510
San Antonio, Texas 78228-0510

Date Sent:

Attached are the following CNWRA controlled documents:

Document Number	Revision/Change Number	Title

Instructions to Recipients:

1. Review and become familiar with the subject documents. Please contact the author for further clarification, if necessary.
2. For revisions and changes, destroy or mark as obsolete the superseded documents or document pages and insert the current document or pages.
3. Sign and date the acknowledgement below attesting that the attached controlled documents, revisions, and changes have been reviewed and understood, and that obsolete documents and pages have been removed.
4. Upon completion, return this form to Document Control at the address indicated above.

Acknowledged by

Date

CNWRA Form DC-1-2

Figure 8

**CENTER FOR NUCLEAR WASTE
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Title
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EFFECTIVITY AND APPROVAL

Revision 0 of this procedure became effective on 10/02/90. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
1-2	1	05/01/92
3-5	0	10/02/90
6-7	1	05/01/92
8-15	0	10/02/90

SUPERSEDED

by Rev 1, Chg 0. 7/17/92

Supersedes Procedure No. QAP-008, Rev. 0, Chg. 0

Approvals

Written By <i>Bob Brient</i> Bob Brient	Date <i>5/1/92</i>	Technical Review <i>Bruce E. Mabrito</i> Bruce E. Mabrito	Date <i>5/1/92</i>
Quality Assurance <i>Bruce E. Mabrito</i> Bruce E. Mabrito	Date <i>5/1/92</i>	Cognizant Director <i>Wesley Patrick</i> Wes C. Patrick	Date <i>5/1/92</i>

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QAP-008 Document Control

1. PURPOSE

The purpose of this procedure is to describe the methods of preparing, approving, distribution and controlling Center plans, procedures, and instructions. This procedure implements the requirements of CQAM Section 6.

2. RESPONSIBILITIES

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3. PROCEDURE

3.1 Document Identification

3.1.1 The Center Quality Assurance Manual (CQAM), Operations Plans, Project Plans, Work Plans and Test Plans 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. During the development of these documents and their revisions and changes, Document Control should be notified by the author in order to update the Master Document List (see paragraph 3.2.4) by listing the document status as "in process."

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3.4 Distribution

3.4.1 Documents shall be distributed to those individuals performing activities so that the procedures are available at the point of use. Individuals requiring documents shall be identified on the Controlled Document Request, CNWRA Form AP-3 (Figure 7), by the Element Manager responsible for the activity controlled by the document. In addition to the affected technical staff, document distribution shall include:

CQAM - Center President, Directors, Element Managers, Principal Investigators, SwRI QA Manager, SwRI QAC Chairman.

TOPs, Operations Plans, Work Plans, Project Plans, Test Plans - Technical Director, Deputy Technical Director of Systems Engineering and Integration, Director of QA, affected Element Managers.

QAPs - Center President, Directors, Element Managers, Principal Investigators.

Controlled distribution to the NRC shall be made as requested.

3.4.2 Additions to the Controlled Document Request, approved by the cognizant Element Manager, shall be made as necessary as new staff are added or as assignments to different activities are made.

3.4.3 Controlled documents, revisions and changes shall be distributed to those listed on the Controlled Document Request by the use of the Controlled Document Transmittal and Acknowledgement Record, CNWRA Form DC-1 (Figure 8). The recipient is required to review the transmitted document, incorporate changes or revisions, destroy or mark as obsolete superseded items, and acknowledge receipt within one month of transmittal.

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3.4.4 The Director of QA shall notify Element Managers of those individuals not acknowledging within the allotted time. The Director of QA and Element Managers shall take action as necessary to obtain the acknowledgements.

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Title

QAP-008 – Document Control

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 by Revision 1, Chg. 1.

Supersedes Procedure No. QAP-008, Rev. 0, Chg. 1

Approvals

Written By <i>Robert [Signature]</i>	Date 7/13/92	Technical Review <i>Samuel Malin [Signature]</i>	Date 7/15/92
Quality Assurance <i>Samuel Malin [Signature]</i>	Date 7/15/92	Cognizant Director <i>Samuel Malin [Signature]</i>	Date 7/15/92

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QAP-008 - Document Control

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2. RESPONSIBILITIES

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- 3.1.2 Operating Procedures (OPs), which include Quality Assurance Procedures (QAPs) and Technical Operating Procedures (TOPs), 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

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preparation of new Ops to obtain the document number, and during preparation of revisions and changes, to update the Master Document List. In general, the next sequential three digit number shall be assigned to new OPs, such as TOP-00n. OPs of similar application may be assigned the same three digit base number with a two digit sub-number, such as TOP-001-02.

- 3.1.3 Unfilled Scientific Notebooks shall be assigned a unique number upon issuance. A log of Scientific Notebook issuance shall be maintained by Document Control containing its number, date of issuance, the Research Project, and the individual to whom the notebook was issued.

3.2 Document Format: CQAM, QAPs, and TOPs

- 3.2.1 The CQAM shall consist of an Introduction and 18 sections corresponding to the 18 criteria of 10CFR50, Appendix B. In general, CQAM Sections include a Purpose, Responsibilities, description of requirements, and Records.
- 3.2.2 The CQAM shall include a policy statement signed by the President of the Center, and an Effectivity and Approval page, CNWRA Form QAP-3 (Figure 1). The Effectivity and Approval page shall indicate the change status and date of the document and its individual pages. In addition, it shall contain the required approval signatures.
- 3.2.3 The body of the CQAM shall be printed on CNWRA Form QAP-4 (Figure 2), each page identifying in headings the Section number, revision and change number, and page number (page 1 of n).
- 3.2.4 OPs shall include, as a minimum, sections describing Purpose, Responsibilities, Procedure, and Records. OPs are the principal media of instructions for conducting Center activities and shall provide sufficient details and step-by-step descriptions of the methods to be used that may be easily understood by the intended user of the procedure.

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3.2.5 OPs shall include an Effectivity and Approval page, CNWRA Forms TOP-1 (Figure 3) or QAP-1 (Figure 4), as applicable, indicating the revision and change status of the procedure and each of its pages, and shall contain the required approval signatures.

3.2.6 The body of OPs shall be printed on CNWRA Forms TOP-2 (Figure 5) and QAP-2 (Figure 6), as applicable, each page identifying in headings the Procedure number, revision and change number, and page number (page 1 of n).

3.3 Document Approval and Effectivity

3.3.1 Original documents, changes and revisions shall receive approvals as specified in the CQAM and QAP-002. Documents not requiring NRC acceptance shall become effective on the date of the latest approval signature. Documents requiring NRC acceptance shall be classified as "Approved Draft" and shall not become effective until NRC comments are resolved.

3.3.2 Documents may be changed on a page by page basis or revised in total. For a changed document, an effectivity page with signatures approving the change and the changed pages (only) shall be prepared. A revised document shall include an effectivity page approving the entire document.

3.3.3 TOPs may be changed in the laboratory or field without the required approvals provided that the change is authorized by the Principal Investigator and that the change is documented in the appropriate Scientific Notebook. The approvals (required by QAP-002) shall be obtained by the Principal Investigator within a reasonable period, and may be documented by signatures in the Scientific Notebook. Field or laboratory changes are not permanent and apply only to the immediately affected activities. Permanent changes to TOPS require the usual (QAP-002) review and approval process.

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4. RECORDS

- 4.1 Controlled Document Request and Controlled Document Transmittal and Acknowledgement Records forms shall be maintained as QA Records in accordance with CQAM Section 17 and retained for the period of use of the documents plus six years thereafter.
- 4.2 The Master Document List quarterly hardcopy printouts shall be retained as QA Records for one year.

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REGULATORY ANALYSES**

QUALITY ASSURANCE MANUAL

CNWRA Form QAP-4

Figure 2

**CENTER FOR NUCLEAR WASTE
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CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES		Proc. Revision Page of	
TECHNICAL OPERATING PROCEDURE			
Title			
EFFECTIVITY AND APPROVAL			
Revision _____ of this procedure became effective on _____ of the pages and changes listed below.		. This procedure consists	
<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>	
Supercedes Procedure No.			
Approvals			
Written By	Date	Technical Review	Date
Quality Assurance	Date	Cognizant Director	Date

CNWR Form TOP-1

Figure 3

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QUALITY ASSURANCE PROCEDURE		Revision	
		Page	of
Title			
EFFECTIVITY AND APPROVAL			
Revision _____ of this procedure became effective on _____		. This procedure consists	
of the pages and changes listed below.			
<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>	
Supersedes Procedure No. _____			
Approvals			
Written By	Date	Technical Review	Date
Quality Assurance	Date	Cognizant Director	Date

CNWRA Form QAP-1

Figure 4

**CENTER FOR NUCLEAR WASTE
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TECHNICAL OPERATING PROCEDURE

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CNWRA Form TOP-2

Figure 5

**CENTER FOR NUCLEAR WASTE
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CNWRA Form QAP-2

Figure 6

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**CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES
CONTROLLED DOCUMENT REQUEST**

PAGE ____ OF ____

_____ authorizes that Center Controlled

(Element Manager or Director)

Document(s) _____

be sent to the following individual(s)

Name

Address

Element Manager (Signature)

Date

Director (Signature)

Date

CNWR A FORM AP-3

Figure 7

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

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**CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES
CONTROLLED DOCUMENT TRANSMITTAL AND ACKNOWLEDGEMENT RECORD**

TO:

FROM:

Center Document Control Office
Center for Nuclear Waste Regulatory Analyses
6220 Culebra Rd.
P.O. Drawer 28510
San Antonio, Texas 78228-0510

Date Sent:

Attached are the following CNWRA controlled documents:

Document Number	Revision/Change Number	Title

Instructions to Recipients:

1. Review and become familiar with the subject documents. Please contact the author for further clarification, if necessary.
2. For revisions and changes, destroy or mark as obsolete the superseded documents or document pages and insert the current document or pages.
3. Sign and date the acknowledgement below attesting that the attached controlled documents, revisions, and changes have been reviewed and understood, and that obsolete documents and pages have been removed.
4. Upon completion, return this form to Document Control at the address indicated above.

Acknowledged by

Date

CNWRA Form DC-1-2

Figure 8

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

Proc. QAP-008
Revision 1, Chg 1
Page 1 of 15

QUALITY ASSURANCE PROCEDURE

Title
QAP-008 – Document Control

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>
1-4	0	7/14/92
5-6	1	12/8/92
7-10	0	7/14/92
11	1	12/8/92
12-13	0	7/14/92
14	1	12/8/92
15	0	7/14/92

SUPERSEDED

Supersedes Procedure No. QAP-008, Rev. 1

Approvals

Written By <i>Robert Burt</i>	Date 12/8/92	Concurrence Review <i>Bruce Malumbo</i>	Date 12/8/92
Quality Assurance <i>Bruce Malumbo</i>	Date 12/8/92	Cognizant Director <i>Bruce Malumbo</i>	Date 12/8/92

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Proc. QAP-008

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- 3.3.4 Document Control shall maintain a Master Document List, and provide hardcopy distribution to Directors, Element Managers, and Principal Investigators quarterly. The Master Document List shall include the following information:

Document Title
Document Number, as applicable
Revision and Change numbers
Document Date (preparation date)
Effective Date
Status: "In Process", "Approved Draft", In
Effect", or "Superseded"
Master Document List Effective Date

Documents that have been revised, changed, or otherwise superseded shall be retained on the Master Document List with their superseded status so indicated.

3.4 Distribution

- 3.4.1 Controlled documents may be distributed by means of access to electronic media (i.e., read only information on computer networks) or by distribution of hard copies. As applicable, hard copies of documents shall be available for general access in each building where electronic distribution is used.

- 3.4.2 Documents shall be distributed to those individuals performing activities so that the procedures are available at the point of use. Individuals requiring documents shall be identified by Element Managers, and recipients shall be documented on the Controlled Document Distribution List, CNWRA Form AP-3 (Figure 7). In addition to the affected technical staff, document distribution shall include:

CQAM - Center President, Directors, Element Managers, Principal Investigators, SwRI QA Manager, SwRI QAC Chairman.

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TOPs, Operations Plans, Work Plans, Project Plans, Test Plans – Technical Director, Deputy Technical Director for Systems Engineering and Integration, Director of QA, affected Element Managers.

QAPs – Center President, Directors, Element Managers, Principal Investigators.

Controlled distribution to the NRC shall be made as requested.

- 3.4.3 Additions to the Controlled Document Distribution List shall be made as necessary as new staff are added or as assignments to different activities are made.
- 3.4.4 Controlled documents, revisions and changes shall be distributed to those individuals on the Controlled Document Distribution List by the use of the Controlled Document Transmittal and Acknowledgement Record, CNWRA Form DC-1 (Figure 8). The recipient is required to review the transmitted document. In addition, the recipient shall incorporate changes or revisions and destroy or mark as obsolete superseded items, as applicable. Recipients shall acknowledge receipt within one month of transmittal by signing and returning the Form DC-1 to Document Control.
- 3.4.5 The Director of QA shall notify Element Managers of those individuals not acknowledging within the allotted time. The Director of QA and Element Managers shall take action as necessary to obtain the acknowledgements.
- 3.4.6 Uncontrolled copies of documents shall be clearly identified as such. No record of uncontrolled distribution is necessary.
- 3.4.7 Element Managers and Principal Investigators shall take actions 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.

**CENTER FOR NUCLEAR WASTE
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QUALITY ASSURANCE PROCEDURE**

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CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES QUALITY ASSURANCE PROCEDURE		Proc. QAP- Revision Page of
Title <p align="center">QAP-</p>		
EFFECTIVITY AND APPROVAL		
Revision of this procedure became effective on of the pages and changes listed below.		. This procedure consists
<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
Supersedes Procedure No.		
Approvals		
Written By	Date	Concurrence Review Date
Quality Assurance	Date	Cognizant Director Date

CNWRA Form QAP 1-1 (12/92)

Figure 4

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-008

Revision 2 Chg 0

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Title

QAP-008 DOCUMENT CONTROL

EFFECTIVITY AND APPROVAL

Revision 2 of this procedure became effective on 08/22/96 . This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
All	0	08/22/96

SUPERSEDED

Supersedes Procedure No. QAP-008, Rev. 1, Chg 1 dated 12/08/92

Approvals

Written By <i>Linda Hearon</i> Linda Hearon	Date <i>8/22/96</i>	Concurrence Review <i>Robert Brient</i> Robert Brient	Date <i>8/22/96</i>
Quality Assurance <i>Bruce Mabrito</i> Bruce Mabrito	Date <i>8/22/96</i>	Cognizant Director <i>Henry Garcia</i> Henry Garcia	Date <i>8/22/96</i>

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QAP-008 DOCUMENT CONTROL

1. PURPOSE

The purpose of this procedure is to describe the methods of preparing, approving, distributing, and controlling Center for Nuclear Waste Regulatory Analyses (CNWRA) plans, procedures, and instructions. 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 Element Managers (EMs) are responsible for identifying recipients of controlled documents.
- 2.3 Controlled document recipients are responsible for acknowledging receipt of documents and incorporating revisions and changes.

3. PROCEDURE

3.1 Document Identification

- 3.1.1 The CQAM, Operations Plans, Project Plans, Work Plans, and Test Plans 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) and Technical Operating Procedures (TOPs) 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 new QAPs/TOPs to obtain the document and revision/change number. In general, the next sequential three digit number shall be assigned to new QAPs/TOPs, such as TOP-00n. QAPs/TOPs of similar application may be assigned the same three digit base number with a two digit sub-number, such as TOP-001-02.

**CENTER FOR NUCLEAR WASTE
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QUALITY ASSURANCE PROCEDURE

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

3.2 Document Format: CQAM, QAPs, and TOPs

3.2.1 The CQAM shall consist of an Introduction and 18 sections corresponding to the 18 criteria of 10CFR50, Appendix B. In general, CQAM Sections include a Purpose, Responsibilities, and 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, CNWRA Form QAP-3 (Figure 1). The Effectivity and Approval page shall indicate the change status and date of the document and its individual pages. In addition, it shall contain the required approval signatures.

3.2.3 The body of the CQAM shall be printed on CNWRA Form QAP-4 (Figure 2), each page identifying in headings the Section number, revision and change number, and page number (page 1 of n).

3.2.4 QAPs/TOPs shall include, as a minimum, sections describing Purpose, Responsibilities, Procedure, and Records. QAPs/TOPs are the principal media of instructions for conducting CNWRA activities and shall provide sufficient details and step-by-step descriptions of the methods to be used that may be easily understood by the intended user of the procedure.

3.2.5 QAPs/TOPs shall include an Effectivity and Approval page, CNWRA Forms TOP-1 (Figure 3) or QAP-1 (Figure 4), as applicable, indicating the revision and change status of the procedure and each of its pages, and shall contain the required approval signatures.

3.2.6 The body of QAPs/TOPs shall be printed on CNWRA Forms TOP-2 (Figure 5) and QAP-2 (Figure 6), as applicable, each page identifying in headings the Procedure number, revision and change number, and page number (page 1 of n).

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-008

Revision 2 Chg 0

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3.3 Document Approval and Effectivity

3.3.1 Original documents, changes, and revisions shall receive approvals as specified in the CQAM and QAP-002.

3.3.2 Documents may be changed on a page-by-page basis or revised in total. For a changed document, an effectivity page with signatures approving the change and the changed pages (only) shall be prepared. A revised document shall include an effectivity page approving the entire document.

3.3.3 TOPs may be changed in the laboratory or field without the required approvals provided that the change is authorized by the PI and that the change is documented in the appropriate Scientific Notebook. The approvals (required by QAP-002) shall be obtained by the PI within a reasonable period, and may be documented by signatures in the Scientific Notebook. Field or laboratory changes are not permanent and apply only to the immediately affected activities. Permanent changes to TOPs require the usual (QAP-002) review and approval process.

3.3.4 Document Control shall maintain an electronic Master Document List updated with each document change. 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
Master Document List Effective Date

3.4 Distribution

3.4.1 Controlled documents may also be distributed by means of access to electronic media (i.e., read-only information on computer networks) or by distribution of hard copies. As applicable, hard copies of documents shall be available for general access in each building where electronic distribution is used.

**CENTER FOR NUCLEAR WASTE
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QUALITY ASSURANCE PROCEDURE

- 3.4.2 Documents shall be distributed so that the procedures are available at the point of use. Individuals requiring documents shall be identified by EMs, and recipients shall be documented on the Controlled Document Distribution List, CNWRA Form AP-3 (Figure 7). In addition to the affected technical staff, document distribution shall include:

CQAM - CNWRA President, Directors, EMs, PIs, SwRI QA Manager, SwRI QAC Chairman

TOPs, Operations Plans, Work Plans, Research Project Plans, Test Plans - CNWRA President, Directors, EMs, and affected PIs.

QAPs - CNWRA President, Directors, EMs, and affected PIs.

- 3.4.3 Additions to the Controlled Document Distribution Lists shall be made as necessary as new staff are added or as assignments to different activities are made.
- 3.4.4 Controlled documents, revisions, and changes shall be distributed to those individuals on the Controlled Document Distribution List.
- 3.4.5 Distribution to CNWRA, SwRI, CNWRA Consultants or Subcontractors shall be by the use of the Controlled Document Transmittal and Acknowledgement Record, CNWRA Form DC-1 (Figure 8). Recipients shall incorporate the changes or revisions and destroy or mark as obsolete superseded documents, as applicable, and acknowledge receipt of transmittal by signing and returning the Form DC-1 to Document Control.
- 3.4.6 As appropriate, information copies may be distributed to clients and others listed in the Controlled Document Distribution Lists, however, receipt acknowledgement (para. 3.4.5) is not required.
- 3.4.7 The Director of QA shall notify EMs of those individuals not acknowledging receipt. The Director of QA and EM shall take action as necessary to obtain the acknowledgements.
- 3.4.8 Uncontrolled copies of documents shall be clearly identified as such. No record of uncontrolled distribution is necessary.
- 3.4.9 EMs 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.

**CENTER FOR NUCLEAR WASTE
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QUALITY ASSURANCE PROCEDURE

Proc. QAP-008

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4. RECORDS

- 4.1 Controlled Document Transmittal and Acknowledgement Record forms shall be maintained as QA Records in accordance with CQAM Section 17 and retained for six years.

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QUALITY ASSURANCE PROCEDURE

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**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE MANUAL

Rev. Chg

Month Year

Page of

EFFECTIVITY AND APPROVAL

Revision of this procedure became effective on mm/dd/yy. This procedure consists of the pages and changes listed below.

<u>Section</u>	<u>Page No.</u>	<u>Change</u>	<u>Date of Effective</u>
----------------	-----------------	---------------	--------------------------

Approvals

Director of Quality Assurance

Date

CNWRA President

Date

CNWRA Form QAP-3

SAMPLE

Figure 1

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

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**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE MANUAL

Section _____

Revision _____ Change _____

Page _____ of _____

CNWRA FORM QAP-4

SAMPLE

Figure 2

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-008

Revision 2 Chg 0

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<p>CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES</p> <p>TECHNICAL OPERATING PROCEDURE</p>	<p>Proc. _____</p> <p>Revision _____</p> <p>Page <u>1</u> of <u>3</u></p>						
Title _____							
<p>EFFECTIVITY</p> <p>Revision _____ of this procedure became effective on _____.</p> <p>This procedure consists of the pages and changes listed below.</p> <table style="width: 100%; margin-top: 10px;"> <tr> <td style="text-align: center;">_____</td> <td style="text-align: center;">_____</td> <td style="text-align: center;">_____</td> </tr> <tr> <td style="text-align: center;">Page No.</td> <td style="text-align: center;">Change No.</td> <td style="text-align: center;">Date Effective</td> </tr> </table>		_____	_____	_____	Page No.	Change No.	Date Effective
_____	_____	_____					
Page No.	Change No.	Date Effective					
Supersedes Procedure No. _____							
Approvals							
Written by _____	Date _____	Technical Review _____	Date _____				
Quality Assurance _____	Date _____	Cognizant Director _____	Date _____				

CNWRA Form TOP-1 (8/93)

SAMPLE

Figure 3

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

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CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES QUALITY ASSURANCE PROCEDURE		Proc. QAP- Revision Page of
Title QAP-		
EFFECTIVITY AND APPROVAL		
Revision of this procedure became effective on of the pages and changes listed below.		This procedure consists
<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
Supersedes Procedure No.		
Approvals		
Written By	Date	Concurrence Review Date
Quality Assurance	Date	Cognizant Director Date

CNWRA Form QAP 1-1 (12/92)

SAMPLE

Figure 4

**CENTER FOR NUCLEAR WASTE
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QUALITY ASSURANCE PROCEDURE

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REGULATORY ANALYSES**

TECHNICAL OPERATING PROCEDURE

Proc. _____

Revision ____ Change _____

Page _____ of _____

CNWR Form TOP-2

SAMPLE

Figure 5

**CENTER FOR NUCLEAR WASTE
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QUALITY ASSURANCE PROCEDURE

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**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. _____

Revision ___ Chg ___

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CNWRA Form QAP-2

SAMPLE

Figure 6

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

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**CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES
CONTROLLED DOCUMENT TRANSMITTAL AND ACKNOWLEDGEMENT RECORD**

TO:

FROM:

Center Document Control Office
Center for Nuclear Waste Regulatory Analyses
6220 Culebra Rd.
P.O. Drawer 28510
San Antonio, Texas 78228-0510

Date Sent:

Attached are the following CNWRA controlled documents:

Document Number	Revision/ Change Number	Title

Instructions to Recipients:

1. Review and become familiar with the subject documents. Please contact the author for further clarification, if necessary.
2. For revisions and changes, destroy or mark as obsolete the superseded documents or document pages and insert the current document or pages.
3. Sign and date the acknowledgement below attesting that the attached controlled documents, revisions, and changes have been reviewed and understood, and that obsolete documents and pages have been removed.
4. Upon completion, return this form to Document Control at the address indicated above within 30 days.

Acknowledged by

Date

CNWRA Form DC-1-2

SAMPLE

Figure 8

**CENTER FOR NUCLEAR WASTE
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QUALITY ASSURANCE PROCEDURE

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Title

QAP-008 DOCUMENT CONTROL

EFFECTIVITY AND APPROVAL

Revision 3 of this procedure became effective on 11/07/2001. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
All	0	11/07/2001

SUPERSEDED

Supersedes Procedure No. QAP-008, Rev. 2, Chg 1 dated 8/22/96

Approvals

Written By <i>Maria Padilla</i> Maria Padilla	Date 11/07/01	Concurrence Review <i>Mark R. Ehnstrom</i> Mark Ehnstrom	Date 11/7/01
Quality Assurance <i>Bruce Mabrito</i> Bruce Mabrito	Date 11/7/2001	Cognizant Director <i>Henry Garcia</i> Henry Garcia	Date 11/7/01

**CENTER FOR NUCLEAR WASTE
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QUALITY ASSURANCE PROCEDURE

QAP-008 DOCUMENT CONTROL

1. PURPOSE

The purpose of this procedure is to describe the methods of preparing, approving, distributing, and controlling Center for Nuclear Waste Regulatory Analyses (CNWRA) plans, manuals, procedures, and instructions. This procedure implements the requirements of CQAM Section 6.

2. RESPONSIBILITIES

- 2.1 The Director of Quality Assurance (QA) is responsible for the overall implementation of this procedure.
- 2.2 Element Managers (EMs) are responsible for identifying recipients of controlled documents.
- 2.3 CNWRA staff performing project work are responsible for assuring they are using the appropriate document revision
- 2.4 Controlled document recipients are responsible for acknowledging receipt and understanding documents and incorporating revisions and changes.

3. PROCEDURE

3.1 Document Identification

- 3.1.1 The CNWRA Quality Assurance Manual (CQAM), Operations Plans, Project Plans, Work Plans, Test Plans, and Documents 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 new QAPs/TOPs/APs to obtain the document and revision/change number. In general, the next sequential three digit number shall be assigned to new QAPs/TOPs/APs, such as TOP-00n. QAPs/TOPs/APs of similar application may be assigned the same three digit base number with a sub-number or revision date.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

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QUALITY ASSURANCE PROCEDURE

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

3.1.4 CNWRA proposals are generated to obtain work for CNWRA staff and to satisfy the needs of clients. These proposals are processed through the approval system of SwRI and are assigned a unique proposal number by the Program Development Office (PDO) in accordance with PDO internal procedures.

3.2 Document Format: CQAM, 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 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, CNWRA Form QAP-3 (Figure 1). The Effectivity and Approval page shall indicate the change status and date of the document and its individual pages. In addition, it shall contain the required approval signatures.

3.2.3 The body of the CQAM shall be printed on CNWRA Form QAP-4 (Figure 2), each page identifying in headings the Section number, revision and change number, and page number (page 1 of n).

3.2.4 QAPs/TOPs/APs shall include, as a minimum, sections describing the Purpose, Responsibilities, Procedure, and Records requirements. QAPs/TOPs/APs are the principal media of instructions for conducting CNWRA activities and shall provide sufficient details and step-by-step descriptions of the methods to be used that may be easily understood by the intended user of the procedure.

3.2.5 QAPs/TOPs/APs shall include an Effectivity and Approval page, CNWRA Forms TOP-1 (Figure 3), QAP-1 (Figure 4), or AP-1 (Figure 5) as applicable, indicating the revision and change status of the procedure and each of its pages, and shall contain the required approval signatures.

3.2.6 The body of QAPs/TOPs/APs shall be printed on CNWRA Forms TOP-2 (Figure 6), QAP-2 (Figure 7), or AP-2 (Figure 8) as applicable, each page identifying in headings the Procedure number, revision and change number, and page number (page 1 of n).

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QUALITY ASSURANCE PROCEDURE

3.3 Document Approval and Effectivity

3.3.1 Original documents, changes, and revisions shall receive approvals as specified in the CQAM and QAP-002.

3.3.2 Documents may be "changed" on a page-by-page basis or revised in total. For a changed document, an effectivity page with signatures approving the change and the changed pages (only) shall be prepared. Changes in such documents shall be identified in the right margin with a vertical bar. A "revised" document shall include an effectivity page approving the entire document, but no vertical bars will be shown.

3.3.3 TOPs may be changed in the laboratory or field without the required approvals provided that the change is authorized by the PI and that the change is documented in the appropriate Scientific Notebook. The approvals (required by QAP-002) shall be obtained by the PI within a 30-day period, and may be documented by signatures in the Scientific Notebook. Field or laboratory changes are not permanent unless officially incorporated as changes, and apply only to the immediately affected activities. Permanent changes to TOPs require the usual (QAP-002) review and approval process.

3.3.4 Document Control shall maintain an electronic Master Document List updated with each document change. 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
Master Document List Effective Date

3.4 Distribution

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

3.4.2 Documents shall be distributed so that the procedures are available at the point of use. Individuals requiring documents shall be identified by EMs, and recipients shall be documented on the Controlled Document Distribution List, CNWRA Form AP-3 (Figure 9). In addition to the affected technical staff, document distribution shall include:

CQAM – CNWRA President, Directors, EMs, and SwRI QA Manager.

TOPs, Operations Plans, Work Plans, Research Project Plans, Test Plans—CNWRA President, Directors, EMs, and affected PIs.

**CENTER FOR NUCLEAR WASTE
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QUALITY ASSURANCE PROCEDURE

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QAPs—CNWRA President, Directors, EMs, and affected PIs.

APs—CNWRA President, Directors, and EMs.

3.4.3 Additions to the Controlled Document Distribution Lists shall be made as necessary as new staff are added or as assignments to different activities are made.

3.4.4 Controlled documents, revisions, and changes shall be distributed to those individuals on the Controlled Document Distribution List.

3.4.5 Distribution to CNWRA staff, SwRI staff, CNWRA Consultants or Subcontractors shall be by the use of the Controlled Document Transmittal, Training and Acknowledgement Record, CNWRA Form DC-1-2 (Figure 10). Recipients shall incorporate the changes or revisions and destroy or mark as obsolete superseded documents, as applicable, 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 listed in the Controlled Document Distribution Lists, however, receipt acknowledgement (para. 3.4.5) is not required.

3.4.7 The Director of QA shall notify EMs of those individuals not acknowledging receipt. The Director of QA and EM shall take action as necessary to obtain the acknowledgements.

3.4.8 The effectivity page of uncontrolled copies of documents shall be clearly identified as such. A record of uncontrolled distribution may be kept.

3.4.9 EMs 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.

3.5 Documents of External Origin

3.5.1 The CNWRA Library shall be the central location for the collection, issuance, and storage for documents of external origin. Documents are entered into the Electronic Library Function (ELF) database and the physical document is labeled accordingly.

3.5.2 The CNWRA staff members can request from the CNWRA Library a document of external origin by identifying the document's title, author, identifying number, or published date.

**CENTER FOR NUCLEAR WASTE
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QUALITY ASSURANCE PROCEDURE

- 3.5.3 The CNWRA staff member is responsible for determining if the external document in the library is acceptable for use on project work. The CNWRA staff member also has the responsibility for assuring that distribution is made of the appropriate revision of the document to CNWRA staff members and consultants/subcontractors for project use.
- 3.5.4 If the CNWRA staff member obtains an external document that should be maintained in the CNWRA library, the staff member shall interface with the CNWRA Document Control staff person. The external document shall be entered in the CNWRA library 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. Appropriate protection shall be provided where necessary.
- 3.5.6 Electronic media, databases, codes, maps, drawings, photos and other non-printed external origin text shall be maintained as shelved library documents and are entered into the ELF database. Such documents of external origin shall be protected so the media/data are not compromised and shall be available for review to CNWRA staff member 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 CQAM Section 17.

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**CENTER FOR NUCLEAR WASTE
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QUALITY ASSURANCE MANUAL**

Rev. Chg

Month Year

Page of

EFFECTIVITY AND APPROVAL

Revision of this procedure became effective on mm/dd/yy. This procedure consists of the pages and changes listed below.

<u>Section</u>	<u>Page No.</u>	<u>Change</u>	<u>Date of Effective</u>
----------------	-----------------	---------------	--------------------------

Approvals

Director of Quality Assurance

Date

CNWRA President

Date

CNWRA Form QAP-3

Sample

Figure 1

CNWRA Form QAP-2

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CNWR Form QAP-4

Sample

Figure 2

CNWR Form QAP-2

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TECHNICAL OPERATING PROCEDURE

Proc. _____

Revision _____

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Title

EFFECTIVITY
Revision _____ of this procedure became effective on _____
This procedure consists of the pages and changes listed below.

_____	_____	_____
Page No.	Change No.	Date Effective

Supersedes Procedure No.

Approvals			
Written by	Date	Technical Review	Date
Quality Assurance	Date	Cognizant Director	Date

CNWRA Form TOP-1 (8/83)

Sample

Figure 3

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CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES QUALITY ASSURANCE PROCEDURE		Proc. QAP- Revision Page of
Title QAP-		
EFFECTIVITY AND APPROVAL		
Revision of this procedure became effective on . This procedure consists of the pages and changes listed below.		
<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
Supersedes Procedure No.		
Approvals		
Written By	Date	Concurrence Review
Quality Assurance	Date	Cognizant Director

CNRA Form QAP 1 (10/2001)

Sample

Figure 4

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ADMINISTRATIVE PROCEDURE		Revision <u> </u> Change <u> </u>	
Title :		Page <u> </u> of <u> </u>	
EFFECTIVITY			
Revision <u> </u> of this procedure became effective on <u> </u> . This procedure consists of the pages and changes listed below.			
<u>Page No.</u>	<u>Change No.</u>	<u>Date Effective</u>	
Supersedes Procedure No. <u> </u>			
Approvals			
Written by	Date	Concurrence Review	Date
Quality Assurance	Date	Cognizant Director	Date

CNRA Form AP-1

Sample

Figure 5

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TECHNICAL OPERATING PROCEDURE

Proc. _____

Revision ___ Change _____

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CNWR Form TOP-2

Sample

Figure 6

CNWR Form QAP-2

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CNWRA Form QAP-2

Sample

Figure 7

CNWRA Form QAP-2

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CNWRA Form AP-2

Sample

Figure 8

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**CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES
DOCUMENT TRANSMITTAL, TRAINING AND ACKNOWLEDGMENT RECORD**

TO:

FROM:

Document Control
CNWRA/Division 20
Southwest Research Institute
6220 Culebra Rd.
San Antonio, Texas 78238

Date Sent:

Attached are the following CNWRA controlled or uncontrolled documents:

Document Number	Revision/Change Number	Title

Instructions to Recipients:

1. Review and become familiar with the subject documents. Contact CNWRA QA at 210.522.5149 for additional training.
2. For revisions and changes, mark or discard the superseded documents or document pages and insert the current document or pages.
3. Sign and date the acknowledgment below attesting that the attached controlled or uncontrolled documents, revisions, or changes have been reviewed and understood, and that obsolete documents or pages have been removed.
4. The objective of this training is to ensure that you have reviewed, understood, and are able to implement the attached procedure(s), which are the content of this training.
5. Upon completion, return this form to CNWRA QA/Document Control at the address indicated above within 30 days.

Acknowledged by

Date

CNWRA Form DC-1-2 (1/2001)

Sample

Figure 10

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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	0	9/12/2003

Supersedes Procedure No. QAP-008, Rev. 3, Chg 0 dated 11/07/2001

Approvals

Written By <i>R. Brient</i> R. Brient	Date 9/12/03	Concurrence Review <i>Maria Padilla</i> M. Padilla	Date 9/12/03
Quality Assurance <i>M. Ehnstrom</i> M. Ehnstrom	Date 9/12/03	Cognizant Director <i>B. Sagar</i> B. Sagar	Date 9/12/03

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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 Element Managers (EMs) 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 and understanding documents and incorporating revisions and changes.

3. PROCEDURE

3.1 Document Identification

3.1.1 The CQAM, Operations Plans, Project Plans, Work Plans, Test Plans, procedures and 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 Operating Procedures {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 new Operating Procedures to obtain the document and revision/change number. In general, the next sequential three digit number shall be assigned to new Operating Procedures, such as TOP-00n. Operating Procedures of similar application may be assigned the same three digit base number with a subnumber or revision date.

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- 3.1.3 Scientific notebooks shall be assigned a unique number upon issuance. A log of scientific notebook issuance shall be maintained by Document Control containing its number, date of issuance, the notebook subject, and the individual to whom the notebook was issued.
- 3.2 Document Format: CQAM, 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 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 in headings the section number, revision and change number, and page number (page 1 of n).
- 3.2.4 Operating Procedures shall include, as a minimum, sections describing the Purpose, Responsibilities, Procedure, and Records requirements. Operating Procedures are the principal media of instructions for conducting CNWRA activities and shall provide sufficient details and step-by-step descriptions of the methods to be used that may be easily understood by the intended user of the procedure.
- 3.2.5 Operating Procedures shall include an Effectivity and Approval page, indicating the revision and change status of the procedure and each of its pages, and shall contain the required approval signatures.
- 3.2.6 Each page of Operating Procedures shall identify in headings the Procedure number, revision and change number, and page number (page 1 of n).
- 3.3 Document Approval and Effectivity
- 3.3.1 Original documents, changes, and revisions shall receive approvals as specified in QAP-002.

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- 3.3.2 Documents may be changed on a page-by-page basis or revised in total. For a changed document, an effectivity page with signatures approving the change and the changed pages (only) shall be prepared. Changes in such documents shall be identified in the right margin with a vertical bar. A "revised" document shall include an effectivity page approving the entire document, but no vertical bars will be shown.
- 3.3.3 TOPs may be changed in the laboratory or field without the required approvals provided that the change is authorized by the Principal Investigator and that the change is documented in the appropriate Scientific Notebook. The approvals (required by QAP-002) shall be obtained by the PI within a 30-day period, and may be documented by signatures in the Scientific Notebook. Field or laboratory changes are not permanent unless officially incorporated as changes, and apply only to the immediately affected activities. Permanent changes to TOPs require the usual (QAP-002) review and approval process.
- 3.3.4 Document Control shall maintain a document 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
 - Master Document List Effective Date
- 3.4 Distribution
- 3.4.1 Controlled documents may also be distributed by means of electronic media (e.g., read-only information on computer networks) or by distribution of hard copies.
- 3.4.2 Documents shall be distributed so that the procedures are available at the point of use. Individuals requiring documents shall be identified by EMs in accordance with QAP-005, and shall be documented on the Controlled Document Distribution List, CNWRA Form AP-3. In addition to the affected technical staff, document distribution shall include:
- CQAM—CNWRA President, Directors, EMs, PIs, and SwRI QA Manager.
 - Operations Plans—President, Directors, EMs, and affected PIs.

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APs QAPs, and TOPs—CNWRA President, Directors, EMs, PIs, Consultants, and SwRI staff members.

- 3.4.3 Additions to the Controlled Document Distribution Lists shall be made as necessary as new staff are added or as assignments to different activities are made as documented in 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 CNWRA staff, consultants, and subcontractors distribution shall be accomplished by e-mail attachment to affected individuals in the Controlled Document Distribution List. Acknowledgment for training purposes (QAP-005) shall be accomplished by return e-mail.
- 3.4.5 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. Recipients shall incorporate the changes or revisions and destroy or mark as obsolete superseded documents, as applicable, 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 listed in the Controlled Document Distribution Lists, however, receipt acknowledgment is not required.
- 3.4.7 The Director of QA shall notify EMs of those individuals not acknowledging receipt. The Director of QA and EM shall take action as necessary to obtain the acknowledgments.
- 3.4.8 The effectivity page of uncontrolled copies of documents shall be clearly identified as uncontrolled.
- 3.4.9 EMs 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 The CNWRA Library shall be the central location for the collection, issuance, and storage for documents of external origin. Documents are entered into the Electronic Library Function (ELF) database and the physical document shall be labeled accordingly.

3.5.2 The CNWRA staff members can request a document from the CNWRA Library by identifying the document's title, author, identifying number, or published date.

3.5.3 The CNWRA staff member is responsible for determining if the external document in the library is acceptable for use on 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 document that should be maintained in the CNWRA library, the staff member shall interface with CNWRA Document Control. The external document shall be entered in the CNWRA library 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. Appropriate protection shall be provided where necessary.

3.5.6 Electronic media, databases, codes, maps, drawings, photos and other nonprinted external origin text shall be maintained as shelved library documents and are entered into the ELF database. Such documents of external origin shall be protected so the media/data are not compromised and shall be available for review to CNWRA staff member 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 Operating Procedures, including superceded versions shall be maintained as QA Records in accordance with QAP-012.