CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

QUALITY ASSURANCE PROCEDURE

Proc. QAP-012

Revision 0

Page 1 of 9

Title

QUALITY ASSURANCE RECORDS CONTROL

EFFECTIVITY AND APPROVAL

Revision 0 of this procedure became effective on 1/8/91. This procedure consists of the pages and changes listed below.

Page No.	Change	Date Effective
ALL	0	1/8/91

SUPERSEDED By Revision 1, Chg 0 3/19/93

Supersedes Procedure No. N/A

Approvals

Written By	Date	Technical Review	Date
[signature]	12/21/90	[signature]	1/2/91
Quality Assurance	**Date**	**Cognizant Director**	**Date**
[signature]	1/6/91	[signature]	1/8/91

CNWRA Form QAP-1

QAP-012 QUALITY ASSURANCE RECORDS CONTROL

1. PURPOSE

The purpose of this procedure is to describe the methods of collecting, validating, processing, storing, and retrieving QA records. This procedure implements the requirements of CQAM Section 17.

2. RESPONSIBILITIES

1. The Director of Administration is responsible for implementation of this procedure.

2. The Director of QA is responsible for collecting and validating QA programmatic records.

3. Element Managers are responsible for collecting, validating, and presenting technical QA records for processing in accordance with this procedure.

4. All personnel producing documents which shall become QA records are responsible for protecting records in-process in accordance with this procedure.

3. PROCEDURE

3.1 QA Records Categories

Documents and items providing objective evidence of quality consist of technical QA records and of QA programmatic records (collectively termed QA records), and shall be captured and retained in accordance with this procedure.

3.1.1 Technical QA records are products of the Center and the supporting documentation associated with the development of the product, such as:

- Technical reports
- Papers and presentation materials

- Guidance documents, such as draft Technical Positions, draft Regulatory Guides
- Technical data; experimental and test results, material analyses, and Scientific Notebooks (including computer files) which provide results or directly support conclusions
- Data analyses and existing data qualification documentation
- Software documentation
- Technical and Peer review results and reports, and
- Procedure and equipment qualification results.

3.1.2 QA programmatic records include those associated with the functioning of the QA program, such as:

- Personnel qualification and training documentation
- Procurement and associated documents
- Calibration reports and procedures
- Document control records
- Nonconformance, corrective action, surveillance, and audit documentation
- CQAM, Operations Plans, Project Plans, QAPs and TOPs.

3.2 Control of Records In-Process

Documents, files, reports, data, computer disks, and other items which shall become QA records shall be controlled to prevent loss and destruction. Reasonable precautions shall be taken while gathering and analyzing data and during interim storage before records processing to preclude loss from fire, water or chemicals, unauthorized access and alteration, and damage or loss of computer files. When harsh conditions may be anticipated, such as when collecting field data, data previously collected shall be copied or otherwise protected to prevent inadvertent loss or damage.

3.3 Records Corrections

3.3.1 Corrections to QA records and QA records in-process shall be made by a single line through the incorrect data and inserting the correct data. Corrections may be made only

by the individual making the original entry, the cognizant Principal Investigator or Element Manager. Corrections shall be initialed and dated by the individual making the correction.

3.3.2 Typewriter correction fluid ("white-out") or correction tape is not permitted. However, a corrected document may be photocopied and an original signature affixed to make it acceptable to become a QA record.

3.4 Records Collection and Validation

3.4.1 Technical QA documents associated with Center products shall be assembled into a records package by the cognizant Element Manager within one month after delivery of the product. Supporting documentation need not be collected until the task is completed. Each document within the package shall be organized in proper order and each page sequentially numbered. A QA Records Processing Form, CNWRA Form QAP-16, Figure 1, shall be initiated for each records package, and shall include the following information:

a) Record Title

b) Author or originating Element

c) Subject Code (as identified on the reverse side of the QA Records Processing Form, Figure 2)

e) Project Number

f) List of the documents comprising the package and the number of pages within each document

g) Retention Time (technical records shall be identified as "Permanent").

The Element Manager shall attest that the Records Package is accurate and complete by signing and dating the form,

and shall forward the package for records processing and storage.

3.4.2 Completed QA Programmatic records shall be collected quarterly and transferred from working files for records processing. The Director of QA shall assemble packages of like QA records (i.e., audit reports, nonconformance reports, etc.) and the pages of each document shall be sequentially numbered. QA program documents (procedures, plans, etc.) shall be processed as individual packages, and may include their associated review documentation. A QA Records Processing Form shall be initiated for each package, and shall include the following information:

a) Record Title or Type of QA document, and time period when initiated

b) Author or Originating Element

c) Record Date

d) Subject Code (see Attachment A for a list of Subject Codes)

e) List of the documents comprising the package and the number of pages within each document, and

f) Retention Time (as specified by the QAP covering the generation of the record).

The Director of QA shall attest that the Records Package is accurate and complete by signing and dating the form, and shall forward the package for records processing.

3.5 Records Processing

3.5.1 Records received from Element Managers for processing shall be examined to verify that the record has been validated by signature on the QA Records Processing Form, that all listed documents and pages are included, and the

record is legible. Any discrepancies shall be identified to the responsible Element Manager and resolved.

3.5.2 The following information found on the QA Records Processing Form shall be entered into the QA Records Index and an accession number shall be assigned. The accession number shall consist of the subject code and an assigned sequential number.

a) Record Title

b) Author

c) Subject Code

d) Project Number, as applicable

e) Record Date

f) Date the record is entered into the index

g) Accession Number

h) Retention Time

The accession number, individual entering the information, and date of entry shall be recorded on the Record Processing Form.

3.6 Records Storage

3.6.1 Until late 1992, processed records shall be retained in an interim storage location (CNWRA offices in SwRI Bldg 168). Records shall be kept in limited access, standard file cabinets. This storage provides climate control and protection from weather with a degree of fire protection.

3.6.2 Permanent storage of records shall be provided by a dedicated vault located in SwRI Building 189 with a (minimum) 2 hour fire rating.

3.6.3 Only designated Records Control personnel shall be permitted access to storage areas.

3.6.4 Records may be checked out from the storage area through the Records Control personnel during working hours. All records shall be returned before the close of business. A log shall be maintained documenting the records checked out, by whom, date and time checked out, and date and time returned.

3.7 Records Retrieval

Records may be retrieved by computer search of the records index by subject code, date, project number, and/or title keywords.

4. RECORDS

QA Records Processing forms and the QA Records Index shall be controlled as QA records in accordance with CQAM Section 17.

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

QA RECORDS PROCESSING WORKSHEET

Record Title:	
Record Date:	
Author:	Subject Code:
Project Number:	Retain Until:

Record Package Contents	*Number of Pages*

VALIDATION — I attest that this record package is accurate and complete.

Element Manager:	Date:

RECORDS PROCESSING

Assigned Accession Number:	
Processed By:	Date:

CNWRA Form QAP 16

QA Records Subject Codes

QA Programmatic Records

101	Allegations of Inadequate Quality Documentation
102	Delegation of Authority Documentation
201	QA Indoctrination Documentation
202	Training Documentation
203	Personnel Qualification Documentation
500	QA Program Document Record Copies
601	Document Control Documentation
602	QA Program Document Review Documentation
701	Procurement Documents
702	Supplier Qualification Documentation
703	Acceptance Documentation
150	Nonconformance Documentation
160	Corrective Action Documentation
170	Records Control Documentation
180	Audit Documentation

Technical QA Records

301	Technical Reports
302	Papers and Presentation Materials
303	Regulatory Analysis Documentation
304	Existing Data Qualification Documentation
305	Software Control Documentation
306	Technical Report/Presentation Review Documentation
307	Regulatory Analysis Review Documentation
308	Technical Activity Supporting Documentation; Experimental Data, Data Reduction and Analysis Documentation, Scientific Notebooks, Computer Files
800	Sample Control Documentation
900	Procedure Qualification Documentation (if not included as supporting documentation)
120	Calibration Documentation (if not included as supporting documentation)

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES QUALITY ASSURANCE PROCEDURE	Proc. QAP-012 Revision 1 Page 1 of 7

Title

QAP-012 — Quality Assurance Records Control

EFFECTIVITY AND APPROVAL

Revision 1 of this procedure became effective on 03/19/93 . This procedure consists of the pages and changes listed below.

Page No.	Change	Date Effective
all	0	03/19/93

SUPERSEDED

Supersedes Procedure No. QAP-012, Rev 0

Approvals

Written By	Date	Concurrence Review	Date
[signature]	3/18/93	[signature]	3/18/93
Quality Assurance	**Date**	**Cognizant Director**	**Date**
[signature]	3/18/93	[signature]	3/18/93

QAP-012 QUALITY ASSURANCE RECORDS CONTROL

1 PURPOSE

The purpose of this procedure is to describe the methods of collecting, validating, processing, storing, and retrieving Quality Assurance (QA) records. This procedure implements the requirements of the Center Quality Assurance Manual (CQAM) Section 17.

2 RESPONSIBILITIES

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

2.2 The Director of QA and Element Managers are responsible for collecting, validating, and presenting records for processing in accordance with this procedure.

2.3 All personnel producing documents which shall become QA records are responsible for protecting records in-process in accordance with this procedure.

3 PROCEDURE

3.1 QA Records Categories

QA records consist of technical records and QA programmatic records, and shall be captured and retained in accordance with this procedure.

3.1.1 Technical QA records include deliverable products and the supporting documentation associated with the development of the product, such as:

- Technical reports;
- Papers and presentation materials;
- Guidance documents;
- Technical data; experimental and test results, material analyses, and Scientific Notebooks (including computer files) which provide results or directly support conclusions;
- Data analyses and existing data qualification documentation;
- Software documentation, and;
- Technical and Peer review results and reports.

3.1.2 QA programmatic records include those associated with the functioning of the QA program:

- Personnel qualification and training documentation;
- Procurement and associated documents;
- Calibration reports and procedures;
- Document control records;
- Nonconformance, corrective action, surveillance, and audit documentation, and;
- CQAM, Operations Plans, Project Plans, Work Plans, Test Plans, Quality Assurance Procedures (QAPs) and Technical Operating Procedures (TOPs).

3.2 Control of Records In-Process

Documents, files, reports, data, computer disks, and other items which shall become records shall be controlled to prevent loss and destruction. Reasonable precautions shall be taken while gathering and analyzing data and during interim storage before records processing to preclude loss from fire, water or chemicals, unauthorized access and alteration,and damage or loss of computer files. When harsh conditions may be anticipated, such as when collecting field data, data previously collected shall be copied or otherwise protected to prevent inadvertent loss or damage.

3.3 Records Corrections

3.3.1 Corrections to QA records and records in-process shall be made by a single line through the incorrect data and inserting the correct data. Corrections may be made only by the individual making the original entry, the cognizant Principal Investigator or Element Manager. Corrections shall be initialed and dated by the individual making the correction.

3.3.2 Typewriter correction fluid ("white-out") or correction tape is not permitted. However, a corrected document may be photocopied and an original signature affixed to make it acceptable to become a QA record.

3.4 Records Collection and Validation

3.4.1 QA records associated with technical activities shall be collected for records processing within one month after completion of the activities, or earlier, as appropriate. The product (technical report) and supporting documentation may be consolidated into one record package,

or may be broken into separate record packages. Each document within the package shall be organized in proper order and each page sequentially numbered.

3.4.2 QA programmatic records in-process shall be stored in QA working files, and completed records shall be processed for final storage bi-annually. Packages of like QA programmatic Records (i.e., Audit reports, nonconformance reports, etc.) shall be assembled and the pages of each document shall be sequentially numbered. QA program documents (procedures, plans, etc.) shall be processed as individual packages, and may include their associated review documentation.

3.4.3 A QA Records Processing Form, CNWRA Form QAP-16 (Figure 1), shall be initiated for each records package, and shall include the following information:

- Record Title;
- Author or originating Element;
- Subject Code, as identified on the reverse side of the QA Records Processing Form, (Figure 2);
- Project Number;
- List of the documents comprising the package and the number of pages within each document, and;
- Retention time (all Technical Records shall be identified as "Permanent" and shall be retained indefinitely, QA Programmatic Records shall be retained as specified by the QAP covering the generation of the record).

3.4.4 The cognizant Element Manager or Director of QA, as applicable, shall attest that the Records Package is accurate and complete by signing and dating the QA Records Processing Form (as the Element Manager), and shall forward the package for records processing.

3.5 Records Processing

3.5.1 Records received for processing shall be examined to verify that the record has been validated by signature on the QA Records Processing Form, that all listed documents and pages are included, and the record is legible. Any discrepancies shall be identified to the responsible Element Manager and resolved.

3.5.2 The information found on the upper portion of the QA Records Processing Form shall be entered into the computerized QA Records Index and an accession number shall be assigned. The accession number shall consist of the subject code and an assigned sequential number. The

accession number, individual entering the information, and date of entry shall be recorded on the Record Processing Form.

3.6 Records Storage

3.6.1 Until approximately November, 1993, processed records shall be retained in an interim storage location (CNWRA offices in Southwest Research Institute Bldg 168). Records shall be kept in standard file cabinets, and access shall be restricted. This storage provides climate control and protection from weather with a degree of fire protection.

3.6.2 Permanent storage of records shall be provided by a dedicated vault located in SwRI Building 189 with a (minimum) 2 hour fire rating.

3.6.3 Only designated Records Control personnel shall be permitted access to storage areas.

3.6.4 Records may be checked out from the storage area through the Records Control personnel during working hours. All records shall be returned daily before the close of business. A log shall be maintained documenting the records checked out, by whom, date and time checked out, and date and time returned.

3.7 Records Retrieval

Records may be retrieved by computer search of the QA Records Index by subject code, date, project number, and/or title keywords.

4 RECORDS

QA Records Processing forms and the QA Records Index shall be controlled as QA records in accordance with CQAM Section 17.

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

QA RECORDS PROCESSING WORKSHEET

Record Title:	
Record Date:	
Author:	Subject Code:
Project Number:	Retain Until:

Record Package Contents	*Number of Pages*

VALIDATION — I attest that this record package is accurate and complete.

Element Manager:	Date:

RECORDS PROCESSING

Assigned Accession Number:	
Processed By:	Date:

CNWRA Form QAP 16

Figure 1
EXAMPLE

QA Records Subject Codes

QA Programmatic Records

101	Allegations of Inadequate Quality Documentation
102	Delegation of Authority Documentation
201	QA Indoctrination Documentation
202	Training Documentation
203	Personnel Qualification Documentation
500	QA Program Document Record Copies
601	Document Control Documentation
602	QA Program Document Review Documentation
701	Procurement Documents
702	Supplier Qualification Documentation
703	Acceptance Documentation
150	Nonconformance Documentation
160	Corrective Action Documentation
170	Records Control Documentation
180	Audit Documentation

Technical QA Records

301	Technical Reports
302	Papers and Presentation Materials
303	Regulatory Analysis Documentation
304	Existing Data Qualification Documentation
305	Software Control Documentation
306	Technical Report/Presentation Review Documentation
307	Regulatory Analysis Review Documentation
308	Technical Activity Supporting Documentation; Experimental Data, Data Reduction and Analysis Documentation, Scientific Notebooks, Computer Files
800	Sample Control Documentation
900	Procedure Qualification Documentation (if not included as supporting documentation)
120	Calibration Documentation (if not included as supporting documentation)

Figure 2
EXAMPLE

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES QUALITY ASSURANCE PROCEDURE	Proc. QAP-012 Revision 2 Chg 0 Page 1 of 8

Title

QAP-012 QUALITY ASSURANCE RECORDS CONTROL

EFFECTIVITY AND APPROVAL

Revision 2 of this procedure became effective on 03/~~00~~/97 . This procedure consists of the pages and changes listed below.

Page No.	Change	Date Effective
All	0	03/~~00~~/97

SUPERSEDED

Supersedes Procedure No. QAP-012, Rev. 1, Chg 0 dated 03/19/93.

Approvals

Written By Linda G. Hearon	Date 3/7/97	Concurrence Review Wesley C. Patrick	Date 3/3/97
Quality Assurance Bruce Mabrito	Date 3/6/97	Cognizant Director Henry Garcia	Date 3/7/97

CNWRA Form QAP 1 (12/92)

QAP-012 QUALITY ASSURANCE RECORDS CONTROL

1. PURPOSE

The purpose of this procedure is to describe the methods of collecting, validating, processing, storing, and retrieving Quality Assurance (QA) Records. This procedure implements the requirement of the CNWRA Quality Assurance Manual (CQAM) Section 17, and provides retention times for categories of records.

2. RESPONSIBILITIES

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

2.2 The Director of QA and each Element Manager (EM) are responsible for collecting, validating, and presenting records for processing in accordance with this procedure.

3. PROCEDURE

3.1 QA Records Categories

QA Records consist of Technical QA Records and QA Programmatic Records, and shall be captured and retained in accordance with this procedure.

3.1.1 Technical QA Records include deliverable products and the supporting documentation associated with the development of each product, such as:

- Technical reports
- Papers, abstracts, and presentation materials
- Guidance documents
- Technical data; experimental and test results, material analyses, and Scientific Notebooks (including computer files) which provide results or directly support conclusions
- Data analyses and existing data qualification documentation
- Software documentation
- Technical and Peer Review documentation

3.1.2 QA Programmatic Records include those associated with the functioning of the QA program, such as:

- Professional Personnel Qualifications, QA Indoctrination, and training documentation
- Calibration reports and procedures
- Document control records
- Nonconformance, corrective action, surveillance, and audit documentation
- Controlled documents

3.2 Control of In-Process Records

3.2.1 Documents, files, reports, data, electronic files, and other items which become records shall be controlled to prevent loss and destruction. Reasonable precautions shall be taken while gathering and analyzing data—during interim storage before records processing—to preclude loss from fire, water or chemicals, unauthorized access and alteration, and damage or loss of computer files. When harsh environmental conditions are anticipated (e.g., collecting field data) data previously collected shall be copied or otherwise protected to prevent inadvertent loss or damage.

3.2.2 QA Programmatic Records in-process shall be stored in working files by QA staff in the QA Records Room, and completed records shall be processed and validated for permanent storage on a semi-annual basis.

3.3 Records Corrections

3.3.1 Corrections to QA Records and records in-process shall be made by a single line through the incorrect data and inserting the correct data. Corrections may be made only by the individual making the original entry, the cognizant Principal Investigator (PI) or EM. Corrections shall be initialed and dated by the individual making the correction.

3.3.2 Typewriter correction fluid (white-out) or correction tape is not permitted. However, a corrected document may be photocopied and an original signature affixed for acceptance as a QA Record.

3.4 Records Collection and Validation

3.4.1 QA Records associated with technical activities shall be collected and submitted to QA staff for processing within one month after completion of the activities. The product(s) of such activities and supporting documentation may be consolidated into one record package, or may require separate record packages but must be identified by one accession number.

3.4.2 Similar QA Programmatic Records (i.e., audit reports, nonconformance reports, etc.) shall be assembled into records packages and the pages of each document within the package shall be sequentially numbered. Review documentation for controlled documents shall be processed as individual packages and the original document and acknowledgement records may be kept in a separate file in the document control section of the QA Records Room.

3.4.3 A QA Records Processing Worksheet, CNWRA Form QAP-16 (figure 1), shall be used for each records package, and shall include the following information:

- Record Title
- Record Date (month/year product was completed)
- Author
- Subject Code as shown in table 1
- Project Number
- Retain Until—All Technical QA Records shall be identified as "Permanent" and shall be retained indefinitely; QA Programmatic Records shall be retained as outlined in table 1, which has retention times listed.
- Record Package Contents—List of the documents comprising the package and the number of pages within each document.

3.4.4 The cognizant EM or Director (DIR), as applicable, shall attest that the records package is accurate and complete by signing and dating the QA Records Processing Worksheet.

3.5 Records Processing

3.5.1 Records received by QA for processing shall be examined to verify that the record package has been validated when the appropriate signature appears on the QA Records Processing Worksheet, the records package is complete, and the

individual records are legible. Any discrepancies shall be identified to the responsible EM/DIR and resolved.

3.5.2 The information found on the upper portion of the QA Records Processing Worksheet shall be entered into the QA Records Database and an accession number assigned. The accession number, individual entering the information, and date of entry shall be recorded on the QA Records Processing Worksheet.

3.6 Records Storage

3.6.1 Permanent storage of records shall be provided by a dedicated vault located in SwRI Building 189 with a (minimum) two hour fire rating.

3.6.2 Only designated personnel shall be permitted access to the QA Records Room.

3.6.3 Records may be checked out from the QA Records Room through QA staff during normal business hours. All records shall be returned daily before the close of business. Check-out cards shall document the record checked out, by whom, and date checked out.

3.6.4 The CNWRA stores permanent and nonpermanent records. Records are designated for permanent retention if they meet any of the following criteria: (i) provide objective evidence of fulfillment of the particular requirements of the CQAM or Quality Assurance Procedures that implement the CQAM (e.g., audits, QA reviews, training, etc.); (ii) provide objective evidence of the fulfillment of the particular requirements of Technical Operating Procedures (e.g., calibration, regulatory analysis reviews, etc.); (iii) are needed to substantiate the results or basis for licensing and prelicensing reviews; (iv) support regulatory decisions; or (v) would be needed by an independent third party to reconstruct the work that was conducted or results that were obtained. Nonpermanent records are those required to show evidence that an activity was performed in accordance to applicable requirements but need not be retained for the life of the item or activity because they do not meet the criteria for permanent records. Nonpermanent records are kept for a minimum six year period.

3.6.5 Retention times are shown in table 1 for both permanent and nonpermanent record categories. These retention times supersede those referenced in other documents.

3.7 Records Retrieval

Records may be retrieved by electronic search of the QA Records Database or manual search of the files.

4. RECORDS

The QA Records Processing Worksheet shall remain with the package it describes for as long as the package is retained.

SAMPLE

Figure 1

Table 1. QA Records Subject Codes

QA RECORDS SUBJECT CODES		
Subject Code	**Record**	**Retention Time**
QA Programmatic Records		
100	SwRI Audit Review	Permanent
101	Allegations of Inadequate Quality Documentation	Permanent
102	Delegation of Authority Documentation	Nonpermanent
150	Nonconformance Documentation	Nonpermanent
160	Corrective Action Documentation	Nonpermanent
161	CNWRA Quality Trends	Nonpermanent
170	Records Control Documentation	Nonpermanent
180	Audit Documentation	Permanent
181	Surveillance Reports	Nonpermanent
201	QA Indoctrination Documentation	Permanent
202	Training Documentation	Permanent
203	Personnel Qualification Documentation	Permanent
204	Periodic QA Status Review & QA Requirements Matrix	Nonpermanent
205	SwRI QA Committee Documentation	Nonpermanent
206	Quality Planning Documentation	Permanent
500	QA Program Document Records Copies	Permanent
601	Document Control Documentation	Nonpermanent
602	QA Program Document Review Documentation	Permanent
701	Procurement Documents	Nonpermanent
702	Supplier Qualification Documentation	Permanent
703	Supplier Documentation (SwRI QVL and ASL)	Permanent
Technical QA Records		
120	Calibration Documentation (if not included as supporting documentation)	Permanent
301	Technical Reports	Permanent
302	Papers and Presentation Materials	Permanent
303	Regulatory Analysis Documentation	Permanent
304	Existing Data Qualification Documentation	Permanent
305	Software Control Documentation	Permanent
306	Technical Report/Presentation Review Documentation	Permanent
307	Regulatory Analysis Review Documentation	Permanent
308	Technical Activity Supporting Documentation: Experimental Data, Data Reduction and Analysis Documentation, Scientific Notebooks, Computer Files	Permanent
800	Sample Control Documentation	Permanent
900	Procedure Qualification Documentation (if not included as supporting documentation)	Permanent
901	Company Sensitive Documentation	Permanent

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Title

QAP-012 QUALITY ASSURANCE RECORDS CONTROL

EFFECTIVITY AND APPROVAL

Revision 2 of this procedure became effective on 03/07/97. This procedure consists of the pages and changes listed below.

Page No.	Change	Date Effective
1 - 2	0	03/07/97
3 - 6	1	02/17/00
7	0	03/07/97
8	1	02/17/00

SUPERSEDED

Supersedes Procedure No. QAP-012, Rev. 2, Chg 0 dated 03/07/97.

Approvals

Written By Mark R. Ehnstrom Mark Ehnstrom	Date 2/15/2000	Concurrence Review Wesley C. Patrick	Date 2/15/2000
Quality Assurance Bruce Mabrito	Date 2/16/2000	Cognizant Director for Henry Garcia	Date 2/16/2000

QAP-012 QUALITY ASSURANCE RECORDS CONTROL

1. PURPOSE

The purpose of this procedure is to describe the methods of collecting, validating, processing, storing, and retrieving Quality Assurance (QA) Records. This procedure implements the requirement of the CNWRA Quality Assurance Manual (CQAM) Section 17, and provides retention times for categories of records.

2. RESPONSIBILITIES

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

2.2 The Director of QA and each Element Manager (EM) are responsible for collecting, validating, and presenting records for processing in accordance with this procedure.

3. PROCEDURE

3.1 QA Records Categories

QA Records consist of Technical QA Records and QA Programmatic Records, and shall be captured and retained in accordance with this procedure.

3.1.1 Technical QA Records include deliverable products and the supporting documentation associated with the development of each product, such as:

- Technical reports
- Papers, abstracts, and presentation materials
- Guidance documents
- Technical data; experimental and test results, material analyses, and Scientific Notebooks (including computer files) which provide results or directly support conclusions
- Data analyses and existing data qualification documentation
- Software documentation
- Technical and Peer Review documentation

3.1.2 QA Programmatic Records include those associated with the functioning of the QA program, such as:

- Professional Personnel Qualifications, QA Indoctrination, and training documentation
- Calibration reports and procedures
- Document control records
- Nonconformance, corrective action, surveillance, and audit documentation
- Controlled documents

3.2 Control of In-Process Records

3.2.1 Documents, files, reports, data, electronic files, and other items which become records shall be controlled to prevent loss and destruction. Reasonable precautions shall be taken while gathering and analyzing data—during interim storage before records processing—to preclude loss from fire, water or chemicals, unauthorized access and alteration, and damage or loss of computer files. When harsh environmental conditions are anticipated (e.g., collecting field data) data previously collected shall be copied or otherwise protected to prevent inadvertent loss or damage.

3.2.2 While project work is being conducted, scientific notebooks (whether maintained in hard copy or electronic) shall be considered as records-in-process. The Principal Investigator or person making entries shall suitably store and protect records-in-process from loss or damage. Every six (6) months the holder shall send to CNWRA QA a copy of the controlled scientific notebook entries since the last version was submitted to QA. Such copies will be accumulated in a folder and kept in the QA Records Room until replaced with the controlled scientific notebook itself.

3.2.3 To minimize loss of CNWRA work in progress on behalf of its clients, scientific and engineering software, databases, and results of analyses to be used in CNWRA products will also be submitted to QA records every six (6) months for retention.

3.2.4 QA Programmatic Records in-process shall be stored in working files by QA staff in the QA Records Room, and completed records shall be processed and validated for permanent storage on a annual basis.

3.3 Records Corrections

3.3.1 Corrections to QA Records and records in-process shall be made by a single line through the incorrect data and inserting the correct data. Corrections may be made only by the individual making the original entry, the cognizant Principal Investigator (PI) or EM. Corrections shall be initialed and dated by the individual making the correction.

3.3.2 Typewriter correction fluid (white-out) or correction tape is not permitted. However, a corrected document may be photocopied and an original signature affixed for acceptance as a QA Record.

3.4 Records Collection and Validation

3.4.1 QA Records associated with technical activities shall be collected and submitted to QA staff for processing within one month after completion of the activities. The product(s) of such activities and supporting documentation may be consolidated into one record package, or may require separate record packages but must be identified by one accession number.

3.4.2 Similar QA Programmatic Records (i.e., audit reports, nonconformance reports, etc.) shall be assembled into records packages and the pages of each document within the package shall be sequentially numbered. Review documentation for controlled documents shall be processed as individual packages and the original document and acknowledgement records may be kept in a separate file in the document control section of the QA Records Room.

3.4.3 A QA Records Processing Worksheet, CNWRA Form QAP-16 (figure 1), shall be used for each records package, and shall include the following information:

- Record Title
- Record Date (month/year product was completed)
- Author
- Subject Code as shown in table 1
- Project Number
- Retain Until—All Technical QA Records shall be identified as "Permanent" and shall be retained indefinitely; QA Programmatic Records shall be retained as outlined in table 1, which has retention times listed.
- Record Package Contents—List of the documents comprising the package and the number of pages within each document.

3.4.4 The cognizant EM or Director, as applicable, shall attest that the records package is accurate and complete by signing and dating the QA Records Processing Worksheet.

3.5 Records Processing

3.5.1 Records received by QA for processing shall be examined to verify that the appropriate signature appears on the QA Records Processing Worksheet, the records package is complete, and individual records are legible before they are considered validated. Any discrepancies shall be identified to the responsible EM and resolved.

3.5.2 The information found on the upper portion of the QA Records Processing Worksheet shall be entered into the QA Records Database and an accession number assigned. The accession number, individual entering the information, and date of entry shall be recorded on the QA Records Processing Worksheet.

3.6 Records Storage

3.6.1 Permanent storage of records shall be provided by a dedicated vault located in SwRI Building 189 or SwRI Building 139 with a (minimum) two hour fire rating.

3.6.2 Only designated personnel shall be permitted access to the CNWRA QA Records Room, although others can be escorted.

3.6.3 Some in-process records are maintained in the CNWRA QA Records Room in folders identified as such. Following completion of activities, a complete QA records packet is assembled and verified by the Element Manager to be filed in permanent records.

3.6.4 Records may be checked out from the QA Records Room through QA staff during normal business hours. All records shall be returned daily before the close of business. Check-out cards shall document the record checked out, by whom, and date checked out.

3.6.5 CNWRA QA stores permanent and nonpermanent records. Records are designated for permanent retention if they meet any of the following criteria: (i) provide objective evidence of fulfillment of the particular requirements of the CQAM or Quality Assurance Procedures that implement the CQAM (e.g., audits, QA reviews, training, etc.); (ii) provide objective evidence of the fulfillment of the particular requirements of Technical Operating Procedures (e.g., calibration, regulatory analysis reviews, etc.); (iii) are needed to substantiate the results or basis for licensing and prelicensing reviews; (iv) support regulatory decisions; or (v) would be needed by an independent third party to reconstruct the work that was conducted or results that were obtained. Nonpermanent records are those required to show evidence that an activity was performed in accordance to applicable requirements but need not be retained for the life of the item or activity because they do not meet the criteria for permanent records. Nonpermanent records are kept for a minimum six year period.

3.6.6 Retention times are shown in table 1 for both permanent and nonpermanent record categories. These retention times supersede those referenced in other documents.

3.7 Records Retrieval

Records may be retrieved by electronic search of the QA Records Database or manual search of the files. QA Records are checked out to individuals and must be returned before the end of the work day. If there is a need for longer review, copies will be made and the original returned to QA Records.

4. RECORDS

The QA Records Processing Worksheet shall remain with the package it describes for as long as the package is retained.

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES QA RECORDS PROCESSING WORKSHEET	
Record Title:	
Record Date:	
Author:	Subject Code:
Project Number:	Retain Until:

Record Package Contents	Number of Pages
WP 5.1 File	No. of Disk(s) 0
VALIDATION — I attest that this record package is accurate and complete.	
Element Manager:	Date:
RECORDS PROCESSING	
Assigned Accession Number:	
Processed By:	Date:

CNWRA Form QAP 16

SAMPLE

Figure 1

Table 1. QA Records Subject Codes

QA RECORDS SUBJECT CODES		
Subject Code	Record	Category
QA Programmatic Records		
100	SwRI Audit Review	Permanent
101	Allegations of Inadequate Quality Documentation	Permanent
102	Delegation of Authority Documentation	Nonpermanent
150	Nonconformance Documentation	Nonpermanent
160	Corrective Action Documentation	Nonpermanent
161	CNWRA Quality Trends	Nonpermanent
170	Records Control Documentation	Nonpermanent
180	Audit Documentation	Permanent
181	Surveillance Reports	Nonpermanent
201	QA Indoctrination Documentation	Permanent
202	Training Documentation	Permanent
203	Personnel Qualification Documentation	Permanent
204	Periodic QA Status Review & QA Requirements Matrix	Nonpermanent
205	SwRI QA Committee Documentation	Nonpermanent
206	Quality Planning Documentation	Permanent
500	QA Program Document Records Copies	Permanent
601	Document Control Documentation	Nonpermanent
602	QA Program Document Review Documentation	Permanent
701	Procurement Documents	Nonpermanent
702	Supplier Qualification Documentation	Permanent
703	Supplier Documentation (SwRI QVL and ASL)	Permanent
Technical QA Records		
120	Calibration Documentation (if not included as supporting documentation)	Permanent
301	Technical Reports	Permanent
302	Papers and Presentation Materials	Permanent
303	Regulatory Analysis Documentation	Permanent
304	Existing Data Qualification Documentation	Permanent
305	Software Control Documentation	Permanent
306	Technical Report/Presentation Review Documentation	Permanent
307	Regulatory Analysis Review Documentation	Permanent
308	Technical Activity Supporting Documentation: Experimental Data, Data Reduction and Analysis Documentation, Scientific Notebooks, Computer Files	Permanent
800	Sample Control Documentation	Permanent
900	Procedure Qualification Documentation (if not included as supporting documentation)	Permanent
901	Company Sensitive Documentation	Permanent

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES QUALITY ASSURANCE PROCEDURE	Proc. QAP-012 Revision 3 Chg 0 Page 1 of 8

Title

QAP-012 QUALITY ASSURANCE RECORDS CONTROL

EFFECTIVITY AND APPROVAL

Revision 3 of this procedure became effective on 04/23/01. This procedure consists of the pages and changes listed below.

Page No.	Change	Date Effective
ALL	0	04/23/01

SUPERSEDED

Supersedes Procedure No. QAP-012, Rev. 2, Chg 1 dated 02/17/2000.

Approvals

Written By Mark Ehnstrom	Date 4/23/01	Concurrence Review Wesley C. Patrick	Date 4/23/01
Quality Assurance Bruce Mabrito	Date 4/23/2001	Cognizant Director Henry Garcia	Date 4/23/01

QAP-012 QUALITY ASSURANCE RECORDS CONTROL

1. PURPOSE

The purpose of this procedure is to describe the methods of collecting, validating, processing, storing, and retrieving Quality Assurance (QA) Records. This procedure implements the requirement of the CNWRA Quality Assurance Manual (CQAM) Section 17, and provides retention times for categories of records.

2. RESPONSIBILITIES

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

2.2 The Director of QA and each Element Manager (EM) are responsible for collecting, validating, and presenting records for processing in accordance with this procedure.

3. PROCEDURE

3.1 QA Records Categories

QA Records consist of Technical QA Records and QA Programmatic Records, and shall be captured and retained in accordance with this procedure.

3.1.1 Technical QA Records include deliverable products and the supporting documentation associated with the development of each product. Table 1 lists categories of QA records that are to be retained. Specific contract requirements and 10 CFR Part 2, Subpart J should be consulted for more detailed definition of records to be retained.

3.1.2 QA Programmatic Records include those associated with the functioning of the QA program, such as:

- Professional Personnel Qualifications, QA Indoctrination, and training documentation
- Calibration reports and procedures
- Document control records
- Nonconformance, corrective action, surveillance, and audit documentation
- Controlled documents

3.2 Control of In-Process Records

3.2.1 Documents, files, reports, data, electronic files, and other items that will become records shall be controlled to prevent loss and destruction. Reasonable precautions shall be taken while gathering and analyzing data—during interim storage before records processing—to preclude loss from fire, water or chemicals, unauthorized access and alteration, and damage or loss of computer files. When harsh environmental conditions are anticipated (e.g., collecting field data) data previously collected shall be copied or otherwise protected to prevent inadvertent loss or damage.

3.2.2 While project work is being conducted, scientific notebooks (whether maintained in hard copy or electronic) shall be considered as records-in-process. The Principal Investigator or person making entries shall suitably store and protect records-in-process from loss or damage. Every six (6) months the holder shall send to CNWRA QA a copy of the controlled scientific notebook entries since the last version was submitted to QA. Such copies will be accumulated in a folder and kept in the QA Records Room until replaced with the controlled scientific notebook itself.

3.2.3 To minimize loss of CNWRA work in progress on behalf of its clients, scientific notebooks documenting ongoing development of scientific and engineering software, databases, and results of analyses to be used in CNWRA products shall be maintained and submitted to QA records every six (6) months for retention.

3.2.4 QA Programmatic Records in-process shall be stored in working files by QA staff in the QA Records Room, and completed records shall be processed and validated for permanent storage on an annual basis.

3.3 Records Corrections

3.3.1 Corrections to QA Records and records in-process shall be made by a single line through the incorrect data and inserting the correct data. Corrections may be made only by the individual making the original entry, the cognizant Principal Investigator (PI) or EM. Corrections shall be initialed and dated by the individual making the correction.

3.3.2 Typewriter correction fluid (white-out) or correction tape is not permitted. However, a corrected document may be photocopied and an original signature affixed for acceptance as a QA Record.

3.4 Records Collection and Validation

3.4.1 QA Records associated with technical activities shall be collected and submitted to QA staff for processing within one month after completion of the activities. The product(s) of such activities and supporting documentation may be consolidated into one record package, or may require separate record packages but must be identified by one accession number.

3.4.2 Similar QA Programmatic Records (i.e., audit reports, nonconformance reports, etc.) shall be assembled into records packages and the pages of each document within the package shall be sequentially numbered. Review documentation for controlled documents shall be processed as individual packages and the original document and acknowledgment records may be kept in a separate file in the document control section of the QA Records Room.

3.4.3 A QA Records Processing Worksheet, CNWRA Form QAP-16 (figure 1), shall be used for each records package, and shall include the following information:

- Record Title
- Record Date (month/year product was completed)
- Author
- Subject Code as shown in table 1
- Project Number
- Retain Until—All Technical QA Records shall be identified as "Permanent" and shall be retained indefinitely; QA Programmatic Records shall be retained as outlined in table 1, which has retention times listed.
- Record Package Contents—List of the documents comprising the package and the number of pages within each document.

3.4.4 The cognizant EM or Director, as applicable, shall attest that the records package is accurate and complete by signing and dating the QA Records Processing Worksheet.

3.5 Records Processing

3.5.1 Records received by QA for processing shall be examined to verify that the appropriate signature appears on the QA Records Processing Worksheet, the records package is complete, and individual records are legible before they are considered validated. Any discrepancies shall be identified to the responsible EM and resolved.

3.5.2 The information found on the upper portion of the QA Records Processing Worksheet shall be entered into the QA Records Database and an accession number assigned. The accession number, individual entering the information, and date of entry shall be recorded on the QA Records Processing Worksheet.

3.6 Records Storage

3.6.1 Permanent storage of records shall be provided by a dedicated vault located in SwRI Building 189 or SwRI Building 139 with a (minimum) two hour fire rating.

3.6.2 Only designated personnel shall be permitted access to the CNWRA QA Records Room, although others can be escorted.

3.6.3 Some in-process records are maintained in the CNWRA QA Records Room in folders identified as such. Following completion of activities, a complete QA records packet is assembled and verified by the Element Manager to be filed in permanent records.

3.6.4 Records may be checked out from the QA Records Room through QA staff during normal business hours. All records shall be returned daily before the close of business. Check-out cards shall document the record checked out, by whom, and date checked out.

3.6.5 CNWRA QA stores permanent and nonpermanent records. Records are designated for permanent retention if they meet any of the following criteria: (i) provide objective evidence of fulfillment of the particular requirements of the Operations Plans, CQAM, QA Procedures, or Administrative Procedures that implement the CQAM (e.g., audits, QA reviews, training, etc.); (ii) provide objective evidence of the fulfillment of the particular requirements of Technical Operating Procedures (e.g., calibration, regulatory analysis reviews, etc.); (iii) substantiate the results or basis for licensing and prelicensing reviews; (iv) support regulatory decisions; or (v) satisfy potential requirement by an independent third party to reconstruct the work that was conducted or results that were obtained. Nonpermanent records are those required to show evidence that an activity was performed in accordance to applicable requirements but need not be retained for the life of the item or activity because they do not meet the criteria for permanent records. Nonpermanent records are kept for a minimum six year period.

3.6.6 Retention times are shown in table 1 for both permanent and nonpermanent record categories. These retention times supersede those referenced in other documents.

3.7 Records Retrieval

Records may be retrieved by electronic search of the QA Records Database or manual search of the files. QA Records are checked out to individuals and must be returned before the end of the work day. If there is a need for longer review, copies will be made and the original returned to QA Records.

4. RECORDS

The QA Records Processing Worksheet shall remain with the package it describes for as long as the package is retained.

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES
QA RECORDS PROCESSING WORKSHEET

Record Title:	
Record Date:	
Author:	**Subject Code:**
Project Number	**Retain Until:**

Record Package Contents	**Number of Pages**
Review Documentation	
Transmittal Letter	
Document	
	No. of CD-ROMs:

VALIDATION - I attest that this record package is accurate and complete.

Element Manager:	**Date:**

RECORDS PROCESSING.

Assigned Accession Number:

Processed By:	**Date:**

CNWRA Form QAP 16

SAMPLE

Figure 1

Table 1. QA Records Subject Codes

QA RECORDS SUBJECT CODES		
Subject Code	**Record**	**Category**
QA Programmatic Records		
100	SwRI Audit Review	Permanent
101	Allegations of Inadequate Quality Documentation	Permanent
102	Delegation of Authority Documentation	Nonpermanent
150	Nonconformance Documentation	Nonpermanent
160	Corrective Action Documentation	Nonpermanent
161	CNWRA Quality Trends	Nonpermanent
170	Records Control Documentation	Nonpermanent
180	Audit Documentation	Permanent
181	Surveillance Reports	Nonpermanent
201	QA Indoctrination Documentation	Permanent
202	Training Documentation	Permanent
203	Personnel Qualification Documentation (PPQ and Training Documentation Forms)	Permanent
204	Periodic QA Status Review & QA Requirements Matrix	Nonpermanent
205	SwRI QA Committee Documentation	Nonpermanent
206	Quality Planning Documentation	Permanent
207	QA Memos	Permanent
208	Organizational COI	Permanent
500	QA Program Document Records Copies (APs, QAPs, and TOPs)	Permanent
601	Document Control Documentation	Nonpermanent
602	QA Program Document Review Documentation (Operations Plans and Project Plans)	Permanent
701	Procurement Documents (Receipt Travelers)	Nonpermanent
702	Supplier Qualification Documentation	Permanent
703	Supplier Documentation (SwRI ASL)	Permanent
Technical QA Records		
120	Calibration Documentation (if not included as supporting documentation)	Permanent
301	Technical Reports	Permanent
302	Papers and Presentation Materials	Permanent
303	Regulatory Analysis Documentation	Permanent
304	Existing Data Qualification Documentation	Permanent
305	Software Control Documentation	Permanent
306	Technical Report/Presentation Review Documentation	Permanent
307	Regulatory Analysis Review Documentation	Permanent
308	Technical Activity Supporting Documentation: Experimental Data, Data Reduction and Analysis Documentation, Scientific Notebooks, Computer Files (see specific contract requirements and 10 CFR Part 2, Subpart J)	Permanent
800	Sample Control Documentation	Permanent
900	Procedure Qualification Documentation (if not included as supporting documentation)	Permanent
901	Company Sensitive Documentation	Permanent

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

QUALITY ASSURANCE PROCEDURE

Proc. QAP-012
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Page 1 of 8

Title

QAP-012 QUALITY ASSURANCE RECORDS CONTROL

EFFECTIVITY AND APPROVAL

Revision 3 of this procedure became effective on 04/23/01. This procedure consists of the pages and changes listed below.

Page No.	Change	Date Effective
1	1	06/29/01
2 – 7	0	04/23/01
8	1	06/29/01

Supersedes Procedure No. QAP-012, Rev. 3, Chg 0 dated 04/23/01.

Approvals

Written By Mark R. Ehnstrom Mark Ehnstrom	Date 4/28/01	Concurrence Review E. C. Pearcy English Pearcy	Date 6/28/01
Quality Assurance Bruce Mabrito	Date 4/28/01	Cognizant Director Stephen Wittmeyer for H. Garcia Henry Garcia	Date 6/28/01

CNWRA Form QAP 1 (12/92)

QAP-012 QUALITY ASSURANCE RECORDS CONTROL

1. PURPOSE

The purpose of this procedure is to describe the methods of collecting, validating, processing, storing, and retrieving Quality Assurance (QA) Records. This procedure implements the requirement of the CNWRA Quality Assurance Manual (CQAM) Section 17, and provides retention times for categories of records.

2. RESPONSIBILITIES

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- Nonconformance, corrective action, surveillance, and audit documentation
- Controlled documents

3.2 Control of In-Process Records

3.2.1 Documents, files, reports, data, electronic files, and other items that will become records shall be controlled to prevent loss and destruction. Reasonable precautions shall be taken while gathering and analyzing data—during interim storage before records processing—to preclude loss from fire, water or chemicals, unauthorized access and alteration, and damage or loss of computer files. When harsh environmental conditions are anticipated (e.g., collecting field data) data previously collected shall be copied or otherwise protected to prevent inadvertent loss or damage.

3.2.2 While project work is being conducted, scientific notebooks (whether maintained in hard copy or electronic) shall be considered as records-in-process. The Principal Investigator or person making entries shall suitably store and protect records-in-process from loss or damage. Every six (6) months the holder shall send to CNWRA QA a copy of the controlled scientific notebook entries since the last version was submitted to QA. Such copies will be accumulated in a folder and kept in the QA Records Room until replaced with the controlled scientific notebook itself.

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3.2.4 QA Programmatic Records in-process shall be stored in working files by QA staff in the QA Records Room, and completed records shall be processed and validated for permanent storage on an annual basis.

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- Author
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- Record Package Contents—List of the documents comprising the package and the number of pages within each document.

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3.5 Records Processing

3.5.1 Records received by QA for processing shall be examined to verify that the appropriate signature appears on the QA Records Processing Worksheet, the records package is complete, and individual records are legible before they are considered validated. Any discrepancies shall be identified to the responsible EM and resolved.

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3.6 Records Storage

3.6.1 Permanent storage of records shall be provided by a dedicated vault located in SwRI Building 189 or SwRI Building 139 with a (minimum) two hour fire rating.

3.6.2 Only designated personnel shall be permitted access to the CNWRA QA Records Room, although others can be escorted.

3.6.3 Some in-process records are maintained in the CNWRA QA Records Room in folders identified as such. Following completion of activities, a complete QA records packet is assembled and verified by the Element Manager to be filed in permanent records.

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3.6.5 CNWRA QA stores permanent and nonpermanent records. Records are designated for permanent retention if they meet any of the following criteria: (i) provide objective evidence of fulfillment of the particular requirements of the Operations Plans, CQAM, QA Procedures, or Administrative Procedures that implement the CQAM (e.g., audits, QA reviews, training, etc.); (ii) provide objective evidence of the fulfillment of the particular requirements of Technical Operating Procedures (e.g., calibration, regulatory analysis reviews, etc.); (iii) substantiate the results or basis for licensing and prelicensing reviews; (iv) support regulatory decisions; or (v) satisfy potential requirement by an independent third party to reconstruct the work that was conducted or results that were obtained. Nonpermanent records are those required to show evidence that an activity was performed in accordance to applicable requirements but need not be retained for the life of the item or activity because they do not meet the criteria for permanent records. Nonpermanent records are kept for a minimum six year period.

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4. RECORDS

The QA Records Processing Worksheet shall remain with the package it describes for as long as the package is retained.

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES
QA RECORDS PROCESSING WORKSHEET

Record Title:	
Record Date:	
Author:	**Subject Code:**
Project Number	**Retain Until:**

Record Package Contents	**Number of Pages**
Review Documentation	
Transmittal Letter	
Document	
	No. of CD-ROMs:

VALIDATION - I attest that this record package is accurate and complete.

Element Manager:	**Date:**

RECORDS PROCESSING.

Assigned Accession Number:

Processed By:	**Date:**

CNWRA Form QAP 16

SAMPLE

Figure 1

Table 1. QA Records Subject Codes

QA RECORDS SUBJECT CODES		
Subject Code	**Record**	**Category**
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180	Audit Documentation	Permanent
181	Surveillance Reports	Nonpermanent
201	QA Indoctrination Documentation	Permanent
202	Training Documentation	Permanent
203	Personnel Qualification Documentation	Permanent
204	Periodic QA Status Review & QA Requirements Matrix	Nonpermanent
205	SwRI QA Committee Documentation	Nonpermanent
206	Quality Planning Documentation	Permanent
207	QA Memos	Permanent
208	Organizational COI	Permanent
500	QA Program Document Records Copies (APs, QAPs, and TOPs)	Permanent
601	Document Control Documentation	Nonpermanent
602	QA Program Document Review Documentation (Operations Plans and Project Plans)	Permanent
701	Procurement Documents (Receipt Travelers)	Permanent
702	Supplier Qualification Documentation (including Confirmatory Analysis Logbook)	Permanent
703	Supplier Documentation (SwRI QVL and ASL)	Permanent
704	Drawings/Sketches	Permanent
	Technical QA Records	
120	Calibration Documentation (if not included as supporting documentation)	Permanent
301	Technical Reports	Permanent
302	Papers and Presentations (including abstracts)	Permanent
303	Regulatory Analysis Documentation	Permanent
304	Existing Data Qualification Documentation	Permanent
305	Software Control Documentation	Permanent
306	Technical Report/Presentation Review Documentation	Permanent
307	Regulatory Analysis Review Documentation	Permanent
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800	Sample Control Documentation	Permanent
900	Procedure Qualification Documentation (if not included as supporting documentation)	Permanent
901	Company Sensitive Documentation	Permanent

Table 1. QA Records Subject Codes

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170	Records Control Documentation	Nonpermanent
180	Audit Documentation	Permanent
181	Surveillance Reports	Nonpermanent
201	QA Indoctrination Documentation	Permanent
202	Training Documentation	Permanent
203	Personnel Qualification Documentation (PPQ and Training Documentation Forms)	Permanent
204	Periodic QA Status Review & QA Requirements Matrix	Nonpermanent
205	SwRI QA Committee Documentation	Nonpermanent
206	Quality Planning Documentation	Permanent
207	QA Memos	Permanent
208	Organizational COI	Permanent
500	QA Program Document Records Copies (APs, QAPs, and TOPs)	Permanent
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602	QA Program Document Review Documentation (Operations Plans and Project Plans)	Permanent
701	Procurement Documents (Receipt Travelers)	Nonpermanent
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Technical QA Records		
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