

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-001

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Title

QAP-001 SCIENTIFIC NOTEBOOK CONTROL

EFFECTIVITY AND APPROVAL

Revision 6 of this procedure became effective on 1/6/2004. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
1-2	1	7/26/2004
3	0	1/6/2004
4	1	7/26/2004
5	0	1/6/2004
6-7	1	7/26/2004

Change 1 incorporates editorial changes, changes to the frequency of notebook capture to six months, and uses the term Manager instead of Element Manager.

Supersedes Procedure No.: QAP-001, Revision 6, Change 0, dated 1/6/2004.

Approvals

Written By	Date	Concurrence Review	Date
/s/Robert Brient	7/27/2004	/s/Patrick Mackin	7/28/2004
Quality Assurance	Date	Cognizant Director	Date
/s/Mark Ehnstrom	7/29/2004	/s/Budhi Sagar	7/27/2004

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QAP-001 SCIENTIFIC NOTEBOOK CONTROL

1. PURPOSE

The purpose of this procedure is to describe the use and control of scientific notebooks that record technical activities such as field work, laboratory experiments, theoretical/computer analyses, and other technical tasks of the Center for Nuclear Waste Regulatory Analyses (CNWRA). This procedure implements the requirements of the CNWRA Quality Assurance Manual (CQAM) section 3.

2. RESPONSIBILITY

2.1 Technical staff members performing the affected activity shall be responsible for the specific implementation of this procedure and the maintenance of the notebook(s).

2.2 The cognizant manager is responsible for the overall implementation of this procedure.

3. PROCEDURE

3.1 General

3.1.1 As defined in the CQAM section 3, scientific notebooks provide the primary mechanism of describing technical activities and documenting technical results. Their use is suited for technical activities in which the precise methodologies are not known and outcomes cannot be predicted. The scientific notebook provides the necessary flexibility for technical activities and the formal documentation of work planning, plan execution, data acquisition, and results interpretation.

3.1.2 Scientific notebooks shall be issued by CNWRA Document Control. A notebook may be assigned to an individual performing a specific CNWRA task or to a project on which several individuals may contribute. When simultaneous activities are being conducted within a task, additional notebooks may be issued to assure that activities are documented on an orderly and timely basis. Cross references shall be made in the notebook entries when additional notebooks are issued and when a notebook is filled and entries are continued in a new notebook.

3.1.3 Scientific notebooks shall be either hardbound, numbered notebooks or electronic. All notebooks shall be identified by a scientific notebook number assigned by Document Control.

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3.2 Scientific Notebook Entries

3.2.1 Each scientific notebook, including those continued from previous notebooks, shall include initial and in-process entries. Entries shall be sufficiently detailed so that an individual with technical qualifications equivalent to those required to perform the original work would be able to duplicate the work without recourse to the author. Initial entries provide the documentation of planning, experimental or software design, experimental or analyses methods, and equipment as appropriate. In-process entries document the specific conduct of the technical activity and results.

3.2.2 Initial Entries shall include:

- Title of the experiment, field investigation, computer simulation, or other technical task.
- Names of the individuals performing the activity.
- Description of the objectives of the task and the proposed approach or procedure for achieving the objectives. This may be accomplished by reference to the appropriate Project Plan or Operations Plan.
- Special personnel training or qualification requirements.

Scientific notebook initial entries shall be made in the beginning of the notebook and whenever substantive changes to the objectives, approach, or methods are made.

3.2.3 Laboratory and Field Activity initial entries shall also include, as appropriate:

- Equipment and materials to be employed during the experiment, including any necessary design or fabrication of experimental equipment and any material/chemical characterizations.
- Measurement parameters and test equipment calibration, accuracy, and precision requirements.
- As applicable, description of suitable and controlled environmental conditions.
- Potential sources of uncertainty and error.

3.2.4 Theoretical/computer analyses initial entries shall also include, as appropriate:

- Description of the hypothesis to be evaluated and/or list of objectives to be accomplished.
- Summary of the technical approach to be used in the analysis.

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- Brief description of the mathematical theory, assumptions, initial/boundary conditions, solution algorithm, and computer code(s) or reference document(s) where this information is contained.
 - Identification of: (a) configuration management status of code(s) in relation to TOP-018 requirements, (b) computer platform used, and (c) directory and file names where codes can be located. If an unconfigured code is used (i.e., not fully under TOP-018), list the test cases used to check the correctness of the calculations. The computer language and compiler used shall be identified.
 - Identification of aspects potentially affecting computational reliability (e.g., adequacy of gridding, time step, stability) and approach to be used to evaluate these aspects (e.g., grid and time step refinement, and comparisons with other calculational approaches).
 - A brief description of primary data/information sources to be used in the theoretical analysis.
- 3.2.5 Scientific notebook in-process entries shall be made at the time work is performed.
- 3.2.6 Laboratory and field activity in-process entries shall include, as appropriate:
- Evidence that experiment/test prerequisites have been met (i.e., special environmental conditions, equipment calibrations, etc).
 - Description of the experiment or field investigation, including detailed description of the step-by-step process followed, either by reference to a Technical Operating Procedure (TOP) or industry Standard Method, or by description in the scientific notebook. Variance from Standard Methods shall be clearly identified as such and documented.
 - Description of any conditions which may adversely affect the results.
 - Identification of samples used and any additional equipment and materials not included as initial entries. Measuring and test equipment shall be identified by item and its calibration status documented.
 - Significant data taken and a brief description of the results, to include notation of any unaccepted results.
 - Any interim conclusions reached, as appropriate.

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3.2.7 Theoretical/computer analyses activities in-process entries shall include, as appropriate:

- Description of the theoretical/computer analysis attempted, including description of the major steps followed, either by reference to a Technical Operating Procedure, computer manual/user-guide, or by description in the scientific notebook. These steps may include, for example: (a) analysis of data to derive model parameters (e.g., curve fitting, statistical regression), (b) discretization of physical problem, (c) implementation of method, (d) verification, benchmarking or testing of method, (e) application of models and codes to simulate physical phenomena, (f) evaluation of the sensitivity of results to parameter variations, (g) evaluation of the propagation of uncertainty as a function of uncertainty representations of input data, and (h) interpretation covered below of theoretical/computer analysis.
- Key data sets, code test results, and/or analysis results. Where this information is too voluminous or in electronic form, it shall be incorporated by reference to file names and location (e.g., computer resource, subdirectory).
- Description of problems encountered, alternative actions considered, and action(s) taken in response to problems. Summary of results achieved as a result of actions taken.
- Documentation of significant changes or variance from the initial plan.
- Concise description of principal computational results and interim conclusions drawn.
- Significant computational results shall be saved and incorporated by reference (i.e., identification of file names and locations where they are stored electronically).
- Brief discussion of final interpretations and/or conclusions drawn for each step of the analysis process. Reference to planned document(s) where interpretations and conclusions are expected to be formally documented (e.g., CNWRA report, journal article, semi-annual research report, etc.)

3.2.8 In-process entries for other types of activities shall include:

- Descriptions of the methods employed in conducting the activity.
- Significant data taken, calculations and analyses performed, and interpretation made during the activity.
- Documentation of significant changes or variance from the initial plan.

3.3 Scientific Notebook Protocol—Please note that these requirements are applicable to both hard copy and electronic notebooks.

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- 3.3.1 Each Initial and in-process entry shall be signed (or initialed) and dated by the authorized individual making the entry.
- 3.3.2 Scientific notebook entries shall be made in permanent ink suitable for reproduction.
- 3.3.3 Corrections to entries shall be made by a single line through the incorrect information and shall be initialed and dated by the individual making the correction. Corrections are permitted only by the individual making the entry originally, the Principal Investigator, or the manager.
- 3.3.4 Scientific notebooks may be of any size or form so long as the pages are bound and sequentially numbered. Photographs, charts, and excerpts from other documents may be included as entries. If used, these shall be labeled to identify their source and securely taped or glued in place.
- 3.3.5 Entries may be made on previously prepared pages so long as the individual entries are initialed and dated. Scientific notebook pages should be completed consecutively; however, pages may be skipped to allow space to add equipment lists, additional data, etc. If a page or portion of a page is left blank and is not being reserved for future use, a diagonal line shall be placed across the blank area to prevent future unauthorized entries.
- 3.3.6 Data, such as computer programs, input files, and output files may be incorporated on a compact disk or other electronic storage medium. The storage medium shall be clearly labeled as an attachment to a specific scientific notebook. The storage medium shall be provided to the Quality Assurance staff either by itself, with the associated scientific notebook or with the associated technical report or paper.
- 3.3.7 Copyrighted material included in scientific notebooks shall be fully referenced and shall be identified by a tab or other means. The copyrighted materials shall be redacted from the scanned files before being transmitted to the U.S. Nuclear Regulatory Commission to meet Licensing Support Network requirements.
- 3.3.8 The following or equivalent statement shall be made by the cognizant manager after the last entry of the hard copy scientific notebook text: "I have reviewed this scientific notebook and find it in agreement with QAP-001." (Signed and dated by the manager)

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3.4 Electronic Notebooks

3.4.1 All provisions of this procedure applicable to hard-copy notebooks shall also be applied to electronically maintained scientific notebooks. Exceptions or additional requirements are identified in the following paragraphs.

3.4.2 Each electronically maintained scientific notebook page will have a consistent header or footer line that shows scientific notebook number, name or initials of person making the entry, date of entry, and sequential page number. Volume, chapter, or section numbers may be included with the header or footer line (e.g., SN No. 185, Vol. 5, p. 1, Name, 01/01/2001).

3.4.3 Electronically maintained scientific notebook entries, once made, shall not be deleted. As with hard copy notebooks (see 3.6.3), corrections shall be made by a single line through the entries by using the available features of the software.

3.4.4 Completed electronic scientific notebooks shall be printed, bound, and submitted to CNWRA Quality Assurance Records. The manager in charge of the project will review the printed copy prior to binding to ensure completeness and sign and date the statement "I have reviewed this scientific notebook and find it in agreement with QAP-001."

4. RECORDS

4.1 Scientific notebooks and attachments, computer files, electronic data, and large print-outs, shall be maintained and protected as Quality Assurance records-in-process and shall be submitted to CNWRA Quality Assurance in accordance with section 4.2.

4.2 While project work is being conducted, scientific notebooks, including electronic media containing codes, databases, and the like, shall be considered as records-in-process and shall be suitably stored and protected from loss by the Principal Investigator or person making entries into them. On six month intervals, scientific notebooks shall be scanned or copied to protect against loss of data.

4.3 When scientific notebooks are filled or at project completion, the notebooks shall be provided to Quality Assurance for validation in accordance with QAP-012, Quality Assurance Records Control. At that time, the notebooks will be processed in accordance with AP-019, Records Management.