Title: **QAP–001 SCIENTIFIC NOTEBOOK CONTROL**

EFFECTIVITY AND APPROVAL

Revision 9 of this procedure became effective on January 30, 2008. This procedure consists of the pages and changes listed below.

Page No.	Change	Date Effective
1	7	08/31/2011
2–4	0	01/30/2008
5	2	04/21/2008
6-7	6	05/12/2010
8	7	08/31/2011

Change 1: Clarifies the process of closing out Scientific Notebooks

Change 2: Addresses proprietary and privileged information

Change 3: Addresses scientific notebook use during reviews

Change 4: Changes how electronic scientific notebook disaster recovery is addressed

Change 5: Clarifies records requirements

Change 6: Reflects quality assurance (QA) title change

Change 7: Expands QA records notebook submission to include electronic notebooks

Supersedes Procedure No: QAP–001, Rev 9, Chg 6, dated 5/12/2010

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QAP–001 SCIENTIFIC NOTEBOOK CONTROL

1.0 PURPOSE

This procedure describes 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 Geosciences and Engineering Division (division).

Scientific notebooks are used throughout the engineering and scientific process, including planning, making field and laboratory observations, gathering data, performing calculations and numerical analyses, and analyzing results. In addition to providing important records for quality assurance purposes, scientific notebooks also support intellectual property ownership claims and other legal matters. The broad scope and real-time nature of scientific notebook entries are essential to developing and preserving accurate records that fulfill these quality assurance and legal purposes.

2.0 RESPONSIBILITY

2.1 Personnel performing affected technical activities are responsible for obtaining and maintaining a scientific notebook in compliance with this procedure.

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

3.0 PROCEDURE

3.1 General

3.1.1 The scientific notebook records the decision paths leading to performance of activities, identifies the methods used, allows for quality verification, and documents the results. The scientific notebook is intended to provide adequate control of activities affecting quality while allowing flexibility and adaptability for developmental and experimental technical activities. As appropriate, a scientific notebook may be dedicated to a limited portion of a task or activity (e.g., dedicated to field observations, data gathering, or data analysis), or encompass the totality of a task or activity.

3.1.2 Scientific notebooks shall be issued and assigned control numbers by division document control. When a notebook is assigned to more than one individual, a primary notebook holder shall be designated. This individual shall be a division staff member. 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. When a new notebook is needed for continuing activities, cross references shall be made between the new notebook and its predecessor.

3.1.3 Scientific notebooks may be either hardbound or electronic.

3.2 Scientific Notebook Entries

3.2.1 Each scientific notebook, including those that continue 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.

3.2.2 Initial entries provide the documentation of planning, experimental or software design, experimental or analytical methods, and equipment as appropriate. Initial entries shall be made before affected activities begin. Initial entries shall include:

- Title of the experiment, field investigation, computer simulation, or other technical task.
- Names and initials of the individuals performing the activity.
- Description of the objectives of the task and the proposed approach or procedure for achieving the objectives.
- 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, and the magnitude of such, if known.
- Sample storage needs and special sample handling requirements.

3.2.4 Theoretical/numerical 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.

- 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 Technical Operating Procedure (TOP)–018 requirements, (b) computer platform used, and (c) directory and file names where codes can be located. If an uncontrolled 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, timestep, stability) and approach to be used to evaluate these aspects (e.g., grid and timestep 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 In-process entries document the specific conduct of the technical activity and results. 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.).

- If not covered in initial entries, a description of the experiment or field investigation, including detailed description of the step-by-step process followed, either by reference to a 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 conditions that 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.

3.2.7 In-process entries for theoretical/computer analyses activities shall include, as appropriate:

- If not covered in the initial entries, a description of the theoretical/computer analysis attempted, including description of the major steps followed, either by reference to a TOP, 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 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 captured on appropriate electronic media attached to the notebook.

- Description of problems encountered, alternative actions considered, action(s) taken in response to problems, and a summary of results achieved by the 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 on appropriate electronic media attached to the notebook.

- 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., report, journal article, etc.).

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

- Descriptions of the methods used to conduct 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.

3.2.9 Copyrighted and proprietary material included in scientific notebooks shall be fully referenced and shall be appropriately identified to permit redaction. If the notebook is to be transmitted to the U.S. Nuclear Regulatory Commission (NRC) to meet Licensing Support Network requirements, copyrighted and proprietary materials shall be redacted from the scanned files before being transmitted. For any material in a scientific notebook that may meet the criteria for primary or secondary privilege, the bibliographic header section of the transmittal form will provide the information required by the pre-License Application Presiding Officer Board's Revised Second Case Management Order when the notebook file is transmitted to NRC in accordance with administrative procedure (AP)–019, Records Management. The Center for Nuclear Waste Regulatory Analyses will not generate privilege logs separate from those maintained by NRC.

3.3 Hard-Copy Notebooks

3.3.1 Each initial and in-process entry shall be signed (or initialed) and dated by the authorized individual making the entry. If initials are used, the notebook shall document the full name associated with the initials.

3.3.2 Scientific notebook entries shall be made in permanent ink suitable for reproduction. Waterproof ink shall be used when exposure to moisture may occur during use or storage. Colored markers or pencils may be used to highlight illustrations, but shall not be used to record numerical or text entries.

3.3.3 Corrections to entries shall be made so that the incorrect data remain visible. Corrections 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 attached to the notebook.

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 identified as an attachment to a specific scientific notebook and referred to in the notebook as well.

3.3.7 When a scientific notebook is filled or no additional entries are anticipated or the project has been completed or terminated, or when the employee holding the notebook is reassigned or terminated, the notebook shall be provided to the project manager for review using the Scientific Notebook Checklist, form QAP–01. When all review criteria are satisfied, the form shall be signed by the manager and included in the quality assurance records package for the notebook. The notebook shall be submitted for reviews and processing in accordance with AP–019, Records Management.

3.4 Electronic Notebooks

3.4.1 Each initial and in-process entry shall be identified as to the individual making the entry and dated. When all entries on a page are made by the same person, the name of that person in a header or footer of each page in lieu of a name on each entry is acceptable. If several persons make entries on a notebook page, each entry requires an identification of the contributor and the date. Initials may be used to identify contributors provided that the notebook records the full name of the person associated with the initials, usually on the first page of the notebook.

3.4.2 Provisions shall be established so that only authorized persons have access to electronic notebook files. Notebooks shall be maintained on password-protected computers on division “D” drives (or a shared drive that is backed up in accordance with AP–018). When shared drives are used to provide access by several persons, controls shall allow only authorized persons to have “write” privileges.

3.4.3 Electronically maintained scientific notebook pages shall identify the scientific notebook number and the sequential page numbers. Volume, chapter, or section numbers shall be included when appropriate (e.g., SN No. 185, Vol. 5, p. 1).

3.4.4 In accordance with paragraph 3.2.5, entries to electronic notebooks shall be made at the time the activity is conducted. Entries, once made, shall not be deleted. Corrections shall be made using the available features of the software (e.g., redline/strike out) and by entering the identification of the person making the correction and the date of the correction. Corrections are permitted only by the individual making the entry originally, the principal investigator, or the manager.

3.4.5 If a page or portion of a page is left blank, a diagonal line shall be placed across the blank area to prevent future unauthorized entries, or a statement such as “No new entries on this page” may be used.

3.4.6 Completed electronic scientific notebooks shall be printed. Any corrections to notebook entries made after printing shall be made only by an authorized individual (see 3.4.4) so that the incorrect data remain visible. Corrections shall be initialed and dated by the individual making the correction.

3.4.7 Data, such as computer programs, input files, and output files may be incorporated into a scientific notebook on a compact disk or other electronic storage medium. The storage medium shall be clearly labeled as an attachment to a specific scientific notebook.

3.4.8 When no additional entries are anticipated for an electronic notebook, the notebook shall be provided to the project manager for review using the Scientific Notebook Checklist, form QAP–01. When all review criteria are satisfied, the form shall be signed by the manager and included as the last page of the notebook. The notebook shall then be submitted for reviews and processing in accordance with AP–019, Records Management.

Division technical reports prepared for the NRC High-Level Waste Repository Safety program identify scientific notebooks containing data and calculations used to support the conclusions of the report. Those scientific notebooks shall be reviewed and processed in accordance with AP–019 prior to delivery of the final report to NRC (if the scientific notebooks are not already processed). Affected scientific notebooks need not be closed before the AP–019 processing, but shall be processed in their current stage of completion.

4.0 RECORDS

4.1 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 notebook holder(s). Protection measures shall also include copying or scanning hard-copy notebooks and printing hard-copies or making compact disks or other electronic storage media of electronic notebooks and submitting to QA Records (at intervals not to exceed 6 months). Electronic notebooks maintained by division staff shall be continually maintained on an individual division computer “D” drive (or a shared drive that is backed up in accordance with AP–018) to assure automatic permanent backup by the network.

4.2 Completed notebooks shall be maintained as QA Records in accordance with QAP–012, Quality Assurance Records Control after AP–019 reviews and processing are complete.

4.3 Under certain circumstances, a hardcopy notebook may be needed for reference use after the notebook has been processed as a quality assurance record (e.g., if scanned images of the notebook are not suitable for the circumstance). In such cases, the notebook may be checked out from the quality assurance records facility, for a limited time approved by the records control staff. If this is done, copies or electronic images of the notebook shall be retained in the quality assurance records to preclude loss of the notebook data.