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CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

CORRECTIVE ACTION REQUEST

CAR No: 98-01Associated AR,SR,NCR No: Audit Report 98-01

PART A: DESCRIPTION OF CONDITION ADVERSE TO QUALITY

Contrary to QAP-001, Rev. 2, "Scientific Notebook Control," paragraph 3.6.7, the provisions of QAP-001 applicable to hardcopy notebooks have not been applied to electronic notebooks 167 and 166, in-that, the nature and extent of a correction, deletion, or addition is not readily apparent.

Initiated by: T. Trbovich *T. Trbovich*

Date: 6/26/98

PART B: PROPOSED ACTION

Responsible EM: A. Chowdhury / B. Sagar

Response Due: 07/27/98

1) Extent of Condition: Varying degrees in a number of electronic scientific notebooks. See attached list of electronic scientific notebooks.

2) Root Cause: QAP-001, Scientific Notebook Control, is not specific enough for the electronic scientific notebook holder to understand his/her responsibilities.

3) Remedial Action: Proposed Completion Date: N/A
None Required. Printed and bound copies have been submitted and are retained in the QA records room.

4) Corrective Action to Preclude Recurrence: Proposed Completion Date: 9/25/98
A committee composed of S. Hsiung, S. Mohanty, R. Pabalan, and B. Hill will recommend the revision of QAP-001 that will preclude recurrence.

Element Manager: *[Signature]*

Date: 7/23/98

PART C: APPROVAL

Comments/Instructions *The committee made recommendations to revise QAP-001 and they were incorporated into Revision 3 Change 0.*

The document went through the CNWRA comment & resolution process, with additional suggestions from the CNWRA Technical Director. The document, QAP-001 Rev 3 Chg 0, was approved 09/16/98.

Director of QA: *[Signature]*

Date: 09/16/98

PART D: VERIFICATION OF CORRECTIVE ACTION IMPLEMENTATION

QAP-001 Rev 3 Chg 0 was distributed 9/14/98. Key changes were sent to each electronic SN holders 9/15/98 separately (see copy in folder).

Distribution:

Verified by: *[Signature]*

Date: 09/16/98

Element Managers-ALL
Technical Director
CNWRA President
Roberto Pabalan
T. Trobovich, Audit
Team Leader (ATL)

**Electronic Scientific Notebook
Check Off List
July 1, 1998**

Issued To:	Notebook No.: / Date Issued Out / Title	July 1, 1998
Ahola, Mikko	165 • 01/26/96 Thermal-Mechanical (TM) Modeling of Emplacement	• Closed Out
Armstrong, Amit	214 03/06/97 Unsaturated/Saturated Flow under Isothermal Conditions KTI 239 09/16/97 Total System Performance Assessment (TSPA) KTI 246 11/20/97 Thermal Effects on Flow (TEF) KTI	
Chen, Rui	159 • 11/30/95 204 • 01/03/97 TEF Implementation of TPA Code 205 • 01/03/97 Modeling of Deformation & Porosity Change form Hormal Faulting 254 01/16/98 Modeling of Large Block Tests (TEF) KTI 274 06/09/98	• Closed Out • Closed Out • Closed Out
Connor, Charles	115 06/28/94 Igneous Activity 267 04/21/98	
Fedors, Randall	245 11/20/97	
Ghosh, Amitava	167 02/26/96 Development of the FAULTING Module and RDTME 250 01/02/98 Development of the FAULTING Module and RDTME	
Hill, Brittain	56 10/20/92 Volcanic Systems of the Basin & Range Research Project 88 08/18/93 Volcanism Research Project	• Closed Out Sec E-mail 7/2/98
Hsiung, Simon	196 10/11/96 Development of the SEISMO Module	
Lichtner, Peter	95 • 11/06/93 Near-Field Environment KTI	• Closed Out
Mohanty, Sitakanta	170 04/03/96 EBSPAC Development	
Pabalan, Roberto	185 07/17/96 Cement-Affected Near-Field (CANE) 278 06/26/98 Radionuclide Transport KTI	No entry No entry
Stothoff, Stuart	163 12/20/95 Ambient Hydrology KTI - Infiltration	
Terhune, Robert	136 02/24/95 137 02/24/95	* Closed Out * Closed Out

• Closed Out

saved under: D:\wpfil\connie\notebook.checklist.wpd

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Date: 9/15/98
Sender: Bruce Mabrito
To: Amit Armstrong, Rui Chen, Charles Connor, Randall Fedors, Brittain Hill, Simon Hsiung, Sitakanta Mohanty, Roberto Pabalan, English Pearcy
cc: #DIRS-MGRS
bcc: Maria Padilla, mehnstrom@swri.edu, Bruce Mabrito, ttrbovich@swri.edu, Arlene Brune, John Castro, Bonnie Caudle, Orlando Cortinas, Cathy Garcia, Janie M. Gonzalez, Lucy Gutierrez, Paul Maldonado, Annette Mandujano, Arturo Ramos, Lee Selvey, Janet Wike, Amy Wornack
Priority: Normal
Subject: Scientific Notebook Control - Revision 3 Change 0

*QAP-001 Training To
Electronic SN Holders.*

*Stan
9/15/98*

There has been a revision to the Scientific Notebook Control procedure, QAP-001, primarily addressing the electronic versions of the Scientific Notebooks based on comments from the 1998 CNWRA QA Audit.

This informational and training message is being sent to all those CNWRA staff members (and, through one Element Manager, a consultant) who currently utilize the electronic Scientific Notebooks. Others who opt to utilize the electronic system have access to this procedure and are instructed as to the requirements when they are issued an electronic Scientific Notebook number.

As electronic SN holders, your attention is drawn to section 3.6.7 which has the vast majority of changes. A Process Improvement Team composed of CNWRA staff members who also use electronic SNs recommended the changes listed below.

1. Electronically maintained Scientific Notebooks are given the acronym "EMSN" and that is now used to identify such "books" in the procedure.
2. Entries to an EMSN are still printed out quarterly, but are submitted UNBOUND to QA Records for safekeeping as an in-process record. The quarterly submittal should now only include entries made during that quarter.
3. When submitting an EMSN quarterly, each page should have a consistent header or footer line showing the SN number, the name or initials of the person making entries, date of entry and a sequential page number. Also volume, chapter or section numbers may be included with the header or footer.
4. The last page of the quarterly submittal must include the statement: "Entries into Scientific Notebook No. XXX for the period _____ to _____ have been made by _____ (showing name/signature/date)." For EMSNs maintained by a PROJECT, at the end of each INDIVIDUAL's entry the following statement shall be made: "Entries into Scientific Notebook No. XXX for pages _____ to _____ have been made by _____ (name/signature/date)."
5. An additional statement to the last page of the quarterly printed entry of an EMSN will have this statement signed and dated: "No original text entered into this Scientific Notebook has been removed."
6. There is no change to the present policy of sending a memo (electronic is sufficient) from the individual SN author or PI indicating the absence of new entries and that no new entries will be filed for the quarter.
7. At the end of the FY or annually (we are currently looking at the end of the FY, but will take recommendations from electronic SN holders), the four (or less) printed segments will be bound (if the project is concluded, they will be bound at that time). The Element Manager in ultimate charge of the project will review the printed copy prior to binding to ensure completeness.
8. Any corrections to EMSNs in the printed version should be made as specified in QAP-001 for "manual" SNs, that is, changes must be clearly identified by using the available features of the software. The purpose here is to include, in one form or another, all entries that have been made into the EMSN.

We are all appreciative to the technical staff team which worked these QAP-001 issues. If you have any specific questions, please contact me at ext. 6149.

Bruce

4/14

Rev 3 Change 0

<p>CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES</p> <p>QUALITY ASSURANCE PROCEDURE</p>	Proc. <u>QAP-001</u> Revision <u>3</u> Change <u>0</u> Page <u>1</u> of <u>8</u>
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Title QAP-001 SCIENTIFIC NOTEBOOK CONTROL

EFFECTIVITY

Revision 3 of this procedure became effective on 09/14/98. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change No.</u>	<u>Date Effective</u>
All	0	09/14/98

Supersedes Procedure No. QAP-001, Rev 2

Approvals			
Written by  BRUCE MABRITO	Date 9/14/98	Consurrence Review  BOBBY FABALAN	Date 9/14/98
Quality Assurance  MARK EHNSTROM	Date 9/14/98	Cognizant Director  HENRY GARCIA	Date 9/14/98

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Date: 9/15/98
Sender: English Pearcy
To: stothoff@insync.net
bcc: Bruce Mabrito
Priority: Normal
Subject: Scientific Notebook Control - Revision 3 Change 0

Stu,

We have revised the procedure governing scientific notebooks. Bruce's email noting the main points of the revision is below. You will receive a copy of the revised procedure by snail mail soon. Please read it and return the signed cover form to us.

English

Forward Header

Subject: Scientific Notebook Control - Revision 3 Change 0
Author: Bruce Mabrito
Date: 9/15/98 11:59 AM

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Bruce

6/14

REV 3 Change 0

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Written by  BRUCE MABRITO	Date 9/14/98	Concurrency Review  BOBBY FABALAN	Date 9/14/98
Quality Assurance  MARK EHNSTROM	Date 9/14/98	Cognizant Director  HENRY GARCIA	Date 9/14/98

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-001

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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 are utilized to 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 Center Quality Assurance Manual (CQAM) Section 3.

2. **RESPONSIBILITY**

2.1 The Principal Investigator of the affected activity shall be responsible for the specific implementation of this procedure and the maintenance of the notebook(s).

2.2 The cognizant Element Manager (EM) is responsible for the overall implementation of this procedure.

3. **PROCEDURE**

3.1 As defined in the CQAM Section 3, Scientific Notebooks provide the primary mechanism of describing technical activities and documenting technical results. Their use is ideally suited for technical activities in which the precise methodologies and outcomes cannot be predicted. The Scientific Notebook provides the necessary flexibility for technical activities as well as providing the formal documentation of work planning, plan execution, data acquisition, and results interpretation.

3.2 The distribution of Scientific Notebooks to Principal Investigators shall be controlled as required by CQAM Section 6. Individual notebooks should be assigned to discrete tasks. When simultaneous activities are being conducted within a task, additional notebooks shall be issued, as necessary, to assure that activities are documented in 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.

3.3 Scientific Notebooks shall include Initial and In-process entries. Initial entries provide the documentation of planning, experimental design, methods, and equipment as appropriate. In-process entries document the specific conduct of the technical activity and results.

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3.4 Initial Entries

Scientific Notebook Initial entries shall be made, where appropriate, and prior to the start of activities, which include the following:

- Title of the experiment or research.
- Names of the individuals performing the activity.
- Description of the objectives of the experiment 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.

3.4.1 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 needed characterization of starting material.
- Measurement parameters and test equipment calibration requirements.
- As applicable, description of suitable and controlled environmental conditions.
- Required levels of measurement accuracy and precision.
- Potential sources of uncertainty and error.

3.4.2 Theoretical/computer analysis activities 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.
- Identify: (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. Computer language and compiler used should be identified (e.g., Lahey Fortran 90, SUN F77, Cray CFT77, Microsoft C/C++ Version 7).
- Identify 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.

3.5 In-Process Entries

Scientific Notebook In-process entries shall be made daily (or as appropriate) throughout the project, and shall be sufficiently detailed so that another qualified individual may understand and/or repeat the activity.

3.5.1 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 research attempted, 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. Deviations from TOPs shall be documented in the entries and shall be controlled as specified in CQAM Section 6.
- Description of any conditions which may adversely affect the results.

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- 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.

3.5.2 Theoretical/computer analysis 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.
- Inclusion of key data sets, code test results, and/or analysis results. Where this information may be too voluminous or in electronic form, this information 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).

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- 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.)

3.5.3 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.

3.6 Scientific Notebook Protocol

- 3.6.1 Each Initial and In-process entry shall be signed (or initialed) and dated by the authorized individual making the entry.
- 3.6.2 Scientific Notebook entries shall be made in permanent ink suitable for reproduction.
- 3.6.3 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 or the Principal Investigator.
- 3.6.4 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.
- 3.6.5 Entries may be entered on previously prepared pages so long as the dates of the individual entries are initialed and dated. It is desirable to use scientific notebook pages consecutively, however, it is understood that pages may be skipped to allow room 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.

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3.6.6 Computer codes and significant data acquired by automated (computer) methods shall be identified by file name, shall be backed up on a portable or removable medium (such as a tape or disk), and the storage location of the item documented. Large volumes of printed data, such as computer printouts, may be incorporated by reference, rather than by physically incorporating the data into the notebook. The storage medium shall be clearly labeled as attachments to the scientific notebook and shall be suitably retained and stored as records-in-process (see CQAM Section 17). The storage medium may be stored in a pocket attached to a page or the back of the scientific notebook.

3.6.7 Scientific Notebooks may be maintained using electronic media. All provisions of this procedure applicable to hard-copy notebooks shall also be applied to electronically maintained Scientific Notebooks (EMSNs), with exceptions or additional requirements identified in the following.

- Entries made in the EMSN will be printed out on a quarterly basis and submitted, unbound, to QA records for safekeeping as an in-process record. The quarterly submittal should include only entries made during the quarter.
- Each EMSN page should 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 (W.O. Snorker, 01/01/2001)].
- For EMSNs maintained by an individual, the last page of the quarterly entry shall include the statement "Entries into Scientific Notebook No.## for the period date to date have been made by name/signature/date." It is not necessary to sign every page of the printed EMSN. For EMSN maintained by a project, the end of each individual's entry shall include the statement " Entries into Scientific Notebook No.## for pages ## to ## have been made by name/signature/date."
- The last page of the quarterly printed entry of an EMSN will have a statement to the effect that "No original text entered into this Scientific Notebook has been removed." The statement will be signed and dated.
- If no entries were made during a quarter, a memo from the individual author or project Principal Investigator indicating the absence of new entries will be included in the QA record.

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<ul style="list-style-type: none">• The printed copies of the EMSN will be bound either annually (at the end of the fiscal year) or at the conclusion of the project, whichever is sooner. The EM in charge of the project will review the printed copy prior to binding to ensure the completeness of the EMSN.• Corrections to entries in the printed version of the EMSN can be made as specified in section 3.6.3, i.e., changes must be clearly identified by using the available features of the computer software. <p>4. <u>RECORDS</u></p> <p>4.1 Scientific Notebooks and attachments, such as computer files and large print-outs, shall be maintained as QA records in accordance with CQAM Section 17 upon completion of the research.</p> <p>4.2 While project work is being conducted, Scientific Notebooks 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 the Scientific Notebook.</p>	

14/14

Date: 8/4/98
Sender: Asadul Chowdhury
To: Bruce Mabrito, Maria Padilla
cc: Asadul Chowdhury
Priority: Normal
Subject: Re(2):Fwd:QAP-001 Revision Meeting

*File Corrective
Action Request
98-01*

Bruce:

Please distribute Audit Report and Corrective Action Request at the meeting for uniformity so that everybody has the same documents.

Also I have dental appointment at 11:30 am, I will be back by 1:15 pm but incase I am a few minutes late, please don't wait for me, go ahead and get the meeting started. As I understand, Randy has another meeting at 2:30 pm.

Thanks.

Asad

Reply Separator

Subject: Fwd:QAP-001 Revision Meeting
Author: Bruce Mabrito
Date: 8/3/98 6:35 PM

Maria,
This meeting will take place Tuesday right after lunch.

Asad,
Do you need copies of the Audit Report or the Corrective Action Request? For each person on the committee?

Bruce

Forward Header

Subject: QAP-001 Revision Meeting
Author: Janet Wike
Date: 8/3/98 8:24 AM

A meeting to discuss the QAP-001 revision will be held in room A137 on Tuesday, August 4, 1998 at 1:15 pm. The following people need to attend:

- Simon Hsiung ✓
- Sitakanta Mohanty ✓
- Bobby Pabalan ✓
- Britt Hill ✓
- Bruce Mabrito ✓
- Rand Folck ✓
- Asad Chowdhury ✓