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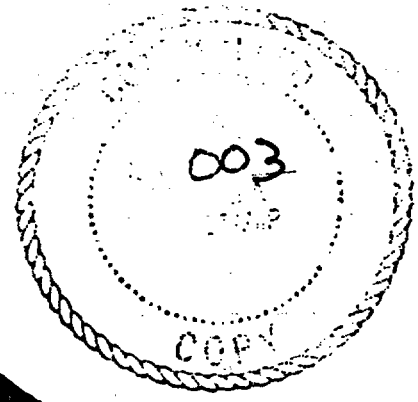
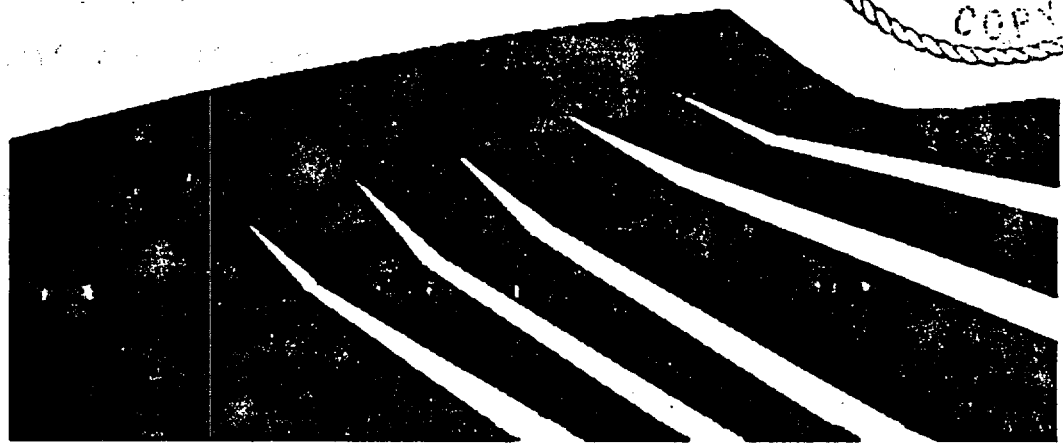
DOCUMENTING SCIENTIFIC INVESTIGATIONS



LOS ALAMOS QUALITY PROGRAM



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Los Alamos
Yucca Mountain Site
Characterization Project

HISTORY OF REVISIONS

REVISION NO.	EFFECTIVE DATE	PAGES REVISED	REASON FOR CHANGE
R0	03/10/92	N/A	Initial procedure.
R1	12/07/92	All	Complete rewrite to simplify process.
R2	01/31/94	All	Complete rewrite to address new QARD requirements and to simplify process.
R3	08/01/94	All	Address QARD requirements and RTN review comments.
R4	NOV 0 3 1994	3, 5-8, Atts. 2 & 3	Revised in response to CAR YM-94-081.

DOCUMENTING SCIENTIFIC INVESTIGATIONS

1.0 PURPOSE

This procedure describes the process for documenting scientific investigations for the Los Alamos National Laboratory (Los Alamos) Yucca Mountain Site Characterization Project (YMP or Project).

2.0 SCOPE

2.1 This procedure governs the documentation of Los Alamos YMP scientific investigations.

2.2 QP-02.12 requires TPO approval to take exemption from quality assurance requirements for prototype or scoping activities at the Planning and Control Systems (PACS) summary account level. If QP-02.12 is utilized, the Exemption Justification reference number will be referenced in the laboratory notebook. However, it is recognized that a PI may require the flexibility for prototype or scoping work within a summary account. In such cases, an initial entry will clearly identify the work as prototype or scoping, e.g., "The following entry documents the work as prototype or scoping activity, and data are not to be used for licensing, " or a similar statement. These entries may be documented in the same notebook that is used to record quality-affecting work.

2.3 This procedure applies to Los Alamos and Los Alamos subcontractor YMP personnel (hereafter referred to as employees) who work under the Los Alamos YMP quality assurance program.

3.0 REFERENCES

LANL-YMP-QP-02.12, Exemption Control
LANL-YMP-QP-08.3, Transfer of Data
LANL-YMP-QP-12.3, Control of Measuring and Test Equipment and Standards
LANL-YMP-QP-17.6, Records Management
LANL-YMP-QP-03.21, Software Life Cycle
LANL-YMP-QP-03.27, Documentation of Software

4.0 DEFINITIONS

4.1 Data

Scientific, environmental, socioeconomic, and engineering numerical values, or factual information generated by any Los Alamos YMP scientific investigation that results from data acquisition and development activities. Data can be qualitative, quantitative, or graphic. For Los Alamos purposes, the information becomes data when it is reviewed, validated, and put into the proper format. Samples (core, soil, grab, water, etc.) are not in and of themselves technical data.

NOTE: The proper format of the data is defined in QP-08.3 and applies to those data to be submitted to the technical data base.

4.2 Scientific and Engineering Software (SES)

Software that uses numerical methods for complex scientific, engineering, and mathematical calculations.

4.3 Scientific Investigation

A scientific investigation is any observation, identification, description, experimental study, or analysis and explanation of natural phenomena (e.g., research and development and field activities).

4.4 Scientific Notebook

A scientific notebook (hereafter referred to as a notebook) is a record of the methodology and results of scientific investigations. Three types of notebooks are used on the Los Alamos YMP, but these need not be mutually exclusive. One notebook may contain field and laboratory data; a notebook may also contain information on miscellaneous activities (e.g., documented phone conversations).

4.4.1 Laboratory Notebook

A laboratory notebook is generally used to record activities performed in the laboratory or to compile laboratory data.

4.4.2 Field Notebook

A field notebook is generally used to record activities performed in the field or to compile field data.

4.4.3 Log Notebook

A log notebook is generally used to record tabulated data (e.g., history of calibrations, sample tracking, numerical data, or other technical data).

5.0 RESPONSIBILITIES

The following personnel are responsible for activities identified in Section 6.0 of this procedure.

- Employees who document work in a scientific notebook
- Responsible Principle Investigator (PI)

6.0 PROCEDURE

6.1 Notebook Entries

Employees are responsible for the following:

6.1.1 Entries are made with photocopyable ink (preferably black).

6.1.2 Prior to submittal as a record, notebook pages are numbered sequentially using alpha or numerical characters or a combination of the two if the notebook is subdivided.

6.1.3 The notebook contains the following information on the first numbered page.

6.1.3.1 A primary record identifier (follow the format in QP-17.6).

6.1.3.2 Name of employee or employees responsible for the notebook.

6.1.3.3 Reference to an approved study plan that describes the work and the title of the activity or activities described by the study plan.

OR

6.1.3.4 When multiple study plans are associated with the work as with a Log Book documenting calibration data, a statement of objective and a description of the work to be performed.

6.1.4 Prior to submittal as a record, each notebook must contain a table of contents or an index that lists the following information:

6.1.4.1 The major sections of the notebook with page numbers.

6.1.4.2 Any applicable attachments to the notebook, (e.g. Attachment 1, 22 pages)

NOTE: Care should be taken to leave the necessary number of pages blank to complete the table of contents or the index.

6.1.5 For work governed by a Los Alamos YMP detailed technical procedure (DP), the notebook must contain the following:

6.1.5.1 Identification number and revision of the applicable DP (e.g., DP-35, R1).

6.1.5.2 Information required by the DP.

6.1.5.3 The identification of a standard or measuring and test equipment (QP-12.3) as per Attachment 1, if applicable.

NOTE: The information in 6.1.5 may be recorded in one section of the notebook instead of at each entry; however, if more than one DP governs entries in a single notebook, the entries must be traceable to the governing DP.

6.1.6 For each different research and development activity that is not covered by a DP or for which the governing DP is inadequate, the initial entry for that research and development activity contains the appropriate information listed on Attachment 2 with "N/A" entered after each item that does not apply to the activity. Any changes to the initial research and development entry are updated as appropriate and are referenced in the table of contents.

6.1.7 For work in which Scientific and Engineering Software (SES) is used, the employee documents the following (except those cases where the SES is used for prototype, scoping, or is non-quality related, in which case documentation in accordance with subsection 2.2 is required):

- The name and version of the software.
- The Software Dissemination Request Number (SDR) that allowed the use of the software.
- The name of the input and output files, if any.
- The specific constraints of the format or the setup, if any.
- Confirmation that the hardware and the input characteristics are within the described environment of the verification and validation report (VVR) (ref. QP-03.27). If the input characteristics are outside the VVR the software may not be used without further validation in accordance with QP-03.21.

6.1.8 Each entry also contains the following information:

6.1.8.1 A description of the work performed in sufficient detail such that another similarly qualified individual could repeat the work described and achieve comparable results without consultation with the employee who made the entry.

6.1.8.2 Signature or initials of the employee making the entry and the date. This is done, at a minimum, at the end of each day that entries are entered in the notebook.

6.2 Notebook Attachments

Employees are responsible for the following:

6.2.1 Prior to submittal as a record, attachments (e.g., maps, charts, graphs, computer printouts, data binders, optical disk, or electronic media) must be identified and traceable to the notebook. The preferred method to identify an attachment is to record the notebook number, attachment number and the page number (sequential), and total pages on each page of the attachment. As a minimum, notebook attachments must be labeled as follows:

6.2.1.1 The notebook number and the attachment number on the first numbered page of the attachment.

6.2.1.2 Sequential numbering of pages.

6.3 Notebook Data Evaluation

Employees are responsible for the following:

6.3.1 Reviews and ensures completeness of data values contained in the notebook, and enters a statement rejecting the data as applicable. All values other than those from prototype or scoping activities are acceptable unless explicitly rejected.

6.3.2 Rejected data are labeled with a statement such as, "These data are unacceptable and are not to be used for licensing," and the employee making the entry signs and dates the statement.

The PI is responsible (accountable) for the following:

6.3.3 If the PI has a reason to believe that the data may be suspect or have been compromised because of equipment malfunction (e.g., M&TE accuracy) or failure during routine daily analysis or experimentation, the responsible PI ensures that the data are evaluated for acceptance and rejection by a qualified individual. Rejected data are labeled in accordance with subsection 6.3.2.

6.4 Technical Review of Notebooks

An employee performs the following:

6.4.1 Has a technical review performed on a notebook and its attachments and/or data, as applicable, annually, when a notebook is closed out, or when the activity or activities terminates, which ever occurs first.

NOTE: It may be time-consuming to conduct a technical notebook review annually, employees are encouraged to do this quarterly. An in-process record package should be maintained to reduce the risk of losing the notebook contents.

6.4.2 Selects a technical reviewer who has the following qualifications:

6.4.2.1 The expertise necessary to understand the reviewed work.

6.4.2.2 Did not perform the reviewed work.

6.4.2.3 Trained in accordance with Section 9.2 of this procedure.

NOTE: The technical reviewer may be the employee's supervisor provided the above requirements are met.

6.4.3 Has a technical review performed to assure that notebook entries meet the following criteria:

6.4.3.1 Sufficient detail is provided such that another similarly qualified individual could retrace the investigation and confirm the results, if feasible, or could repeat the investigation and achieve comparable results without recourse to the investigator.

6.4.3.2 That the SES used is applicable to the investigation performed and the input parameters and assumptions are documented and valid.

6.4.3.3 Information in the notebook is applicable to the notebook activity listed in the notebook according to subsection 6.1.3.

6.4.3.4 Entries are correct, accurate, technically adequate, and complete.

6.4.4 Corrects each entry that does not meet the above requirements.

6.4.5 Has the technical reviewer enter a statement, such as the following, on the notebook page after the last entry reviewed or in a section designated for review. "I have reviewed the entries on pages (*) through (*) and they meet the requirements described in QP-03.5, subsection 6.4.3," document the notebook pages reviewed, and sign and date the notebook.

*Enter page numbers

6.5 Quality Assurance Review of Notebook

6.5.1 After the last technical review of a notebook is completed, the employee has a quality assurance review performed on the notebook, and attachments and/or data, if applicable, to ensure the following conditions are met.

6.5.1.1 The entries are legible and the configuration of the notebook is to the requirements of this procedure.

6.5.1.2 Technical reviews were performed and documented according to subsection 6.4.5.

NOTE: The employee may have the review performed by the group's Quality Assurance Liaison or may contact the QAPL for assignment of the review. It is recommended that a quality assurance review be performed after each technical review.

6.5.2 The employee corrects each entry that does not meet the requirements stated in subsection 6.5.1.

6.5.3 The employee has the quality assurance reviewer enter a statement, on the notebook page after the last entry reviewed or in a section designated for review, such as the following, "I have reviewed the entries on pages (*) through (*) and they meet the requirements described in QP-03.5, subsection 6.5.1," followed by the reviewer's signature and date.

*Enter page numbers

6.6 After the last review of the notebook has been performed, the employee transmits a copy of the notebook to a YMP Records Processing Center in accordance with QP-17.6. The transmittal should be within 20 working days of the final Quality Assurance Review.

7.0 RECORDS

7.1 The following records resulting from this procedure are transmitted as a record to a YMP Los Alamos Records Processing Center in accordance with QP-17.6.

- A copy of the completed and reviewed notebook.
- Copies of notebook attachments, and/or data, as applicable.

7.2 The Notebook Reviewer Qualification, if applicable, is sent to the Training Coordinator as a privileged record for retention and processing in accordance with QP-17.6.

8.0 PROCEDURE ACCEPTANCE

Proper completion and submittal of the records, listed in Section 7.0, to a YMP Los Alamos Records Processing Center provide evidence of satisfactory implementation of this procedure.

9.0 TRAINING REQUIREMENTS

9.1 Prior to conducting work described in Section 6.0, the employees who document work in a scientific notebook, the responsible PI, and QA reviewers require training to this procedure. Training is accomplished by "read only."

9.2 Technical reviewers either train to this procedure in accordance with subsection 9.1, or read, sign, and date the "Reviewer's Instructions" on the Notebook Reviewer Qualification (Attachment 3).

10.0 ATTACHMENTS

Attachment 1: Entries for Measuring and Test Equipment (M&TE) and Consumable Standards (2 pages)
Attachment 2: Entries for Research and Development and Field Activities (2 pages)
Attachment 3: Notebook Reviewer Qualifications (1 page)

ENTRIES FOR MEASURING AND TEST EQUIPMENT (M&TE) AND CONSUMABLE STANDARDS

A. CONSUMABLE STANDARDS

Identify and document the use of Consumable Standards in accordance with QP-12.3 and the notebook entry requirements contained in this procedure.

B. MEASURING AND TEST EQUIPMENT

a. "USED IN A ONE-TIME-ONLY APPLICATION"

M&TE used in a one-time-only application must be calibrated before and after use. If the M&TE becomes inoperable, or its accuracy is suspected, or it is out of calibration, the user notifies the responsible PI for the acceptance or rejection of the results. When performing calibrations, the following information must be recorded:

- Identification of the M&TE calibrated
- Identification of the standard used for calibration (use the ID number shown on the applicable Standards Report or document in accordance with the requirements for Consumable Standards)
- Method of Calibration
- Calibration data
- Calibrator's name
- Date of calibration
- Results of calibration and a statement of acceptability
- Reference to any action taken in connection with out-of-calibration condition, including the evaluation of the results, as applicable

b. "CALIBRATE AT EACH USE"

M&TE controlled according to QP-12.3 as calibrated at each use must have the following information recorded:

- Identification of the M&TE calibrated (use the ID number shown on the applicable M&TE report)
- Identification of the standard used for calibration (use the ID number shown on the applicable M&TE Report)

- Identification of the Detailed Technical Procedure (including the revision level) or the notebook and page number of the procedure used in performing the calibration
- Calibration data
- Date of calibration and, if applicable, calibration due date
- Results of calibration and statement of acceptability
- Reference to any action taken with respect to out-of-calibration or nonconforming M&TE including evaluation of results for acceptability

c. **"CURRENTLY CALIBRATED M&TE"**

- Identification of the M&TE being used (use the ID number shown on the applicable M&TE Report) and the M&TE label
- Verification that the current date is within the calibration period

ENTRIES FOR RESEARCH AND DEVELOPMENT AND FIELD ACTIVITIES

A. DESCRIPTION

Enter the statement, "This is an R&D entry," and describe the proposed work, or reference the study plan or other planning documents that describe the work to be done. The description may include reference to other notebooks, manuals, texts, etc. For field investigations describe the location where the field activities are to take place, or make reference to a map or photograph that shows the location of the site.

B. METHODS AND OBJECTIVES

State the methods to be employed and objectives of the work. Changes to methods must be described and approved by the responsible PI.

C. EQUIPMENT

List any major equipment and any special materials to be used. Special materials include items such as standards or specific labware (e.g., pyrex instead of plastic). Common laboratory and field equipment does not need to be identified.

D. MEASURING AND TEST EQUIPMENT (M&TE)

Identify M&TE and Consumable Standards in accordance with the applicable requirements in Attachment 1.

E. SET UP REQUIREMENTS

Identify setup procedures. This includes characterization of starting materials; provisions for ensuring that experimental prerequisites are met; special measures to be taken in handling, shipping, and storing equipment; and required controlled environmental conditions.

F. SAMPLES COLLECTED OR UTILIZED

Identify samples by unique identification number.

G. ACCEPTANCE CRITERIA

Identify required levels of precision or accuracy, as applicable. Acceptance criteria may be qualitative or quantitative.

H. SOURCES OF ERROR

Identify potential sources of error or uncertainty that will be measured or controlled that could affect the results or conclusions. Identify any suspected conditions that may adversely affect the results.

I. CONCLUSIONS

At the conclusion of the work, state conclusions or observations, addressing whether the original referenced objectives as stated in the initial entry (reference notebook page entry) were achieved. Incorporate deviations from the original approach into the discussion.

NOTEBOOK REVIEWER QUALIFICATIONS

REVIEWER: _____ PHONE: _____
Print name

ADDRESS: _____

REVIEWER'S QUALIFICATIONS:

REVIEWER'S INSTRUCTIONS:

1. Ensure that the notebook entries meet the following requirements.
   a. Sufficient detail is provided such that another similarly qualified individual could repeat the work described and achieve comparable results without recourse to the original investigator.
   b. Scientific and Engineering Software is applicable to the problem being solved and, input parameters and assumptions are documented and valid.
   c. Information is applicable to the notebook activity that is listed on the first numbered page of the notebook.
   d. Entries are correct, accurate, technically adequate, and complete.
2. Have the employee correct any entries that do not meet the requirements listed in Item 1 above.
3. Enter a statement in the notebook such as the following, "I have reviewed the entries on pages (*) through (*) and they meet the requirements described in step 1 of the reviewer's instructions of the notebook reviewer qualification form."
   * Enter page numbers.
4. Sign and date the notebook and this form, return them to the employee.

I HAVE READ AND UNDERSTOOD THE ABOVE INSTRUCTIONS.

REVIEWER'S SIGNATURE: _____ _____
Date

EMPLOYEE'S APPROVAL:

NAME: _____ _____ _____
Print name Signature Date

THIS FORM IS PRIVILEGED INFORMATION. FORWARD TO TRAINING COORDINATOR, MS M321