

PROCEDURE FOR DOCUMENTING SCIENTIFIC INVESTIGATIONS

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## PROCEDURE FOR DOCUMENTING SCIENTIFIC INVESTIGATIONS

### 1.0 PURPOSE

This procedure describes the necessary steps to be used by Los Alamos National Laboratory (LANL) personnel documenting scientific investigations performed for the Yucca Mountain Project (YMP or Project).

### 2.0 SCOPE

This procedure applies to all LANL Project personnel performing either research and development (experimental) investigations or repetitive activities that follow detailed technical procedures (DP) for the Project.

### 3.0 REFERENCES

LANL-YMP-Quality Assurance Program Plan (QAPP), Section 3.1.6.  
TWS-QAS-QP-02.1, Procedure for Personnel Selection, Indoctrination, and Qualification.  
TWS-QAS-QP-02.2, Procedure for Personnel Training.  
TWS-QAS-QP-05.1, Preparation of Quality Administrative Procedures.  
TWS-QAS-QP-05.2, Preparation of Detailed Technical Procedures.  
TWS-QAS-QP-06.1, Procedure for Document Control.  
TWS-QAS-QP-17.1, Procedure for the LANL Group Resident File.

### 4.0 DEFINITIONS

#### 4.1 Entry

An entry is information placed in a notebook or logbook during a period of activity not to exceed one day. If only one individual makes entries in a book, one entry can describe the activities of the entire day. The experimenter signs and dates the entry at the end of the day's activities. When two or more individuals make entries in the same book, each individual must sign and date his/her entry. Multiple experimenters may make multiple daily entries in a single book.

#### 4.2 Experimenter

The experimenter is the Project member conducting the procedures of the scientific investigation activity. The experimenter is the principal investigator (PI) for the activity or the person assigned by the PI to perform the activity.

#### 4.3 Field Notebook

Field observations, sample locations, field data, and similar information are documented in bound field notebooks. Documentation in a field notebook may complement a field DP.

#### 4.4 Laboratory Notebook

Scientific investigations are documented in bound laboratory notebooks. For repetitive activities, notebook documentation may complement a DP; for

research and development activities the notebook is the principal record of the work. The notebook may be supplemented by manuals, forms, data sheets, files, and other referenced information.

#### 4.5 Logbook

Logbooks are used to document repeated activities (e.g., calibrations, data runs, and down times for a specific instrument) or to document additions and withdrawals from the inventory of controlled sample archives. Logbooks may also be used to record information about samples received for analysis and sample preparation procedures. Logbooks may record activities performed following a DP.

Logbooks may be in bound or loose leaf format, but pages must be consecutively numbered and may be numbered page x of y. Each logbook may be dedicated to and identified for a specific instrument or activity or may be sectioned and used for several instruments and activities, if clearly marked.

#### 4.6 Repetitive Activities

Repetitive activities are those performed by qualified individuals using an approved DP that describes a sequence of actions, most often to be followed precisely. Deviations from this sequence may endanger the validity of results. This work is generally performed by a PI or by other technically trained individuals under the supervision of a PI or another scientific investigator. Repetitive activities are documented in a notebook, a logbook, and/or appropriate forms. Documentation of repetitive activities is sometimes referred to as the technical implementing procedure or DP system.

#### 4.7 Research and Development

Research and development covers experiments performed by qualified individuals using a high degree of professional judgment in developing the methodology for accomplishing an activity. The experiments are performed within the scope of the experimenter's study plan or similar planning document that has been technically reviewed. The work may be done as a part of the development of a methodology that results in a DP. Research and development involves changes in concept, in experimental methods, or in conditions. Research and development activities are documented primarily in a laboratory notebook. Documentation of research and development activities is sometimes referred to as the scientific notebook system.

#### 4.8 Technical Reviewer

For the purposes of laboratory and field notebook and logbook review, a competent technical reviewer has the training and experience to understand and repeat the work being reviewed but has not performed the work documented in the notebook. For a logbook, the reviewer must not have made the majority of the entries being reviewed.

### 5.0 RESPONSIBILITIES

Each Project participant has the responsibility to document the work being performed with sufficient care and in sufficient detail that another similarly

qualified individual could use the records generated (DP, notebook, and other documents) to retrace the investigation and confirm the results without recourse to the original experimenter.

The PI has the responsibility to maintain control over all aspects of scientific investigation by documenting the work in notebooks, logbooks, and/or other appropriate forms.

## **6.0 PROCEDURE**

### **6.1 Identification of Laboratory and Field Notebooks, Logbooks, and Other Documents**

To each notebook and logbook, the Resident File Custodian (RFC) assigns a unique group identification number, such as a TWS number. The following information is recorded inside the front of each notebook and logbook:

- unique identification number,
- assignee's name, or
- instrument(s) or activity covered by the book, and
- starting date for the book's use.

When loose leaf pages are used as a logbook, the pages must be kept together in a ring binder or folder and must be consecutively numbered. The instrument or activity documented and the logbook's unique identification number must be written on the first page.

### **6.2 Entry Requirements for Field Notebooks**

The experimenter notes daily or as appropriate:

- activity title,
- activity objective,
- field location, and
- other relevant information such as sample identification number(s).

The experimenter signs and dates the entries.

### **6.3 General Entry Requirements for Laboratory Notebooks and Logbooks**

The experimenter makes all entries in notebooks and logbooks following these requirements:

- entries are made in a color of ink that can be photocopied,
- blank pages may be left at the beginning of the book for an index,
- no open spaces (except for column entry spaces) or partially filled pages are left for later entries, and
- loose materials (e.g., charts, recorder print-outs, and graphs) placed in the notebook are securely fastened to the page.

Entry checklists for research and development activities and for work performed following a DP appear as Attachments 1 and 2, respectively. They are included for information only; their use is optional.

#### **6.4 Logbook Entries**

The experimenter enters information appropriate for the instrument or activity in a logbook, signs or initials, and dates the entry.

#### **6.5 Laboratory Notebook Initial Entry: General Information**

At the beginning of an experiment, the individual who will be performing the work enters the following information in the notebook:

- activity title,
- name of PI, and
- signature and date of the individual making the entries.

##### **6.5.1 Initial Entry When Following a DP**

Information required by a DP is discussed in QP-05.2 on preparing DPs. The experimenter records the general information specified above, identification number of the DP to be followed, and initial information required by the specific DP.

##### **6.5.2 Initial Entry for Research and Development**

In addition to the initial general information, the experimenter performing research and development activities documents the following, as appropriate:

- objective(s) of the activity;
- description of the proposed approach or a reference to the study plan or other planning document that describes the approach;
- potential sources of error or uncertainty, affecting the results or conclusions, that will be measured or controlled;
- equipment and materials to be used;
- sample identification;
- calibration requirements;
- any required characterization of starting materials;
- required levels of precision and accuracy; and
- controlled environmental conditions.

#### **6.6 In-Process Entries**

In-process entries are made as the experimenter conducts the scientific investigation. Entries are made daily or as appropriate, depending upon the experiment's progress.

##### **6.6.1 In-Process Entries When Following a DP**

The experimenter documents all data and other information as required by the specific DP. The experimenter signs and dates entries on the day the entry is made.

### 6.6.2 Deviation When Following a DP

When following a DP, the experimenter may deviate from the normal performance of the procedure because equipment malfunctions or fails. Any data that could be compromised by this malfunction or failure must be evaluated for acceptance or rejection by the PI. The PI writes and signs a statement explaining data acceptance or rejection in the notebook or logbook. If the statement is not immediately adjacent to the data, the PI signs and dates the initial data entry to signify acceptance or places a signed, dated diagonal line through the data to signify rejection.

### 6.6.3 In-Process Entries for Research and Development

The experimenter describes activities performed. The following information is recorded, as appropriate:

- activity title if more than one activity is being documented concurrently;
- any provisions for ensuring that experimental prerequisites are met;
- sample identification if different from the initial entry;
- description of the process followed, including reference to descriptions in notebooks, manuals, and texts;
- identification of measuring and testing equipment (M&TE) by manufacturer and model number, property number, or serial number (sufficient that the equipment is uniquely identified);
- identification of any additional equipment used;
- calibrations performed;
- all data or references to data files;
- any conditions that may adversely affect the results;
- brief description of results;
- notation of unacceptable or rejected results;
- any deviations from the planned experiment; and
- interim conclusions.

The experimenter signs and dates entries on day the entries are made.

### 6.6.4 Change in a Planned Experiment

Before making a change in the planned experiment that

- is not within the scope of the study plan or other planning document, and
- is not a repeatable experiment, or
- could affect the site's waste isolation capability, or
- could interfere with other site characterization activities,

the experimenter must obtain approval from the PI or LANL Project Leader. This approval is documented either in the laboratory notebook or in a memo to the group Resident File.

### 6.6.5 Data Files

If, during research activities, the researcher creates files of data (e.g., print-outs, work sheets, or electronic media), these are referenced in the notebook by a unique identification number and storage location. The researcher must consecutively number the loose pages of the file.

### 6.7 Summary of Research Activities

When final results have been obtained for the experiment and research, the PI documents in a Project report a summary of the outcome, including whether the original objectives as stated in the initial entry were achieved. The report references the identification numbers of notebooks in which the research was recorded. The report becomes a Project QA record.

### 6.8 Corrections

The individual making a correction to a notebook or logbook draws a single line through the incorrect entry. The original entry must remain legible. The individual who makes corrections to data, interpretations, or other information initials and dates the correction. When an editorial change, such as a spelling correction, that does not alter the meaning of the entry is made, no initials or date is needed.

Any necessary corrections may be made by the individual who made the original entry or by the PI. The technical reviewer may make only editorial corrections. If the reviewer has technical corrections, he/she puts them in a memo to the experimenter.

### 6.9 Technical Review

#### 6.9.1 Technical Review of Laboratory and Field Notebooks and Logbooks

At a minimum, all notebooks and logbooks must be independently reviewed when they are completed or when the activity is terminated. The PI selects a technical reviewer who is competent in the required field of knowledge. The reviewer determines whether the information presented, including any referenced information, is understandable, legible and reasonable. The reviewer states that the notebook or logbook has been reviewed and understood and signs and dates the final entry reviewed. The reviewer may add as comments in the book or as a memo to the group Resident File

- any concerns about technique;
- other interpretations of results, if appropriate; and
- further investigations to clarify the results, if appropriate.

The logbook receives a QA, rather than a technical, review for clarity and for correction of obvious errors.

The notebook or logbook is then a completed record for the Project.

### **6.9.2 Interim Review of Notebooks and Logbooks**

The experimenter is encouraged to have notebooks and logbooks examined by a technical reviewer at suitable intervals before completion. Quarterly review is suggested. The reviewer writes any comments in the book or in a memo and states that the book has been reviewed and understood. The reviewer signs and dates the book. The experimenter may add comments concerning the review.

## **7.0 QUALITY ASSURANCE REQUIREMENTS**

### **7.1 Records**

Completed, reviewed laboratory and field notebooks, logbooks, and memos pertaining to review are Project records. Any files of data referenced in these notebooks are Project records also. They are retained in the group Resident File until copies are submitted to the Records Processing Center (RPC) by the RFC, following the requirements of QP-17.1, Procedure for the LANL Group Resident File.

Special training and qualifications are contained in the experimenter's position description and training record prepared following QP-02.1 and QP-02.2.

### **7.2 Document Control**

This QP will be issued, controlled, and revised in accordance with QP-06.1, Procedure for Document Control, and QP-05.1, Preparation of Quality Administrative Procedures.

## **8.0 ACCEPTANCE CRITERIA**

The criteria that demonstrate satisfactory compliance with the requirements for documenting scientific investigations are the following records:

- technical reviews shown in notebooks and logbooks and review memos in the group Resident File;
- copies of completed, reviewed notebooks and logbooks submitted to the RPC; and
- reports of surveys and audits where notebooks and logbooks were inspected.

## **9.0 ATTACHMENTS**

**Attachment 1: Notebook or Logbook Entry Checklist for Following a DP**

**Attachment 2: Notebook Entry Checklist for Research and Development Activities**

## ATTACHMENT 1

### Notebook or Logbook Entry Checklist for Following a DP

#### Initial Entry

Enter the following information, as appropriate for the DP, at the beginning of the activity unless included in the DP:

- \_\_\_\_\_ 1. activity title;
- \_\_\_\_\_ 2. name of PI;
- \_\_\_\_\_ 3. identification number of the DP to be followed;
- \_\_\_\_\_ 4. identification of any measuring and testing equipment (M&TE) by property number or serial number (sufficient that the equipment is uniquely identified);
- \_\_\_\_\_ 5. any potential sources of error or uncertainty that will be measured or controlled;
- \_\_\_\_\_ 6. identification of any sample material;
- \_\_\_\_\_ 7. any provisions to reduce the risk of an undetected instrument malfunction or failure;
- \_\_\_\_\_ 8. any expected differences from the instruments, calibrations, etc., specified in the DP; and
- \_\_\_\_\_ 9. dated signature of the individual making the entries.

#### In-Process Entries

The following information, as appropriate for the activity, should be entered at least once every day that relevant work is performed by the experimenter:

- \_\_\_\_\_ 1. data, references to data files, and other information required by the DP;
- \_\_\_\_\_ 2. sample identification number if different from the original entry;
- \_\_\_\_\_ 3. any deviations from the DP; and
- \_\_\_\_\_ 4. dated signature of the individual making the entry.

## ATTACHMENT 2

### Notebook Entry Checklist for Research and Development Activities

#### Initial Entry

Write the following information in the notebook at the beginning of the activity, as appropriate for the activity:

- \_\_\_\_\_ 1. activity title,
- \_\_\_\_\_ 2. name of PI,
- \_\_\_\_\_ 3. objective(s) of the activity,
- \_\_\_\_\_ 4. description of the proposed approach or reference to the planning document where it is described,
- \_\_\_\_\_ 5. potential sources of error or uncertainty that will be measured or controlled,
- \_\_\_\_\_ 6. other equipment and materials to be used,
- \_\_\_\_\_ 7. sample identification,
- \_\_\_\_\_ 8. calibration requirements,
- \_\_\_\_\_ 9. required characterization of starting materials,
- \_\_\_\_\_ 10. required levels of precision and accuracy,
- \_\_\_\_\_ 11. controlled environmental conditions, and
- \_\_\_\_\_ 12. dated signature of the individual making the entries.

#### In-Process Entries

The following information, as appropriate for the activity, should be entered at least once every day that relevant work is performed by the experimenter:

- \_\_\_\_\_ 1. activity title if needed,
- \_\_\_\_\_ 2. any provisions for ensuring that experimental prerequisites are met,
- \_\_\_\_\_ 3. sample identification if different from the initial entry,
- \_\_\_\_\_ 4. description of the process followed or a reference to the notebook or other source where it is described,
- \_\_\_\_\_ 5. identification of measuring and testing equipment (M&TE) by property number or serial number (sufficient that the equipment is uniquely identified),
- \_\_\_\_\_ 6. identification of any additional equipment used,
- \_\_\_\_\_ 7. calibrations performed,
- \_\_\_\_\_ 8. all data or references to data files,
- \_\_\_\_\_ 9. any conditions that may adversely affect the results,
- \_\_\_\_\_ 10. brief description of results,
- \_\_\_\_\_ 11. notation of unacceptable or rejected results,
- \_\_\_\_\_ 12. any deviations from the planned experiment,
- \_\_\_\_\_ 13. interim conclusions where appropriate, and
- \_\_\_\_\_ 14. dated signature of the individual making the entry.