



CHANGE NOTICE

CN No.: 3.4-2-4

Effective Date: 3/27/92

Affected Document: 033-YMP-QP 3.4 Scientific Notebooks

Barbara Bryan

N/A

Prepared by:

Approved by: (Technical Area Leader) Date

Royce S. Monte 3/04/92  
Approved by: (YMP QA Manager) Date

W. L. Blane 3/16/92  
Approved by: (YMP Leader) Date

Training Required: Yes  No

Major Changes  Minor Changes

Reason for Change:

Addition of information to decontrol notebooks.

1. Section 3.4.6: Add new third paragraph.

Replace page 5 of 5.

NOTE: THIS CHANGE NOTICE IS TO BE FILED AT THE FRONT OF THE AFFECTED DOCUMENT



### CHANGE NOTICE

CN No.: 3.4-2-3

Effective Date: 10/23/91

Affected Document: 033-YMP-QP 3.4 Scientific Notebooks

James Blink/Barbara Bryan

N/A

Prepared by:

Approved by: (Technical Area Leader)

Date

[Signature] 10/18/91  
Approved by: (YMP QA Manager) Date

[Signature] 10/21/91  
Approved by: (YMP Leader) Date

Training Required: Yes  No

Major Changes

Minor Changes

Reason for Change:

Change made to differentiate between a change in text and a correction to text.

1. Change Notice 3.4-2-1, item #2 that changed Section 3.4.5.2.2, fifth bullet: Replace bullet to read:

Mark-outs that are made during the development of a record such as Scientific Notebooks or other records are not considered corrections. A memo or statement signed by the record source identifying those mark-outs as being made during the record generation process is required before that record is accepted by the LRC.



CHANGE NOTICE

CN No.: 3.4-2-2

Affected Document: 033-YMP-OP 3.4, "Scientific Notebooks"

Prepared by: Raymond E. Hamati

Approved by: N/A  
(Technical Area Leader) (Date)

Approved by: *RK Deum* 6/6/91  
(YMP QA Manager) (Date)

Training Required:  
Yes  No

Approved by: *D. J. Jardine* 6/6/91  
(YMP Leader) (Date)

1. Section 3.4.5.2.1: Add the following paragraph:

"If an activity requires more than one Scientific Notebook before it is completed, the Investigator may enter the initial Scientific Notebook entries on the first Scientific Notebook only and may refer to such entries at the beginning of every subsequent or linked Scientific Notebook."

NOTE: THIS CHANGE NOTICE IS TO BE FILED AT THE FRONT OF THE AFFECTED DOCUMENT



CHANGE NOTICE

CN No.: 3.4-2-2 / <sup>BB</sup> 5-14-91

Affected Document: 033-YMP-QP 3.4, "Scientific Notebooks"

Prepared by: <sup>043</sup> James Bink

Approved by: N/A  
(Technical Area Leader) (Date)

Approved by: RK Dann 5-14-91  
(YMP QA Manager) (Date)

Training Required:  
Yes  No

Approved by: Philip Jardine 5/14/91  
(YMP Project Leader) (Date)

- 1. Section 3.4.4: Scientific Notebook Technical Reviewer: last sentence. Change to read:

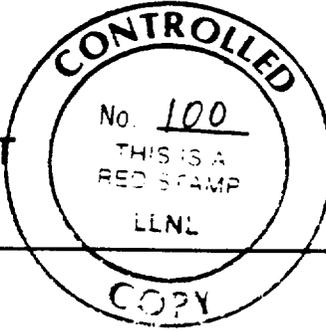
Last sentence now reads: "The LLNL-YMP Leader or designee must approve, in advance and in writing, the use of a supervisor."

- 2. Section 3.4.5.2.2: fifth bullet: delete last two sentences. Replace with new sentence.

Fifth bullet now reads: "Have errors corrected by a single line through the incorrect entry which leaves the incorrect entry readable. Each correction must be initialed and dated."

NOTE: THIS CHANGE NOTICE IS TO BE FILED AT THE FRONT OF THE AFFECTED DOCUMENT

# YCCA MOUNTAIN PROJECT



No.: 033-YMP-QP 3.4  
Revision: 2  
Date:  
Page: 2/25/91 of 1 5

Subject:

SCIENTIFIC NOTEBOOKS

Approved by: *J. A. Bl...* 21 Feb 91 Approved by: *RKT...* 2-21-91  
Yucca Mountain Project Date YMP Quality Assurance Date  
Leader Manager

- COMPLETE PROCEDURE REVISION -

### 3.4.1 PURPOSE

This procedure describes the control and use of Scientific Notebooks for LLNL-YMP activities. Scientific Notebooks are intended for use in activities that require the exercise of professional judgment, but they may be used for recording any information or data whenever deemed appropriate by the Task Leader or Principal Investigator.

### 3.4.2 SCOPE

This procedure applies to activities where the use of the Scientific Notebook is appropriate.

### 3.4.3 RESPONSIBILITIES

The Technical Area Leader (TAL) is responsible for:

- Overall direction of the work, and
- Providing guidance to the Task Leader.

Task Leaders (TLs) are responsible for:

- Assuring that Scientific Notebooks are used and maintained as required by this procedure,
- Conducting periodic review and approval of activities documented in Scientific Notebooks,
- Selecting the personnel who conduct independent technical review of experiments, analyses, calculations and interpretations.

The QA Manager is responsible for:

- Conducting QA surveillances or audits of ongoing scientific investigations to verify compliance with this procedure,
- Concurring with the assignment of technical reviewers when technically competent independent personnel are not available,
- Providing quality assurance assistance to Task Leaders for close-out verification of scientific investigations.

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YMP Personnel to whom Scientific Notebooks are assigned are responsible for implementing the requirements of this procedure.

The Local Records Center (LRC) is responsible for issuing Scientific Notebooks and processing completed Scientific Notebooks as QA Records in accordance with established procedures.

#### 3.4.4 TERMS AND DEFINITIONS

**INVESTIGATOR:** An individual who is qualified as described in 033-YMP-QP 2.10 and who is conducting the scientific or engineering work of an activity.

**SCIENTIFIC NOTEBOOK CUSTODIAN:** The individual to whom the LRC has issued a Scientific Notebook.

**SCIENTIFIC NOTEBOOK ENTRY:** Information placed in a Scientific Notebook over a period of one day or less. Entries made by each Investigator are signed and dated by that Investigator each day or more frequently. Any number of entries may be made on any given day in a single Scientific Notebook by any number of Investigators

**SCIENTIFIC NOTEBOOK:** A bound book having numbered pages, a table of contents, and controlled identification issued by the Local Records Center (LRC) which is used to record data, calculations, observations, and opinions that are (or might become) important in the execution of a YMP activity. Notebooks may be used in lieu of a Technical Implementing Procedure.

**SCIENTIFIC NOTEBOOK TECHNICAL REVIEWER:** An Investigator who is capable of performing the described work but has not performed the work to be reviewed. If the supervisor (usually the TL) is the only competent available individual to perform the technical review, this supervisor shall not have made scientific input or specified or excluded a particular approach. The QA Manager or designee and the TAL must approved in advance and in writing, the use of a supervisor.

See Tab C, "Terms and Definitions," for other definitions that particularly apply to this procedure:

- Local Records Center
- One-of-A-Kind Records
- QA Records
- Record Package

#### 3.4.5 PROCEDURE

##### 3.4.5.1 Identification and Control of Scientific Notebooks.

The LRC shall issue all YMP Scientific Notebooks and each shall be marked with a unique identifier. The LRC shall keep a record of the Scientific Notebook Custodian, the unique identifier, and the date of issue of each Scientific Notebook.

Scientific Notebook Custodians are responsible for Scientific Notebooks except when they are surrendered to the LRC, TL, QA organization or as otherwise required by this or other procedures.

Responsibility for Scientific Notebooks may be reassigned to other personnel. The LRC must be informed regarding which Scientific Notebook has been reassigned, to whom, and when.

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### 3.4.5.2 Scientific Notebook Entry Requirements

#### 3.4.5.2.1 Initial Scientific Notebook Entries

The Investigator is responsible for entering the following initial Scientific Notebook entries:

- The title, number and version of the applicable Activity Plan (or any other Plan such as an Individual Software Plan) and the number and version of a Technical Implementing Procedure [TIP(s)] to be used with this Scientific Notebook, if any.

Plans and TIPs may be used in conjunction with Scientific Notebooks but are not required to make Scientific Notebooks acceptable. Plans and TIPs may be referenced in the initial entry or in subsequent entries of the Scientific Notebook. If Plans and TIPs are not referenced or if these documents do not contain the following items, the initial Scientific Notebook entries must describe the following subject areas to the extent known at the time the initial entries are made: The research objective, proposed approach, equipment to be used, any starting material characterization required, calibration requirements, training/qualification requirements, environmental requirements, accuracy and precision requirements, and potential sources of error.

- A list of personnel using the notebook and examples of their signatures and initials.
- Any other information necessary to understand the research to be documented. In general, this will be information not in the referenced documents.
- Date and signature of an Investigator and of the TL. If the Investigator is a TL or TAL, a second signature is not required; however, the Investigator may solicit a review/signature from a technically qualified reviewer.
- Other entries if appropriate.

#### 3.4.5.2.2 All Scientific Notebook Entries

All Scientific Notebook Entries shall:

- Be recorded in the Table of Contents. If entries are made in the Scientific Notebook more frequently than once per week, one consolidated Table of Contents entry per week is acceptable.
- Be in permanent ink that is legible after photocopying. Any doubt about photocopying can be resolved by making entries on similar paper and evaluating the results of photocopying. Alternatively, the Scientific Notebook may be declared a one-of-a-kind record (see 033-YMP-QP 17.0).
- Have loose materials securely fastened so they can not be removed without detection. The LRC can furnish archival glue or tape for this purpose.
- Avoid excessive blank space without purpose. Blank pages or substantial blank space on a page shall be identified as either blank or reserved for a purpose. This restriction shall not be construed as forbidding blank spaces, indentation, or other format options used to improve readability.

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- Have errors corrected by a single line-through the incorrect entry which leaves the incorrect entry readable. If the correction is made on a different date from the entry or if it is made by a person other than the one who made the entry, then the correction must be initialed and dated. Corrections made on the same date by the same investigator may optionally be initialed and dated.
- Make reference to changes in the initial entries or the referenced documents as they apply to the work covered by the Scientific Notebook.
- Include reference to YMP LRC numbers of other records created while conducting the work. These records might be computer listings, floppy disks, magnetic tape or large plots that cannot be conveniently included in the Scientific Notebook. These records must be logged by the LRC. If a copy of the record cannot be submitted to the LRC until the activity is completed, the LRC log must state its interim storage location. If LRC logging is inconvenient, an alternate procedure (such as a TIP or a log established within the Scientific Notebook) may be developed to document the control method for these records until they are submitted to the LRC.
- Include the Investigator's name/initials and date for each entry.

When viewed as a group, the Scientific Notebook entries in conjunction with plans and TIPs must state the objectives, the step-by-step process, and the results of research in sufficient detail to allow a Scientific Notebook Technical Reviewer to retrace the investigation without recourse to the original investigator. All results are documented including those that do not meet acceptance criteria of referenced Documents. Entries will, if appropriate, note the accomplishment of prerequisite actions, describe conditions that may adversely affect the research described in the entry, identify samples or equipment not previously described in the Scientific Notebook or referenced documents, discuss deviations from planned actions, and discuss interim conclusions.

The Scientific Notebook may also be used to record technical verification or repetition of research by an Investigator, supervisor, or Reviewer.

#### 3.4.5.2.3 Final Scientific Notebook Entries

Final Scientific Notebook entries shall include signatures of the scientific notebook custodian and a Technical Reviewer prior to the final submittal of the Scientific Notebook to the LRC.

#### 3.4.5.3 Review Requirements

##### 3.4.5.3.1 TL Review

The Scientific Notebook shall be reviewed by the TL at least annually, at the completion of the Scientific Notebook, and at completion of the activity. Additional review may be conducted as specified in the Activity Plan, TIP or whenever the TAL, TL or Investigator deems appropriate. The TL shall sign and date the review and indicate that the entries were read and understood. Some Scientific Notebooks have preprinted spaces for this purpose. If the Investigator is a TL or TAL, a TL review is not required.

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### 3.4.5.3.2 Scientific Notebook Technical Review

Scientific Notebooks shall be technically reviewed by a Scientific Notebook Technical Reviewer who is selected by the TL. A review is required when the Scientific Notebook is full and also when the activity has been completed. The Reviewer determines whether the information presented, including any referenced information, is understandable, legible, and reasonable. The Reviewer indicates that the Scientific Notebook has been reviewed and understood, then signs and dates the entry. The Reviewer may add comments detailing any concerns about technique, interpretation, documentation, and may recommend further investigations.

### 3.4.5.3.3 Qualifications of Scientific Notebook Technical Reviewers

The Scientific Notebook technical reviewer can be an individual from the Investigator's organization or from another organization. The direct supervisor can be the reviewer only if the following requirements are met:

- The supervisor is the only individual in the organization competent to perform the review,
- The supervisor did not establish the design or technical input used, specify a singular design or technical approach, or rule out certain design or technical considerations, and
- The rationale for satisfying the two requirements above is documented and approved by the YMP Leader and concurred with by the QA Manager.

### 3.4.5.3.4 Informal Reviews

Investigators are encouraged to solicit interim technical reviews of their Scientific Notebooks by Scientific Notebook Technical Reviewers and/or other Investigators of their choice. These interim technical reviews shall be signed, dated and documented as described above.

## 3.4.6 RETAINED DOCUMENTATION

The Scientific Notebook is submitted to the LRC for photocopying annually or when the Scientific Notebook is full. Alternatively, the Scientific Notebook may be copied by the Investigator and these copies submitted to the LRC. If the Scientific Notebook contains photocopies of original data, then the Scientific Notebook must be submitted since third generation photocopies are not acceptable. The Scientific Notebook will be returned to the Custodian after photocopying.

The Custodian submits the Scientific Notebook to the LRC as a QA Record when it is complete or it is no longer needed for YMP activities.

**A Scientific Notebook is decontrolled and destroyed by the LRC if it is returned with no entries. A Scientific Notebook can also be decontrolled by the custodian's supervisor if the supervisor: (1) notes the entries are not of technical value; and (2) signs and dates the notation. The Notebook can then be destroyed or retained by the custodian for his information only. This information is entered into the Scientific Notebook log. A copy of the supervisor's entry is retained as a QA record.**

## 3.4.7 REFERENCES

033-YMP-QP 17.0 Quality Assurance Records