



CHANGE NOTICE

CN No.: 3.0-2-3

Effective Date: 8/24/92

Affected Document: QP 3.0, "Scientific Investigation Control"

D. Wolfe

Prepared by:

NA DW, 8-13-92
Approved by: (Technical Area Leader)

Date

Dan Wolfe

8/13/92

Approved by: (YMP QA Manager)

Date

W. L. Selaru

8/13/92

Approved by: (YMP Leader)

Date

Training Required: Yes No

Major Changes

Minor Changes

Reason for Change:

Addition of review mechanisms for verification of scientific investigation

Replace pages 4 and 5
Rewrite of Section 3.0.7

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



CHANGE NOTICE

CN No.: 3.0-2-2

Effective Date: 5/20/92

Affected Document: 033-YMP-QP 3.0 "Scientific Investigation Control"

J. Blink
Prepared by:

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

[Signature] 5/14/92
Approved by: (YMP QA Manager) Date

[Signature] 5/15/92
Approved by: (YMP Leader) Date

TALs & TLs only

Training Required: Yes No

Major Changes

Minor Changes

Reason for Change: To comply with YMP0-controlled document, ESF Plan, Rev. 2

1. Replace page 4 of 11.

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CHANGE NOTICE

CN No.: 3.0-2-1

Effective Date: 10/8/91

Affected Document: 033-YMP-QP 3.0 "Scientific Investigation Control"

J. Blink
Prepared by:

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

[Signature] 10/1/91
Approved by: (YMP QA Manager) Date

[Signature] for W. Clarke 10/1/91
Approved by: (YMP Leader) Date

Training Required: Yes No

Major Changes

Minor Changes

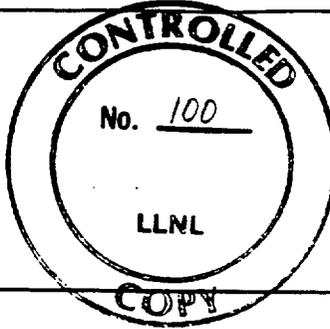
Reason for Change:

Clarification, to permit use of the procedure for activities not designated "quality affecting".

1. Section 3.0.2, Replace the last sentence of the first paragraph. The paragraph then reads:

"... course of the project. This procedure is optional for other activities."

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Subject:

SCIENTIFIC INVESTIGATION CONTROL

Approved: *L. J. Jardine* / FOR L. J. JARDINE 4/11/91
Yucca Mountain Project Leader
Approved by: *R. J. Downey* 4-7-91
YMP Quality Assurance
Manager

3.0.1 PURPOSE

The purpose of this Quality Procedure is to describe the control of scientific investigations for the LLNL Yucca Mountain Project (YMP).

3.0.2 SCOPE

This procedure applies to all scientific investigation activities which are quality affecting as determined in accordance with Procedure 033-YMP-QP 2.8 "Quality Assurance Grading." Control of these activities is maintained throughout the course of the project. This procedure does not apply to non-quality affecting activities.

Scientific investigation activities involving the development or use of computer software are described in Procedure 033-YMP-QP 3.2 "Software QA."

3.0.3 RESPONSIBILITIES

3.0.3.1 The Principal Investigator (PI), Task Leader (TL) or designee is responsible for:

- Preparation and revisions of work planning documents.
- Overall conduct of work and reporting of experiments, analysis and conclusions.
- Specifying personnel qualifications and selections of qualified personnel.
- Preparation of Scientific Investigation Plans (SIP), Study Plans (SP) and Activity Plans.
- Coordination of verification as described in paragraph 3.0.9, if specified by the next level of project management.
- Transmittal of QA records as described in Procedure 033-YMP-QP 17.0, "Quality Assurance Records."
- Identification of interfaces which transcend technical area boundaries.

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3.0.3.2 The next level of project management above the individual performing the work is responsible for assuring that:

- The work is proceeding according to the work planning document(s).
- Modification or changes to the work are within the limitations stated in paragraph 3.0.9.
- Revisions which may be required to the work planning documents are identified and implemented in a timely manner to allow the work to continue according to an approved plan.
- The data collected and/or analysis performed meet the objectives of the work planning documents and will lead to a supportable conclusion.
- Any required verifications have been performed.

3.0.3.3 The Technical Area Leader or designee is responsible for:

- Assuring that activities described in the work planning documents meet the objectives of the programmatic requirements for which he/she is responsible.
- Approval of work planning documents identified in the responsibility matrix in QP 2.1.
- Identifying any interfacing Technical Area Leaders whose activities may be effected. Interfacing Technical Area Leaders will be added to the planning document approval list.

3.0.3.4 The YMP Quality Assurance Manager or designee is responsible for:

- Concurring with the QA grading of activities identified in the Scientific Investigation Plans in accordance with Procedure 033-YMP-QP 2.8 "Quality Assurance Grading."
- Assuring that the applicable work planning documents are prepared.
- Approval of work planning documents identified in the responsibility matrix in QP 2.1.
- Performing audits and surveillances to verify compliance with quality assurance requirements.
- Transmittal of SIPs and SPs to the DOE Project Office for reviews and approval.

3.0.3.5 The YMP Project Leader or designee is responsible for:

- Approval of work planning documents identified in the responsibility matrix in QP 2.1.
- Concurring with the QA grading of activities identified in the Scientific Investigation Plans in accordance with Procedure 033-YMP-QP 2.8, "Quality Assurance Grading."

3.0.4 WORK PLANNING DOCUMENTS

Before work begins, i.e., before data is generated, analysis is performed or conclusions are reached, the work is planned, reviewed and approved by preparation of one or more of the following work planning documents:

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Scientific Investigation Plans
Study Plans (for Site Characterization activities)
Activity Plans

Contents of work planning documents are described as follows and in paragraph 3.0.5.

3.0.4.1 Scientific Investigation Plans (SIPs)

Scientific Investigation Plans are high level planning documents prepared by the Task Leader or Principal Investigator that contain a description of the activities to be performed and include a discussion of the overall purpose and objectives, applicable regulations, QA requirements, performance criteria from high level documents, issues, information needs, higher level scientific investigation planning documents, or Work Breakdown Structure (WBS) items. The discussion identifies, at an appropriate level, all of the factors and concerns that are important for the planning or the performance of the scientific investigation. All quality affecting activities subject to the QA grading process are identified in the SIP.

The intent to use scientific notebooks and the purpose for their use is identified in the SIP.

If applicable, the SIP contains a description of any previous work which will be used in support of the scientific investigation, including the Quality Assurance controls, under which that previous work was performed.

Each SIP contains one or more activities that may be further subdivided. Activities are identified by an activity number. Each SIP is reviewed for the purpose of providing guidance for the QA grading of these activities.

The SIPs are submitted to the DOE Project Office for approval.

3.0.4.2 Study Plans (SPs)

Study Plans are high level planning documents comparable to SIPs. They are prepared for Site Characterization investigations in accordance with the requirements of Appendix K of the QAPP. They are approved by YMP, the DOE Project Office, and by the Office of Civilian Radioactive Waste Management (OCRWM) prior to use as identified in the responsibility matrix in QP 2.1.

3.0.4.3 Activity Plans and Test Plans

Activity Plans describe the specifics of how an activity is to be performed and typically provide more detail than an SIP or SP. Prior to initiating work, an Activity Plan is prepared for each quality affecting activity or combination of activities identified in the SIP or Study Plan. In addition to technical details, Activity Plans may include schedules, relationship to other activities and programs, use of supplementing TIPs, expected results, etc. The technical scope of any Activity Plan is limited by the activity description contained in the higher level SIP or SP. Activity Plans are reviewed and approved by the Technical Area Leader.

The level of detail will vary on a case by case basis but must be appropriate for the work to be performed and be in sufficient detail that a reviewer with qualifications comparable to those of the author could review and understand the plan.

The suggested content and format for Activity Plans is detailed in Appendix A.

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In some cases, Test Plan(s) are written by subcontractors or by LLNL researchers. Test Plans typically describe the detailed process of conducting research, including test matrices and experimental protocols. These Test Plans are associated with Activity Plans. The Activity Plan is the parent document, and it should reference the linkage to a subordinate Test Plan(s). However, Test Plan revision numbers or dates need not be specified since that information could change after the Activity Plan is published.

Activity Plans are prepared, reviewed, and approved by LLNL-YMP. For work performed under the LLNL QAPP, the Test Plan review and approval process is the same as for an Activity Plan. For work performed by a subcontractor with an approved Quality Assurance Program Plan, Test Plans may be written, reviewed, and approved by the subcontractor using its approved QAPP. A controlled copy of each Test Plan approved or changed by a subcontractor must be provided to the LLNL-YMP Technical Representative.

3.0.4.4 Test Planning Packages and Job Packages

For field tests in the Yucca Mountain area or in the ESF, a Test Planning Package (TPP) must be prepared. YMPO must approve the TPP. Following approval of the TPP, a Job Package must be prepared and approved by YMPO prior to conduct of the test.

3.0.5 TECHNICAL IMPLEMENTING PROCEDURES (TIPs)

TIPs are documented, approved procedures that provide detailed direction for the performance of work. They include instructions, procedures, plans, sketches, drawings or other information to define and control operations which do not require technical judgement and may be performed by qualified personnel.

TIPs are generally used when qualified personnel are performing repetitive work that does not include the use of professional judgement or trial and error methods. TIPs are used when it is not possible to deviate from a prescribed sequence of actions, without compromising quality of the results that will be obtained from the work.

TIPs are described in Procedure 033-YMP-QP 5.0, "Technical Implementing Procedures."

3.0.6 SCIENTIFIC NOTEBOOKS

The scientific notebook will be used to record data, information, analysis and work progress on a daily or as appropriate basis. It is the principal recording document from which work related to an activity can be traced.

The scientific notebook system will generally be used by qualified individuals who are using a high degree of professional judgement or trial and error methods, or both, in their work. The extent of documentation in the scientific notebook is such that another qualified scientist can use the notebook to retrace the investigation and confirm the results or repeat the experiment without recourse to the original investigator. Control of scientific notebooks is in accordance with Procedure No. 033-YMP-QP 3.4, "Scientific Notebooks."

3.0.7 VERIFICATION

Verification of scientific investigation is accomplished through the implementation of one or more review mechanisms as described in the following:

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- 033-YMP-QP 2.2, "Peer Review"
- 033-YMP-QP 2.4, "Technical Review"
- 033-YMP-QP 3.2, "Software Quality Assurance" (Software Verification)
- 033-YMP-QP 3.3, "Review of Technical Publications and Data"
- 033-YMP-QP 18.1, "Surveillances"

Means for verification is prescribed in the "Activity Plan" (or Individual Software Plan).

3.0.8 REVIEW AND APPROVAL

SIPs, SPs, Activity Plans, and TIPs are revision controlled documents. Their review, approval and revision is performed in accordance with Procedure 033-YMP-QP 2.1, "Preparation, Approval, and Review of Quality Procedures and Requirements." Review is for in-depth technical and programmatic content. cursory supervisory reviews will not satisfy the intent of this review. The QA Manager transmits the SIP or SP to the DOE Project Office for review and approval.

3.0.9 HOLD POINTS

The Principal Investigator/Task Leader will identify the hold points in the Activity Plan to assure that during the progress of work:

- The activity is proceeding according to the plan.
- Data and other Quality Assurance Records are properly recorded and maintained.
- Verifications have been accomplished, if required.
- Experiments, data and analysis are traceable through information contained in the scientific notebooks.

A hold point is established when it is appropriate that work not continue until after review has been completed.

Waiver of a specified hold point is approved by the QA Manager and documented before work can proceed beyond the designated hold point.

3.0.10 INTERFACE CONTROLS

- The Principal Investigator/Task Leader identifies in the planning document(s) any interfaces and interface controls which transcend boundaries between LLNL technical areas. During review of the planning document(s), the originating Technical Area Leader identifies any additional interfaces of which the Principal Investigator/Task Leader may not be aware and adds other Technical Area Leaders to the approval list for the planning document. Internal technical scientific information interfaces are controlled in accordance with Procedure 033-YMP-QP 3.5, "Control of Internal Technical Interfaces."

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- Interface controls may also be in the form of TIPs or in accordance with Procedure 033-YMP-QP 8.0, "Identification and Control of Items, Samples, and Data."
- Interface controls between LLNL YMP and Subcontractors/Suppliers are in accordance with Procedure 033-YMP-QP 4.0, "Procurement Control and Documentation."
- Interface controls between LLNL YMP and other Participating Organizations are in accordance with requirements defined by the DOE Project Office.
- Ongoing field or laboratory scientific investigations must be identified to preclude inadvertent interruption and to ensure operational compatibility. Such identification is clearly evident at the location at which the scientific investigation is being performed. The location of the investigation is identified for field investigations.
- The method of transmittal of information or items, including samples of natural or man-made materials, across interfaces are documented.

3.0.11 REVISIONS TO WORK PLANNING DOCUMENTS

When interim results necessitate a change in work plans, the work planning documents are updated and approved by revision or change notice as described in Procedure 033-YMP-QP 2.1, "Preparation, Approval and Revision of Quality Procedures and Requirements."

Impact of changes on the associated QA Grading are assessed and handled in accordance with 033-YMP-QP 2.8, "Quality Assurance Grading."

Revisions to work planning documents that are outside the scope of the controlling document require revision of the controlling document.

3.0.12 DOCUMENTATION OF RESULTS

Results of activities are documented in sufficient detail as to purpose, method, assumptions, input, references, and units such that a technically qualified person may review, understand, and verify the analysis without recourse to the originator. These documents shall be legible and in a form suitable for reproduction, filing, and retrieval. Calculations shall be identifiable by subject, originator, reviewer and date.

Documentation of interpretation/analysis includes the following:

- Summary of results.
- Definition of the objective of the interpretation/analysis.
- Discussion of whether the work's objectives as outlined in the planning document(s) were achieved.
- Definition of input and their sources.
- A listing of applicable references.

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- Results of literature searches or other background data.
- Statement of assumptions.
- Identification of any computer calculation, including computer type, program name, revision, input, output, evidence of program verification, and the basis of application to the specific problem.
- Signatures and dates of review and approval by appropriate personnel.

3.0.13 QUALITY ASSURANCE RECORDS

Quality Assurance records created by the implementation of this procedure are collected, handled, stored, and maintained in accordance with the requirements of 033-YMP-QP 17.0, "Quality Assurance Records."

Quality Assurance records include the following:

- Planning documents, revisions and Change Notices.
- Data sheets or other data records.
- Analyses, conclusions and reports.
- Returned planning document review copies.
- Comment resolution meeting minutes.
- Verification records.
- Interface control records.

A3.0 APPENDIX A SUGGESTED CONTENT AND FORMAT FOR ACTIVITY PLANS

Activity Plans are the principal working documents that describe how an activity is to be performed. The level of detail of an Activity Plan is greater than that of a Scientific Investigation Plan (SIP). The Activity Plan is reviewed and approved consistent with Procedure No. 033-YMP-QP 2.1. The QA controls that apply to this activity are identified in accordance with Procedure No. 033-YMP-QP 2.8 "Quality Assurance Grading". The Activity Plan provides a means of planning, controlling, and documenting an investigation and provides a reference that can be used in a scientific notebook in lieu of repeated entries.

The content of Activity Plans will vary depending upon the nature of the activity and the appropriate level of planning and control as determined by the responsible Task Leader. Subjects for consideration in the Activity Plan are:

A3.0.1 SCIENTIFIC INVESTIGATION PLAN

Identify the Work Breakdown Structure (WBS) number and title of the Scientific Investigation Plan (SIP) which describes this activity.

A3.0.1.1 Activity Identity

This is the activity identification number developed during the QA Level Assignment process.

A3.0.1.2 Responsibilities

Identify the individual(s) responsible for performing the work.

A3.0.2 PURPOSE AND OBJECTIVES

Describe the objectives of the activity, the information that will be obtained, and how that information will be used to achieve YMP objectives.

A3.0.3 ACTIVITY DESCRIPTION

Describe the sequence of the activity, including the technical sequence and decision points that are required to complete the activity. If tests or measurements are planned, describe the general approach that is to be used, the key parameters to be measured, and the conditions under which the measurements are to be conducted.

A3.0.3.1 Technical Reviews

Identify any planned technical and/or peer review(s) to be conducted for this activity. Indicate where in the activity sequence the review(s) are to be conducted. Also identify any planned management review(s) other than review of this plan and the final report publication.

A3.0.3.2 Hold Points

Hold points (or surveillance points) are identified in the Activity Plan to assure that work is proceeding according to the plan.

A3.0.3.3 Equipment

Identify the equipment that is required for the activity.

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A3.0.3.4 Materials

Identify any unique materials that are to be used in the activity. This would include high level waste samples (synthetic or actual), Special Nuclear Materials, rock/soil samples from the proposed site, special metal alloys, etc. Discuss how they are to be provided.

A3.0.3.5 Special Environmental Conditions

If special environmental conditions are required in the conduct of the activity, discuss how these special conditions are to be achieved.

A3.0.3.6 Special Training/Qualification Requirements

Identify any special training or personnel qualification requirements. Discuss how these requirements are to be met.

A3.0.3.7 Activity Closeout

Discuss plans for closeout of the activity including turnover of QA records to the Local Records Center. Indicate how records and one-of-a-kind items will be handled. Conclude with a description of the final deliverable products expected of the activity.

A3.0.4 PRECISION AND ACCURACY

Specify the tolerance, accuracy, and precision of any measurements planned. Also indicate the expected range of results and the basis for expecting the range if known.

A3.0.4.1 Calibration Requirements

Discuss any calibration requirements and how they are to be met. Identify any Technical Implementing Procedures that may be required to calibrate systems. Note any components that are to be added to the project equipment recall listing.

A3.0.4.2 Conditions Which May Adversely Affect Results

Discuss any conditions that could have a negative impact on the overall results of the activity. Where the ability to detect these conditions is questionable, identify any special provisions to be taken to reduce the risk of undetectable failures or malfunctions.

A3.0.4.3 Sources of Uncertainty and Error to be Controlled and Measured

Discuss sources of error and identify any provisions for measurement and control of the error. Include plans for any error analysis that is to be performed. Estimate the overall error in any measurements to be made and discuss any provisions to evaluate and control the uncertainty during the activity.

A3.0.5 IN-PROCESS DOCUMENTATION

Discuss the types of documents or other record forms that are to be produced during the conduct of the activity. Discuss how these records are to be maintained and stored during the activity prior to being identified as records.

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A3.0.5.1 Data Recording and Data Reduction

Describe the techniques that are expected to be used for data reduction and analysis. Identify the data to be recorded and the form in which they are to be collected. Note computer programs that are to be used to control testing equipment and automated data collection equipment. Note the scientific notebook method of data recording.

A3.0.5.2 Analysis

Where applicable, define the methods and techniques that are to be used to analyze the data/measurements including any analytical expressions and numerical models that are to be employed. Include references to any technical procedures document to be followed during the analysis. Where analysis techniques are determined based on review of data and professional judgment, state that techniques used are to be specified in a scientific notebook.

A3.0.6 INTERFACES

Interfaces are identified which are related to or affected by this activity. Identify any other activity within the LLNL YMP program that requires coordination with this activity. Specify the technical contact(s). Identify any external interfaces to LLNL that requires coordination. Identify procedures that are to be used to control and document information passed across these interfaces.

A3.0.7 SCHEDULE

Provide the expected durations of and interrelationships among the principal work elements of the activity. Indicate any key milestones such as decision points associated with the activity.

Describe the timing of this activity relative to other activities in the YMP program that are affected by this activity.

A3.0.8 TECHNICAL IMPLEMENTING PROCEDURES

Identify the Technical Implementing Procedures (TIPs) that are expected to be used during conduct of the activity. For those TIPs that do not yet exist, discuss the sequence/schedule for preparation.

A3.0.9 SOFTWARE

Identify any software to be used. Refer to the LLNL Software QA Plan for requirements.

A3.0.10 SPECIAL CASES (PROCUREMENT)

Where the activity is to be conducted by a subcontractor so specify in the Activity Plan. Include the following information in the Activity Plan.

A3.0.10.1 QA Requirements Specification

Indicate whether a QA Requirements Specification is required. If a QA Requirements Specification is not required, identify the means to verify compliance with the LLNL QA Program Plan.

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A3.0.10.2 Statement of Work

Describe the work that the subcontractor is to perform. Denote specifications, standards, codes, and procedures that are to be followed. In-process reviews and acceptance tests necessary to evaluate conformance of an item or service to the technical requirements are specified.

A3.0.10.3 Subcontractor Interface Control

The technical contacts at LLNL and at the subcontractor are identified along with any reporting requirements of the subcontractor. Include those interim documents/reports that must be approved by LLNL. Include information that is provided to the subcontractor by LLNL and note how it is documented and controlled. Note any schedule requirements imposed on interim documents/reports.

A3.0.10.4 Materials/Equipment Provided

Identify any materials or equipment that are provided to the subcontractor to perform the work and discuss how these are documented and controlled.

A3.0.10.5 Deliverable Products

Identify the deliverable products (e.g., scientific notebooks, progress reports, samples, etc.) that are to satisfy the procurement requirements. Discuss how these are to be evaluated. Identify any schedule requirements attached to these deliverables.

A3.0.11 REFERENCES

Identify references that are used in the conduct of this activity. Include any literature searches that have been conducted in prior phases of this work activity. Also reference any previous activity plans that have been prepared.

A3.0.12 APPENDIXES

Identify any appendices that are included as part of the Activity Plan.