

NMA.901115.0025

MANAGEMENT PROCEDURES MANUAL

CHAPTER 5 - INSTRUCTIONS, PLANS, PROCEDURES, AND DRAWINGS

SECTION 1 - PREPARATION OF TECHNICAL PROCEDURES

1. **PURPOSE.** As a logical progression of an approved Study Plan (AP-1.10Q) (or Scientific Investigation Plan (SIP), QMP-3.06, if applicable), this procedure defines the requirements to identify, prepare, review, approve, and modify technical procedures required to conduct quality-affecting technical activities in support of the Yucca Mountain Project (YMP).
2. **SCOPE OF COMPLIANCE.** This procedure applies to all USGS and contractor personnel who are assigned to perform the work described by the procedures for QA graded technical activities that produce data, maps, recommendations, or other bases for the YMP site characterization. It is applicable to activities conducted as established and/or standard practices, including activities involving data reduction; and when it is not permissible to deviate from a prescribed sequence of actions without endangering the validity of the results that will be obtained from the work. Technical activities or methods not sufficiently advanced to permit the preparation of a technical procedure shall be conducted under the controls of QMP-5.05, Scientific Notebook Control of Technical Activities.
3. **DEFINITIONS.** For the purposes of this procedure, the following definitions apply:
 - 3.1 **Contributing Investigators** are scientists with part- or full-time responsibilities who lend their areas of expertise to the resolution of the various tasks under the supervision of a Principal Investigator.
 - 3.2 **Technical Procedure** is a document prepared prior to beginning a technical activity that is to be conducted as standard, routine, and/or industry accepted practice and that may include interpretive or data reduction components.
 - 3.3 **Scientific Notebook System (SNS)** is the flexible documentation of technical activities used in lieu of a technical procedure. The SNS is used to provide a written record of the methodology and results of scientific investigations and experiments when the work involves significant professional judgement, trial-and-error methods, or accommodates emerging technologies developed as an investigative activity progresses (refer to QMP-5.05).
4. **RESPONSIBILITIES.**
 - 4.1 **The Principal Investigator (PI)**, is responsible for identifying the need for a technical procedure, preparing the appropriate procedure(s) in compliance with this QMP, determining and documenting the need for revision or modification to procedures, and coordinating the review and approval process. The PI may delegate tasks as needed, but the PI maintains ultimate responsibility for the task.

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- 4.2 The Contributing Investigator, as applicable, is responsible for the performance of duties designated by the PI in preparation and implementation of the technical procedure.
- 4.3 The Technical Reviewer selected by the GD Branch/NHP Chief, or delegate, as described in QMP-3.07, is responsible for an independent technical review of the procedure, in accordance with the requirements presented herein and for documenting this review.
- 4.4 The GD Branch/NHP Chief, or delegate, is responsible for reaching concurrence with the decisions of the PI in the identification of need, preparation, and change of technical procedures. This concurrence is documented by approval signature on the procedure. The GD Branch/NHP Chief, or delegate, also assigns the technical reviewer(s).
- 4.5 The YMP-USGS QA Manager, or delegate, is responsible for reviewing and approving the technical procedure(s) in accordance with Para. 5.5 of this procedure and YMP-USGS-QMP-3.07, YMP-USGS Review Procedure.
- 4.6 The Technical Project Officer (TPO), or delegate, has overall responsibility for ensuring that technical procedures are identified and documented, for approval of the procedure, and for monitoring their use in compliance with this QMP.

5. **PROCEDURE:** One of two basic kinds of documents shall be used for the quality assurance, documentation, and control of scientific work: 1) A scientific notebook system, as described in QMP-5.05; or 2) a technical procedure system. This QMP concerns the technical procedure system, and how the decision is made for the applicability of the resulting technical procedure.

- 5.1 Selection of Procedure Approach: Prior to beginning technical work on QA graded technical activities the PI shall evaluate the nature of the activity to determine which of two kinds of documentation should be used for the quality assurance, documentation, and control of the scientific work. If the methodology required for conduct of the subject activity is 1) beyond the state of the art, requiring development and experimentation; 2) largely requires professional judgment; or 3) requires trial-and-error methods then the scientific notebook system described in QMP-5.05 is applicable. When none of the above criteria apply, then the directives of this QMP shall be followed.
- 5.2 Unique Identifying Number: As controlled documents, technical procedures shall comply with the identification requirements of QMP-6.01. The identifying number is obtained from the QA Office during the initial draft preparation stage and displayed on the draft technical procedure as required using Rev. 0 for the original issue.
- 5.3 Technical Details: Technical procedures shall provide sufficient description of the activities such that qualified personnel performing the task at a later date under the same conditions could reproduce the work using the described procedures.

5.3.1 Technical procedures shall contain all necessary information required to achieve full compliance with the YMP-USGS QAPP requirements

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for site investigation control. Attachment 1 incorporates the minimum required topics in a format that guides the preparer through the necessary input requirements. Mandatory hold points should be considered in the technical procedure when necessary, to initiate the conduct of a verification activity (QMP-3.10).

5.3.2 Software used to perform data-acquisition, data-reduction, or other technical functions as part of the activity covered by the procedure shall be identified in Para. 4.7 of the procedure. If software is documented in Para. 4.7 of the procedure, this documentation shall include, at a minimum:

- o Specification of the purpose and functional capabilities of the software
- o Description of the data-manipulation, analytic, or numerical methods used
- o Instructions for invoking the software
- o Test data and results (state when the correct operation of the software can be demonstrated through calibration, and describe it in Para. 5.2.1 of the procedure)
- o A source-code listing, if available, for software coded in a high-level programming language such as Basic, Fortran, Pascal, or C.

Source code listings, sample test data, and test results shall be provided either as attachments and listed in Para. 10.0 of the procedure, or as a part of the support documents per Para. 6.2.

5.3.3 Attachment 1, an annotated format for a YMP-USGS technical procedure, includes pre-worded sections of requirements that are common to most technical procedures. To accommodate the special needs of an individual technical procedure, the preparer may modify the pre-wording as required; however, no topic listed shall be omitted. For example, if there are no limitations involved with the procedure, "NA" or "None" would be indicated in Para. 4.6 of the technical procedure outline. As a minimum, "NA" shall be used to indicate recognition and non-applicability of the section.

5.4 Technical Review: A technical review of the technical procedure and its revisions shall be performed and documented in accordance with QMP-3.07 and Para. 5.4.1 of this QMP. This review shall be performed by a subject matter expert selected by the GD Branch/NHP Chief. The reviewer shall be someone other than a person immediately responsible for the procedure's content, supplying details to the preparer/ author concerning the methods described in the procedure, or performance of the procedure's activities.

5.4.1 At a minimum, the technical review shall show evidence that the following criteria have been considered in the review.

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- o Is there sufficient information to support meeting the objective and purpose?
- o Are special qualification/training needs adequately addressed?
- o Were appropriate concepts, methods, or techniques used?
- o Are materials, equipment, and calibration requirements adequately addressed?
- o Are limitations, qualitative/quantitative criteria, accuracy, sources of error and/or holdpoints addressed?
- o Are data output and handling information satisfactory?
- o Was consideration given to repeatability, impact on waste isolation capability and interference with other activities, when applicable?

5.4.2 The review comments, documented and resolved per QMP-3.07, shall be submitted to the PI, or delegate. Each major technical review comment, shall be evaluated and resolved by the procedure's preparer(s) in coordination with the Reviewer. Upon completion of comment resolution, all documentation of reviewer comments and their resolution shall be attached to the original reviewed copy and submitted to the PI, or delegate, along with the corrected draft.

5.5 Quality Assurance Review: A QA review of the technical procedure shall be performed by a QA Office representative for compliance with applicable QA requirements per para 5.5.1 and documented in accordance with QMP-3.07.

5.5.1 At a minimum, the quality assurance review shall show evidence that the following criteria have been considered in the review.

- o Are the purpose, objective, and scope included?
- o Are personnel responsibilities and training addressed?
- o Is the methodology complete enough to allow understandable scientific work to be repeated without further verbal instruction?
- o Are assumptions and limitations described?
- o Is there a description of the required materials/equipment?
- o When needed, are calibration instructions addressed to the satisfaction of QMP-12.01?
- o Is sample handling and control addressed to the satisfaction of QMP-8.01 and Sample Management Facility procedures?
- o Are data information and quantitative/qualitative criteria addressed?
- o Are QA records listed?
- o Are attachments included and do referenced technical procedures address the required function?
- o Is technical review documented, including any attached comments and/or responses?

5.5.2 Each major QA review comment, disagreement, or remark shall be evaluated and resolved by the procedure's preparer(s) in coordination with the YMP-USGS QA Office. Upon completion of comment resolution, all documentation of reviewer comments and their resolution shall be attached to the original reviewed copy and submitted to the PI, or delegate, for concurrence.

5.6 Technical, QA, and Management Approvals: The final draft of the technical procedure along with the review documentation shall be submitted

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for approving signatures to the Principal Investigator, the technical reviewer(s), the Branch/NHP Chief, the Technical Project Officer, and the YMP-USGS QA Manager. The procedure shall be returned to the preparer with appropriate explanation and suggestions for remedial action if further changes are identified during the approval process. This review process shall be repeated as necessary with all documentation being included with the initial reviews as part of the procedure record until concurrence is achieved. Each signature shall indicate acceptance according to responsibilities as designated in Para. 4 above.

- 5.7 Effective Date and Distribution: Upon full approval of a technical procedure, the QA Office shall assign an effective date to the technical procedure and submit it for controlled distribution according to QMP-6.01. The effective date may be any date subsequent to full approval that allows for personnel training, as necessary, and controlled distribution.
- 5.8 Change Control: Minor or editorial changes to a technical procedure shall be made in accordance with the provisions of QMP-6.01. Major changes that result in a procedure modification or revision are made as described below. Any revisions to the technical procedure shall be developed, reviewed, approved, distributed, and controlled in the same manner as the original procedure.

5.8.1 The latest revision of a technical procedure shall remain in effect until it is revised or rescinded.

5.8.2 Modifications may be made to the technical aspects of technical procedures by the individual utilizing the procedure to allow the technical work to continue uninterrupted or to accommodate an expedited procedural change. Documentation of a justification for the modification, and a determination of the need to revise the technical procedure shall be prepared and submitted with the Modification at the time of review and approval. The Modification shall not be used as a permanent change to a technical procedure. If it is determined that the Modification is a permanent change and that a procedure revision is required, the revision shall be completed within 90 calendar days of the Modification. If the determination is that no procedure revision is required, the Modification shall expire after 90 calendar days following approval, or sooner if the special reason for its existence no longer exists.

5.8.2.1 Modification documentation shall be reviewed for both technical and QA content within 30 days of the change by the original reviewers if possible, or by equally qualified reviewers otherwise, in accordance with the criteria of Paras. 5.4 and 5.5. If the change or modification is not within the scope of the Study Plan and the investigation is not repeatable, or the change could potentially impact the waste isolation capability of the site or interfere with other site characterization activities, approval shall be obtained from a subject-area reviewer at the work site, qualified and directed by the PI of the Study Plan to address these specific issues.

5.8.2.2 If the technical review, or QA review, of the modification reveals changes that potentially impact the quality of the data, the modification shall automatically result in issuance of a Nonconformance Report (QMP-15.01). Conduct of an activity changed by the modification may revert to the previous approved technical procedure as deemed appropriate by the responsible PI. In this case, the scope of the NCR shall be limited to the lifespan of the modification.

5.8.2.3 Modifications require only the approval of the QA Manager and the Technical Project Officer. They are a controlled document requiring assignment of a unique identifying number, incorporating the control number of the procedure being changed, and controlled distribution, per QMP-6.01. The Modification shall contain the approval signatures, an effective date, and a description of the changes.

5.8.3 Rescission of a technical procedure shall be accomplished by a written request to the QA Office, Document Control, including a brief justification or explanation and concurrence by signature of all approval authorities except for the technical reviewer(s).

6. RECORDS MANAGEMENT:

6.1 Controlled Documents: All technical procedures and associated field modifications are YMP-USGS controlled documents and shall be distributed in accordance with QMP-6.01. The USGS shall provide the YMPO PQM and the SAIC/T&MSS Project Quality Assurance Department Manager with controlled distribution of all implementing procedures used for QA graded technical activities.

6.2 Records Center Documents: Records associated with this procedure shall be submitted to the YMP-USGS Local Records Center as individual QA records or as a QA Record Package in accordance with QMP-17.01, as follows:

Technical Procedure Record Package:

- o The fully approved procedure and related support documents
- o Technical Review documentation
- o Quality Assurance Review documentation

Technical Procedure Modification Record:

- o Field modifications
- o Review comments and comment resolution

Individual QA Record:

- o Rescission documentation
- o Requests for revision

7. RELATED DOCUMENTS.

7.1 Superseded Documents: This QMP supersedes YMP-USGS-QMP-5.01, R3, Preparation of Technical Procedures.

7.2 References Cited:

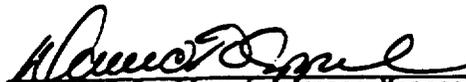
- o AP-1.10Q, Preparation, Review, and Approval of SCP Study Plans
- o YMP-USGS-QAPP-01, Quality Assurance Program Plan
- o YMP-USGS-QMP-3.03, Scientific and Engineering Software
- o YMP-USGS-QMP-3.06, Scientific Investigation Plans
- o YMP-USGS-QMP-3.07, Technical Review Procedure
- o YMP-USGS-QMP-3.10, Verification of Scientific Investigations
- o YMP-USGS-QMP-5.02, Preparation and Control of Drawings
- o YMP-USGS-QMP-5.05, Scientific Notebook Control of Technical Activities
- o YMP-USGS-QMP-6.01, Document Control
- o YMP-USGS-QMP-8.01, Identification and Control of Samples
- o YMP-USGS-QMP-12.01, Instrument Calibration
- o YMP-USGS-QMP-13.01, Handling, Storage, and Shipping of Instruments
- o YMP-USGS-QMP-15.01, Control of Nonconforming Items
- o YMP-USGS-QMP-17.01, YMP-USGS Records Management

8. ATTACHMENTS.

Attachment 1: Annotated outline for preparation of technical procedures for the YMP-USGS Quality Assurance Program

9. APPROVALS AND EFFECTIVE DATE.

EFFECTIVE DATE: September 4, 1990



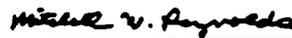
YMP-USGS Quality Assurance Manager

8/6/90
Date



YMP-USGS Technical Project Officer

8/6/90
Date



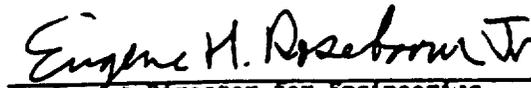
Chief, Office of Regional Geology

08-20-90
Date



Assistant Chief Hydrologist for Program
Coordination and Technical Support

08-21-90
Date



Assistant Director for Engineering
Geology

8/27/90
Date

USGS TECHNICAL PROCEDURE <1> _____ Rev <2>
(Document No.) (Original - Rev 0)

Title <3> _____

1.0 PURPOSE.

- 1.1 To assure the accuracy, validity, and applicability of the methods used to <4> _____
(Give a brief work description)

this procedure is a guide for U.S. Geological Survey (USGS) personnel and contractors performing the described activity.

- 1.2 This procedure describes the components of the work, the principles of the methods used, and their limits. It also describes the detailed methods to be used for calibration, operation, and performance verification of any equipment, if needed. In addition, it defines the requirements for data acceptance, documentation, and control; and it provides a means of data traceability.

2.0 SCOPE OF COMPLIANCE.

- 2.1 This procedure applies to all YMP-USGS personnel and their contractors who may perform work referred to in Para. 1.1, or use data obtained from this procedure.
- 2.2 For all technical activities, data collected from using this procedure and any equipment calibrations or recalibrations that may be required shall be in accordance with this technical procedure. Variations are allowed only if and when this procedure is formally revised, or otherwise modified, as described in Para. 8.

- 3.0 **PERSONNEL RESPONSIBILITIES.** The Principal Investigator (PI) is responsible for assuring full compliance with this procedure. The PI shall require that all personnel assigned to work to this procedure shall have the necessary qualifications and training to adequately perform the procedure; and they shall have a working knowledge of the YMP-USGS QA Program. Responsibilities of others including the reviewer(s), contributing investigators, Geologic Division (GD) Branch/Nuclear Hydrology Program (NHP) Chief, QA Office, and the Technical Project Officer are as described in Para. 4, YMP-USGS-QMP-5.01. When procedure-specific responsibilities are to be delegated to contributing investigators or other personnel, the details of these responsibilities are as stated in this procedure. Special qualifications and/or training unique to the conduct of this procedure (choose one) <5> are not required. <5> are as follows: _____

All ongoing investigations shall be identified, at the location of the scientific investigation, to preclude inadvertent interruption and to ensure compatibility of the investigations.

4.0 DETAILED PROCEDURE. <6> _____
(Introduce the work by relating how it contributes to the DGP Project.)

4.1 Objective: <7> _____
(What specifically will be accomplished by the activities described in the technical procedure?)

4.2 Methods Used: <8> _____
(Organize and summarize the methods to be used, referencing input where possible. Be complete and add as many pages and subheadings as necessary.)

4.3 Materials/Equipment Required: (No special handling, storage and/or shipping is required unless otherwise noted.) <9> _____
(List instrument systems, equipment

and materials needed including special or unique items. State manufacturer's operational range of equipment plus accuracy required or operating range and any handling, storage and shipping requirements per YMP-USGS-QP-12.01 and 13.01.)

4.4 Assumptions Affecting the Procedure: <10> _____
(Detail assumptions concerning design,

performance and interpretation; to be referenced when possible.)

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4.5 Data Information: <11> _____
(What type of data comes from this procedure and in what form is it recorded?)

4.5.1 QUANTITATIVE/QUALITATIVE CRITERIA: <12> _____
(Specify quantitative criteria: e.g., operational range, tolerances, and limits; and qualitative criteria: e.g., comparative samples, as appropriate, against which job performance or completion can be evaluated.)

4.6 Limitations: <13> _____
(List any constraints that might affect the results obtained including (1) those of equipment - frequency response, pressure limits, drill accuracy, flow rates, depth limits, etc., (2) physical barriers - accessibility, depth limits, electronic noise, etc., and (3) emerging technology, e.g., state of the art of equipment.)

4.7 Other: <14> _____
(Detail anything pertinent to the activity but not covered above, e.g. interfaces, with other activities or Project organizations, hold points, special process requirements, software applications, drawings per YMP-USGS-QMP-5.02, etc.)

5.0 CALIBRATION REQUIREMENTS. Calibration (choose one) <15> is <15> is not required as a part of this technical procedure. All instruments and/or instrument systems shall be calibrated in compliance with the YMP-USGS-QMP-12.01, Instrument Calibration for producing data under graded QA controls. (When the answer indicates no calibration are required, skip to Section 6.0.)

5.1 Calibration Responsibility: The PI is responsible for calibrations required by this procedure. Calibration shall be in accordance with procedures described or referenced in Para. 5.2. Maintenance of all calibration records described in Para. 5.3 may be done by a contributing investigator under the direct supervision of the PI.

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5.2 Calibration Procedures: All calibrations, unless otherwise specified, shall be performed according to manufacturer's range and accuracy specifications. <16> _____

(List the instruments instrument systems that require calibration.)

5.2.1 Calibration of the <17> _____

(Summarize the procedure(s) for each instrument and

instrument system listed in Para. 5.2. Reference manufacturer's procedure or the applicable USGS

technical procedure, when possible. State calibration procedure(s) used; interval; standard used,

including traceability; accuracy, and range.)

5.3 Calibration Records: In compliance with YMP-USGS-QMP-12.01, calibration data will be entered, signed and dated, into a notebook or other organized documentation. Computer software used in calibration exercises shall meet the requirements stipulated in YMP-USGS-QMP-3.03. Notebooks and other documents shall be protected and submitted to the LRC in accordance with YMP-USGS-QMP-17.01 (YMP-USGS Records Management).

5.4 Labeling of Equipment Calibration Status: Labeling of equipment shall be in compliance with YMP-USGS-QMP-12.01.

6.0 IDENTIFICATION AND CONTROL OF SAMPLES. Samples (choose one) <18> will be <18> will not be collected or handled as part of this procedure. (If no samples, skip to section 7.0.)

6.1 Sample Identification: As part of the data records and documentation and in compliance with YMP-USGS-QMP-8.01, all samples shall be identified as follows: <19> _____

(State how samples are marked.)

6.2 Control and Storage: In compliance with YMP-USGS-QMP-8.01, the collected and identified samples shall reside in the custody of <20> _____

(Responsible individual.)

who shall store them <21> _____

(State where samples are stored, their eventual disposition, and

what system is used to track them, per QMP-8.01. Do the requirements of DOE AP-6.3Q and AP-6.4Q apply?)

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6.3 Special Treatment: <22> _____
(Identify and explain any special treatment/processing that is
required due to time, moisture, temperature, oxidation, dehydration, etc.)

7.0 QUALITY ASSURANCE RECORDS. Documents and data will be prepared and submitted per appropriate governing project procedures.

7.1 Anticipated documents and data generated from implementation of this procedure may include the following: <23>

(List all forms, calibration records, notebooks, paper or magnetic data recording tapes, etc. that are anticipated to be produced.)

7.2 Notebooks, forms, or other organized documentation shall be prepared, as appropriate, by the PI or a contributing investigator to record data from this procedure and shall include any information considered by the originator to be pertinent. When in loose-leaf form, each page shall be numbered consecutively and chronologically. All documents shall be signed (or initialed) and dated by the investigator as entries are made. Any revisions shall be lined out, initialed, and dated. Notations by pencil shall be submitted in legible photocopy form.

8.0 MODIFICATIONS. When modifications become necessary, per Para. 5.8.2 of YMP-USGS-QMP-5.01, the PI shall fully document the changes, submit the documentation for the same review signature and distribution process as for the original procedure, and indicate whether the change should result in a subsequent revision to the technical procedure.

9.0 REFERENCES CITED.

<24> _____
(Use USGS format. Include any procedures written according to YMP-USGS-QMP-5.05 that preceded this procedure.)

10.0 ATTACHMENTS.

<25> _____
(List all attached data forms, software listings, checklists, equipment brochures, etc.)

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11.0 SUPERSEDED DOCUMENTS. This technical procedure supersedes NWM-USGS- <26>

(Number and title of superseded document, including revision number.)

12.0 APPROVALS AND EFFECTIVE DATE.

EFFECTIVE DATE:

Principal Investigator: <27> Date

YMP-USGS QA Manager Date

Technical Reviewer: <28> Date

Technical Project Officer Date

GD Branch/NHP Chief: <29> Date

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QUALITY MANAGEMENT PROCEDURE PACKAGE TABLE OF CONTENTS

Quality Management Procedure No. YMP-USGS-OMP-5.05 R2

Record Package Sections (Brief Description and/or Record Date)	No. of Pages
Table of Contents	1
Approved Quality Management Procedure - Effective <u>11/5/90</u>	12
Quality Assurance Review Form for Quality Management Procedures (required 10/4/88 and after)	1
Geologic Division and Nuclear Hydrology Program reviewer's evaluation of document including comments and comment resolution, if applicable (required 2/17/88 and after)	*
Other (continue on additional page if necessary):	
+ NHP Comments - J. WOOLVERTON 12/20/89	2
- K.W. CAUSSEAU 3/28/90	16
GD COMMENTS - V.M. GUANEMAN 12/7/89	4
J.J. BARTH 4/11/90	1
RECORDS MGMT COMMENTS - P.J. WARNER 12/7/89	3
P.J. WARNER 3/5/90	4
MEETING ATTENDANCE ROSTER - CONCURRENCE MEETING 10/5/90	1
Total Pages: 45	

Authenticated by: MEB Mary E. Bennington

Date: 10/24/90

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MANAGEMENT PROCEDURES MANUALCHAPTER 5 - INSTRUCTIONS, PLANS, PROCEDURES, AND DRAWINGSSECTION 5 - Scientific Notebook System

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1. **PURPOSE.** This procedure defines the requirements to identify, review, approve, modify, and document planned experimental and research work, through the development of a Scientific Notebook Plan and the maintenance of a scientific notebook, to produce data in support of the Yucca Mountain Project.
2. **SCOPE OF COMPLIANCE.** This QMP applies to all USGS and contractor personnel assigned to perform the work related to QA graded technical activities that produce data, maps, or supports any other product that is a basis for the YMP site characterization or licensing. This procedure applies to experimental or research activities such as those largely requiring professional judgement, trial-and-error methods, or developing methodology. Activities conducted under established and/or standard practices require technical procedures described in QMP-5.01.
3. **DEFINITIONS.** The following definitions are applicable to this procedure.
- 3.1 **Contributing Investigators** are scientists with part- or full-time responsibilities who lend their areas of expertise to the resolution of the various tasks under the supervision of a Principal Investigator.
- 3.2 **Experiments** are operations carried out under known conditions to establish characteristics or values not previously known.
- 3.3 **Research** is a systematic inquiry or extensive investigation into a subject area in order to discover or revise theories, knowledge, etc. Research often requires the development of new methodology.
- 3.4 **Scientific Notebook** is a QA record maintained by an investigator to record the details of the events, activities, and pertinent assessments of the investigation as it progresses, in accordance with the requirements of this procedure.
- 3.5 **Scientific Notebook Plan** (Attachment 1) is a controlled document that describes the experimental/research approach and requirements that are applicable.
- 3.6 **Scientific Notebook System (SNS)** is the flexible documentation of technical activities used in lieu of a technical procedure. The SNS is used to provide a written record of the methodology and results of scientific investigations and experiments when the work involves professional judgment, trial-and-error methods, or accommodates emerging technologies developed as an investigative activity progresses.

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Scientific Notebook System shall be applied when the methodology necessary for conduct of a scientific activity 1) largely requires professional judgment; 2) requires trial-and-error methods; or 3) is beyond the state of the art, requiring development and experimentation. When one or more of the above criteria applies, then the directives of this QMP shall be followed.

5.2 Associated Planning Document: When it has been determined that the Scientific Notebook System is to be used, the Study Plan shall be the controlling document used to describe the proposed approach for accomplishing the work. (A Scientific Notebook Plan, to be described later, is required as part of the scientific notebook to expand upon the details from the Study Plan that are pertinent to the scientific notebook activities.) All further details concerning conduct of the work shall be maintained in a bound notebook in accordance with this procedure. The content of the notebook shall be sufficient to the extent that another qualified scientist can use the notebook to retrace or repeat the investigation or experiment to confirm the results, if feasible, without recourse to the PI.

5.3 Unique Identifying Number: As controlled documents, the Scientific Notebook System shall comply with the identification requirements of QMP-6.01. To distinguish the identification of the scientific notebook from a technical procedure, a "T" shall be placed after the document identification number of the scientific notebook. For example, a hydrologic scientific notebook might be designated as NWM-USGS-HP-181T.R0. The identifying number is obtained from the QA Office during draft preparation of the Scientific Notebook Plan and shown as Revision 0 during review, approval and use. If the scientific notebook is subsequently changed to a technical procedure, the "T" shall be removed from the scientific notebook number but the revision number shall be incremented by one. The above example would become NWM-USGS-HP-181.R1 for a technical procedure.

5.4 Procedure Documentation: Documentation requirements are met by fully completing the three steps of the Scientific Notebook System: 1) Initial entry, 2) in-process entries, and 3) final entries.

5.4.1 INITIAL ENTRY - The preparation of a Scientific Notebook Plan is required to initiate the Scientific Notebook System. This step produces a controlled document that provides both technical and QA management with a means to approve and track research and experimental activities, and to provide other Project participants with information regarding the activity(ies). As appropriate, the following required topics shall be addressed to initiate and justify the scientific notebook procedure:

- o Title of the experiment or research
- o Description of the experiment's objectives

- o Description of the proposed approach or procedure. (This may be accomplished by reference to the appropriate Study Plan.)
- o Name of qualified individual(s) performing the work activity
- o Special personnel qualification or training requirements
- o Equipment and materials to be employed during the experiment or research, including any necessary fabrication of experimental equipment and any needed characterization of starting material
- o Calibration requirements
- o Potential sources of uncertainty and error
- o Input data that is suspect or whose quality is beyond the control of the performing organization
- o Documentation of suitable and controlled environmental conditions
- o Required levels of precision and accuracy
- o Dated signature of the individual(s) making the initial entry.

5.4.1.1 A Scientific Notebook Plan. Attachment 1, which incorporates the above requirements shall be completed and entered into the official record prior to commencing technical work (see Para. 6). A controlled copy of the approved Scientific Notebook Plan shall be permanently attached at the front of the scientific notebook.

5.4.1.2 Modifications to the described approach may be made by the individual performing the investigation while the investigation is in progress. Full details of this modification shall be recorded in the scientific notebook. If this in-process modification is not within the scope of the Study Plan and the investigation is not repeatable, or if the change could potentially impact the waste isolation capability of the site, or interfere with other site characterization activities, approval shall be obtained from a reviewer who is qualified and directed by the PI of the Study Plan before the modification can be put into effect. All modifications affecting Sections 1, 2 and 3 of the Scientific Notebook Plan (Purpose, Objectives, or Proposed Work Plan) shall be prepared in accordance with the review and approval requirements of this procedure. The PI shall determine if a modification affecting Sections 1, 2, or 3 is to be permanent. If affirmative, the Scientific Notebook Plan shall be revised within 90 calendar days of making the modification. If it is determined that the modification has a potential impact on the quality of the data, then the modification shall automatically result in issuance of a Nonconformance Report (QMP-15.01). Conduct of an activity changed by the modification may

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revert to the previous approved Scientific Notebook Plan as deemed appropriate by the responsible PI. In this case, the scope of the NCR shall be limited to the life span of the modification.

5.4.2 IN-PROCESS ENTRIES - The Scientific Notebook is used to record the work as it occurs. Activities shall be noted in sufficient detail to allow another researcher to repeat the work without recourse to the PI. In-process entries shall provide the following information, as appropriate:

- o Date and name of individual making the entry
- o Description of the experiment or research attempted, including detailed step-by-step process followed; either by reference to implementing procedure or by actual entry into the notebook
- o Provisions for assuring that prerequisites have been met (e.g., commitments specified in the Scientific Notebook Plan)
- o Conditions which may adversely affect the results of the experiment or research investigation
- o Identification of samples collected and/or used and any additional equipment and materials not included as part of the initial entries
- o Entry of data or reference to identification and location of data record(s), including notation of any unaccepted results
- o Any deviations from the planned experiment or research
- o Computer software invoked
- o Interim conclusions reached, as appropriate, and
- o Final disposition of facilities.

5.4.2.1 Computer software invoked in scientific notebook procedures and used to collect, reduce, analyze, or interpret data shall be subject to the software quality assurance and controls set forth in QMP-3.03.

5.4.2.2 The scientific notebook shall be permanently pre-bound with the pages consecutively numbered up to the last page used. A control number for each notebook shall be assigned by the QA Office. This number and the title shall be displayed on the first page of each volume. Any changes to entries in the notebook shall be made as described in QMP-17.01; however, no further entries may be made on any portion of the scientific notebook previously submitted to the YMP-USGS Local Records Center (see Para. 5.9). Ongoing entries shall be made continuous

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on the page with no open spaces left for subsequent entries. Such open spaces as might inadvertently occur shall have black lines drawn diagonally across them to indicate that no further entries are to be incorporated.

5.4.3 **FINAL ENTRIES:** When the work described in accordance with the Scientific Notebook Plan has been completed, the notebook shall be closed out. This could entail a wrap-up statement, a brief summary of the work, or a statement that "this is the end of the record", for the scientific notebook. The date and signature of the experimenter and a technical reviewer (Para. 5.5) is required.

5.4.4 **FINAL RESULTS** and a summary of the outcome of the experiment or research shall be documented, such as by a statement in the scientific notebook or inclusion in a technical report, etc. As appropriate, this documentation shall include a discussion of whether the experiment's objectives as outlined in the initial entries were achieved. This documentation shall become part of the QA records of the activity.

5.5 **Technical Review:** Two different technical reviews are required by this procedure. First, the Scientific Notebook Plan and any subsequent revisions are to be reviewed. Later, when the scientific notebook is completed and the final entries are made the second review is performed and documented in accordance with QMP-3.07.

5.5.1 The Scientific Notebook Plan shall be reviewed by a subject matter expert who is not immediately responsible for either the procedure's content or for supplying details to the preparer (author) concerning the methods described. The supervisor may serve as a reviewer. At a minimum, the Scientific Notebook Plan review shall show evidence that the contents of Para. 5.4.1 have been appropriately addressed.

5.5.2 A colleague of the PI shall perform the subsequent review of a completed scientific notebook itself, which is done to confirm the adequacy of the technical methods used, and to show concurrence that the notebook adequately documents the technical investigations as required by the procedure and as specified in the Scientific Notebook Plan. This reviewer shall be independent of the work performed. At a minimum, the scientific notebook entries review shall show evidence that the contents of Para. 5.4.2 have been appropriately addressed. The reviewer signature is required to be a part of the final entry in the scientific notebook.

5.6 **Quality Assurance Review:** A QA review of the Scientific Notebook Plan shall be performed by a QA Office representative for compliance with applicable QA requirements of this procedure and documented in accordance with QMP-3.07.

5.6.1 Each major QA review comment, shall be evaluated and resolved by the PI in coordination with the YMP-USGS QA Office. Upon completion of comment resolution, all documentation of reviewer comments and their

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Resolution shall be attached to the original reviewed copy and returned to the PI by the person responsible for the comment resolution. The PI forwards this information to the LRC in accordance with QMP-17.01.

5.6.2 REVIEW CRITERIA: At a minimum, the QA review shall show evidence that the following criteria have been considered in the review of a Scientific Notebook Plan (SNP).

- o Are the purpose, objective, and scope included?
- o Is the proposed Work Plan complete enough to give understanding to others?
- o Are special personnel qualification and training requirements addressed?
- o Is there a description of the required materials/equipment?
- o When needed, are calibration instructions addressed to the satisfaction of QMP-12.01?
- o Is sample handling and control addressed to the satisfaction of QMP-8.01 and Sample Management Facility Procedures?
- o Are data information and quantitative/qualitative criteria addressed?
- o Are work environmental issues addressed as appropriate?
- o Has a Notebook No. been issued?

5.7 Technical, QA, and Management Approvals: The final draft of the Scientific Notebook Plan shall become effective after receiving, in sequence, the signatures of the PI, technical reviewer(s), GD Branch/NHP Chief, the YMP-USGS QA Manager, and the YMP-USGS Technical Project Officer. The Scientific Notebook Plan shall be returned, if needed, with appropriate explanation and suggestions, for remedial action to the PI (bypassing the reviewer(s)) if problems are encountered at this stage. Documentation of comments and resolutions shall be included as part of the procedure's record. Each signature shall signify acceptance according to responsibilities as designated in Para. 4 above.

5.8 Conversion From the Scientific Notebook System: The Scientific Notebook System may be used throughout the activity or, when it has reached a mature stage and the methods will be in continued use, this system can be converted to a technical procedure in accordance with QMP-5.01. The PI shall determine the stage at which the scientific notebook can be converted to a technical procedure. Upon conversion the new technical procedure (QMP-5.01) shall contain a reference to the superseded scientific notebook.

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5.9 Technical Data Record Protection: A copy of scientific notebook entries shall be made by the PI, or delegate, semi-annually following the first entry, or more frequently when required by the Project's data management procedures. The copies shall be sent to the QA Office for QA records compliance review and subsequently sent by the QA Office to the YMP-USGS LRC to satisfy duplicate records requirements. No changes shall be made thereafter in the scientific notebook to that portion copied. Should there be no entries during the preceding period, or if there is some extenuated reason why no transmittal can be made at the required intervals, this information shall be submitted directly to the LRC.

5.10 Effective Date: The effective date shall be recorded on the Scientific Notebook Plan following its approval. This date shall be either the latest date of approval or some later date as may be required for personnel training or document control purposes.

6. RECORDS MANAGEMENT.

6.1 Controlled Documents: The Scientific Notebook Plan is a controlled document and shall be distributed in accordance with the specifications of QMP-6.01.

6.2 Records Center Documents: Records associated with this procedure shall be submitted to the YMP-USGS Local Records Center at intervals in accordance with QMP-17.01 and this procedure. A QA Record package shall be compiled by the PI, or delegate, which will include:

Scientific Notebook Record Package:

- o Approved Scientific Notebook Plan
- o Technical Review documentation
- o Quality Assurance Review documentation

Individual Records:

- o Semi-annual submittal of scientific notebook entries
- o The statement of final results and summary of the outcome of the experiment (see Para. 5.4.4).

7. RELATED DOCUMENTS.

7.1 Superseded Documents: This QMP supersedes YMP-USGS-QMP-5.05, R1, Scientific Notebook Control of Technical Activities, and QMP-5.05-Mod.01, R0.

7.2 References Cited:

- o YMP-USGS-QAPP-01, YMP-USGS Quality Assurance Program Plan
- o YMP-USGS-QMP-3.03, Software Quality Assurance
- o YMP-USGS-QMP-3.07, YMP-USGS Review Procedure
- o YMP-USGS-QMP-5.01, Preparation of Technical Procedures
- o YMP-USGS-QMP-6.01, Document Control

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- o YMP-USGS-QMP-8.01, Identification and Control of Samples
- o YMP-USGS-QMP-12.01, Instrument Calibration
- o YMP-USGS-QMP-15.01, Control of Non-Conforming Items
- o YMP-USGS-QMP-17.01, YMP-USGS Records Management

8. ATTACHMENTS.

Attachment 1: Scientific Notebook Plan

9. APPROVALS AND EFFECTIVE DATE.

EFFECTIVE DATE: November 5, 1990

Robert D. Jones
YMP-USGS Quality Assurance Manager

10/9/90
Date

Larry R. Hays
YMP-USGS Technical Project Officer

10/09/90
Date

Richard W. Reynolds
Chief, Office of Regional Geology

10-11-90
Date

Arnold J. Frank for
Assistant Chief/Hydrologist for Program
Coordination and Technical Support

10/12/90
Date

Ernest H. Roseboom Jr for
Assistant Director for Engineering
Geology

10/12/90
Date

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SCIENTIFIC NOTEBOOK PLAN

< > _____
Title

1.0 **PURPOSE:** This Scientific Notebook Work Plan has been prepared to meet the requirements of YMP-USGS-QMP-5.05 for documenting activities conducted under Study Plan No. <3> _____, Title: <4> _____

_____ for the purpose of
<5> _____

Modifications to the activities introduced here shall be documented, in accordance with QMP-5.05, Para. 5.4.1.2, and controlled in the notebook specifically assigned to the PI responsible for conduct of this work.

2.0 **OBJECTIVE:** The planned objective is <6> _____
(Give sufficient detail to permit reviewers and others

to understand what the work is intended to accomplish.)

3.0 **TENTATIVE WORK PLAN:** In summary, the activity shall be conducted as follows:

<7> _____
(Describe proposed approach including procedures and methods for achieving the objectives. Include any mandatory hold-points that can be identified at this stage of the procedure. Add additional pages as required.)

4.0 **PERSONNEL:** Persons responsible for the work are <8> _____

Principal Investigator and other contributing investigators who may be delegated responsibilities appropriate to their qualifications and training. Key contributing investigators and other personnel include <9> _____

(List positions such as tech-

_____ Special qualifications and training required are as follow:
nicians when possible.)

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<10>

(State the special requirements for each position.)

5.0 **EQUIPMENT:**

5.1 **Essential Equipment and Materials:** <11>

(List of materials/equipment planned for the

conduct of the activity; including any design or fabrication or experimental equipment, special handling,

shipping, and storage requirements for equipment.)

5.2 **Calibration Requirements:** All instruments and methods or systems shall be calibrated in accordance with YMP-USGS-QMP-12.01, Instrument Calibration, for quality affecting activities.

5.2.1 Equipment requiring calibration includes <12>

(List equipment requiring

calibration.)

5.2.2 Calibration procedure is <13>

List a calibration procedure for each item in Para. 5.2.1.)

6.0 **POTENTIAL LIMITATIONS:** <14>

(Describe potential sources of uncertainty/error which must be con-

trolled and measured, input data that is suspect, and any other limitations.)

QMP-USGS REVIEW/COMMENT RESOLUTION FORM

Document No. and Title: QMP-5.05, R2 Scientific Notebook System

Reviewer Name(s): Wayne R. Roman Governing Procedure: QMP-5.03,

Reviewer Signature(s): Wayne R. Roman Date: 1/19/83

Technical Review QA Review Other: _____

REVIEWER'S COMMENTS

RESPONSE

COMMENT NO. MAJOR/MINOR	PAGE NO.	COMMENTS	RESPONSE		JUSTIFICATION
			ACCEPT	REJECT	
N/A	N/A	This QMP has been reviewed for compliance with the review criteria in QMP-5.03, R5 Para. 5.3.1 and has been found to meet the following: 1) Complies with QMP-5.03 2) Complies with requirements of the QAPP 3) Interfaces with other pertinent documents and presents no apparent conflicts <i>No Comments.</i>	x x x		

* Justification(s) for rejection of reviewer's comment(s) is/are found to be justified:

NA
 CD Branch/NHF Chief/TPO/QA Manager Date

THP-USGS REVIEW/COMMENT RESOLUTION FORM

WB:
QA

Document No. and Title: QMP-5.05, R2 Scientific Notebook Control of Technical Activities

Page

Reviewer Name(s): Jon B. Woolverton

Reviewer Signature(s): Jon B. Woolverton

Date: 12

REVIEWER'S COMMENTS

RESOLUTION

COMMENT NO. MAJOR/MINOR	PAGE NO.	COMMENTS	RESOLUTION		REASONING
			ACCEPT	REJECT	
1 MAJOR	1	PARA. 2 <u>DELETE</u> "RECOMMENDATIONS."		x	1. The QA Office has determined that this QMP will undergo immediate revision and review and this comment will be considered at that time. See response to comment #1. See response to comment #1.
2 MAJOR	ATT. 1 p. 1	PARA. 5 <u>ADD</u> SPECIAL HANDLING, SHIPPING, & STORAGE REQUIREMENTS FOR EQUIPMENT.	x		
3 MAJOR	ATT. 1 p. 2	PARA. 5.2 - CALIBRATION GUIDELINES ARE SPARSE. * CAL. NEEDS TO BE PERFORMED OVER THE RANGE OF OPERATION FOR EACH EQUIPMENT ITEM OR DATA COLLECTION SYSTEM. * CALIBRATION ACCURACIES SHOULD BE STATED. * REFERENCE TO MANUFACTURER'S CALIBRATION PROCEDURES, VENDOR'S CAL. PROCEDURES NEED TO BE STATED. * STANDARDS USED NEED TO BE STATED. * ACCURACY OF STANDARDS USED NEEDS TO BE STATED.		x	
4 MAJOR	ATT. 1 p. 2	<u>ADD</u> SECTION 5.2.3 "EQUIPMENT USED TO MEASURE, GAGE, ETC. THAT IS EXEMPTED FROM REQUIRING CALIBRATION (LIST COMMERCIAL DEVICES USED TO MEASURE, GAGE, ETC. WHERE THE OPERATIONAL VARIABILITY DOES NOT EXCEED ACCURACY REQUIREMENTS FOR THE PURPOSES INTENDED. INDICATE MANUFACTURER'S ACCURACY VERSUS ACCURACY REQUIREMENTS FOR THE WORK BEING PERFORMED).		x	

NA

* Rejection of resolution is found to be justified:

GD Branch/NHP Chief/TPO/QA Manager

Date

YMP-USGS REVIEW/COMMENT RESOLUTION FORM

WBS #: 1.2.9.3
QA: QA

Document No. and Title: QMP-5.05, R2 Scientific Notebook Control of Technical Activities

Page 2 of 2

Reviewer Name(s): Jon B. Woolverton

Reviewer Signature(s): Jon B. Woolverton

Date: 12/20/07

REVIEWER'S COMMENTS			RESOLUTION			* REVIEWER DISPOSITION FOR MAJOR COMMENTS	
COMMENT NO. MAJOR/MINOR	PAGE NO.	COMMENTS	ACCEPT	REJECT	REASONING	ACCEPT	REJECT
MAJOR	Att. 1 P. 2	PARA. 7.0 - CHANGE "TOLERANCES, OPERATING LIMITS" TO A RANGE OF OPERATION, ACCURACIES REQUIRED. ADD - OVERALL QUANTITATIVE ACCURACY REQUIRED FOR EACH TYPE OF MEASUREMENT.		X	See response to comment #1.	Jon 02/14/08	
MAJOR	Att. 1 P. 2	PARA. 8.0 IMPACTS ON OTHER ACTIVITIES IS ONLY PART OF WHAT NEEDS TO BE ADDRESSED ACCORDING TO UPLINE DOCUMENTS (I.E. IMPACT ON WASTE ISOLATION, ETC.) OVERALL, PORTIONS OF 5.05 NEED TO BE MORE IN ALIGNMENT WITH 5.01 - FOR THE SAKE OF CONSISTENCY. EXAMPLE:)		X	See response to comment #1.	Jon 02/14/08	
MAJOR	Att. 1 P. 1	EQUIPMENT & MATERIALS SECTION SHOULD STATE THE MANUFACTURER'S OPERATING RANGE INCLUDING ACCURACY FOR EACH EQUIPMENT ITEM. OR, RANGE & ACCURACY FOR A DATA COLLECTION SYSTEM SHOULD BE ADDRESSED IN AN OVERALL SENSE (IF APPLICABLE).		X	See response to comment #1.	Jon 02/14/08	

NA

* Rejection of resolution is found to be justified:

CD Branch/NHP Chief/TPO/QA Manager Date

NHP-USGS REVIEW/COMMENT RESOLUTION FORM

WBS #: 1.2.9.3
QA: QA

Document No. and Title: OMP-5.05, R2 Scientific Notebook Control of Technical Activities Page 1 of 16

Reviewer Name(s): K.W. Causseaux, A. Riggs, M. Ciesnik, T. Mendez-Vigo Governing Procedure: QMP-5.03, R4
W. Wilcoxon, C. Peters

Reviewer Signature(s): *KW Causseaux* Date: 3/28/90

Technical Review QA Review Other: NHP Comments

REVIEWER'S COMMENTS			RESPONSE			REVIEWER'S DISPOSITION FOR MAJOR COMMENTS	
COMMENT NO. MAJOR/MINOR	PAGE NO.	COMMENTS	ACCEPT	REJECT	JUSTIFICATION	ACCEPT	REJECT
1-major	1	Change Title to "Scientific Notebook Documentation of Technical Activities". The purpose of the Scientific Notebook is to document technical activities, not control them.	<i>SR</i>	<i>SR</i> <i>10/10/90</i>	The QARD, R3 lists the requirement for this procedure under "CONTROL OF SCIENTIFIC INVESTIGATIONS". Under para. (b) it further states "...two approaches that will be used to control scientific investigations activities." We need to leave the title as it is. <i>Change of title confirmed.</i> See revised text.	<i>SR</i>	
2-major	1	Para. 1: Line 1, delete prepare. This procedure has little to do with the preparation of work- whatever that means.	<i>SR</i>			<i>SR</i>	
3-major	1	Para. 1: Line 4, change to "of a Scientific Notebook as a record in support of the Yucca Mountain. The Notebook is used to record data, not produce it."	<i>SR</i>	<i>SR</i> <i>10/10/90</i>	The Scientific Notebook, including the scientific notebook plan is used to control, including documentation of, the scientific activity in order to produce data. This procedure is intended to do more than provide a means to document the collected data. <i>Added Comment to clarify.</i>	<i>SR</i>	

* Justification(s) for rejection of reviewer's comment(s) is/are found to be justified:

NA
CD Branch/NHP Chief/TPO/QA Manager Date

1750A-00721

YMP-USGS REVIEW/COMMENT RESOLUTION FORM CONTINUATION SHEET

WBS #: 1.2.9.3

Document No. and Title: QMP-5.05, R2 Scientific Notebook Control of Technical Activities

Page 2 of 16

Reviewer Name(s): See page 1

Governing Procedure: QMP-5.03, R4

Reviewer Signature(s):

Date: 3/28/90

Technical Review

QA Review

Other: NHP Comments

REVIEWER'S COMMENTS			RESPONSE			REVIEWER DISPOSITION FOR MAJOR COMMENTS	
COMMENT NO. MAJOR/MINOR	PAGE NO.	COMMENTS	ACCEPT	REJECT	JUSTIFICATION	ACCEPT	* REJECT
4-major	1	Para.2: Line 2, what "YMP-USGS procedures"? Procedures need to be unambiguously identified.	x		See revised text.	See ↓	
5-major	1	Para 2: Line 3, Is "QA Level I and II" applicable to graded QA? QA Levels are inappropriate in the age of graded QA.	x		See revised text.		
6-major	1	Para 3.2: Line1, "Controlled Conditions"- any experiments will be carried out under conditions that are only partially controlled at best. Real world experiments can almost never be carried out under controlled conditions.	x		See revised text.		
7-minor	2	Para 3.3: Second line delete "item or"	x		See revised text.		
8-major	2	Para 3.3: Line 2, "revise facts" if they are facts, they're not subject to revision.	x		See revised text.		
9-minor	2	Para 3.4: Move "considerations" line 3 to follow "investigation" in line4. Also, delete "of" in line 3 replace it with "to".	x		See revised text.		
10-major	2	Para 3.5: The meaning of this paragraph is unclear	x		See revised text.		
11-minor	2	Para 3.7: Needs editing to more clearly state its message. Change to "Technical Procedures are procedures, prepared prior to beginning a technical activity, that describe standard, routine, and/or industry accepted practices. They may include..."	x		See revised text.		

YMP-USGS REVIEW/COMMENT RESOLUTION FORM CONTINUATION SHEET

WBS #: 1.2.9.3

Document No. and Title: QMP-5.05, R2 Scientific Notebook Control of Technical Activities Page 3 of 16

Reviewer Name(s): See page 1 Governing Procedure: QMP-5.03, R4

Reviewer Signature(s): _____ Date: 3/28/90

Technical Review QA Review Other: NHP Comments

REVIEWER'S COMMENTS			RESPONSE		REVIEWER DISPOSITION FOR MAJOR COMMENTS		
COMMENT NO. MAJOR/MINOR	PAGE NO.	COMMENTS	ACCEPT	REJECT	ACCEPT	REJECT	
12-major	2	Para 4.1: PI needs to be defined in the definition section.		<input checked="" type="checkbox"/>	<p>ALB, 2/1/90 JUSTIFICATION</p> <p>PI is defined in several other places in the QA Program, and is not worthy of restatement in this procedure. It is a commonly used term in the management and conduct of the YMP program.</p>		<p>No change needed as PI is still defined in</p>
13-major	2	Para 4.1: Line 2, "controlled" is inappropriate Technical Activity should be documented, but control is inappropriate in work requiring judgement as in SNS.		<input checked="" type="checkbox"/>	<p>In many respects even the performance of judgement calls are done in a controlled setting, and under guidelines. Controlled is used in a wide sense in this program, and is not to be taken as negative or necessarily restrictive. See comment 1 above for further information.</p>		<p>No longer applicable</p>
14-minor	2	Para 4.1: Insert ":" after the "for" in line 1	<input checked="" type="checkbox"/>		See revised text.		See
15-minor	3	Para 4.1: Line 7, insert a comma after "that:	<input checked="" type="checkbox"/>		See revised text.		See
16-major	3	Para 4.2: Line 2, change to "this procedure when performing duties in an investigation covered by the SNS." A contributing investigator may perform important duties not designated by PI-important part is that duties performed, for whatever reason, conform to SNS.	<input checked="" type="checkbox"/>		See revised text.		See

YMP-USGS REVIEW/COMMENT RESOLUTION FORM CONTINUATION SHEET

WBS #: 1.2.9.3

Document No. and Title: QMP-5.05, R2 Scientific Notebook Control of Technical Activities Page 4 of 16

Reviewer Name(s): See page 1 Governing Procedure: QMP-5.03, R4

Reviewer Signature(s): _____ Date: 3/28/90

Technical Review QA Review Other: NHP Comments

REVIEWER'S COMMENTS			RESPONSE			REVIEWER DISPOSITION FOR MAJOR COMMENTS	
COMMENT NO. MAJOR/MINOR	PAGE NO.	COMMENTS	ACCEPT	REJECT	JUSTIFICATION	ACCEPT	REJECT
17-major	3	Para 4.3: Line 4, Need to specify qualifications for technical reviewers.		x	The qualifications of technical reviewers vary with the assigned review, and are therefore difficult to specify, and probably unduly restrictive. The requirement for reviews, and reviewers appear in QMP-3.07.		
18-minor	3	Para 4.4: Line 3, change to "...Chief, o delegate," for consistency with QMP-5.05.	x		See revised text.		
19-minor	4	Sec. 5: Lines 3-5, change to "...or 2) a Technical Procedure system. This QMP concerns the the Scientific Notebook System, and how the decision is made for the Technical Procedure System.	x		See revised text.		
20-minor	4	Para 5: 2nd line, insert "of" following "assurance". Delete "implementing" in line 3.		x	"of" is a part of the sentence at the appropriate place. "Implementing" was deleted as part of comment 19.		
21-major	4	Para 5.1: line 2, Reference to QA Levels is inappropriate now that graded QA is in place.	x		See revised text.		
22-major	4	Para 5.1: Suggest to replace the sentence "If the methodology required for conduct of the subject shall be followed" by "The scientific notebook system shall be applied when the methodology	x		See revised text.		

YMP-USGS REVIEW/COMMENT RESOLUTION FORM CONTINUATION SHEET

WBS #: 1.2.9.3

Document No. and Title: OMP-5.05, R2 Scientific Notebook Control of Technical Activities Page 5 of 16

Reviewer Name(s): See page 1 Governing Procedure: OMP-5.03, R4

Reviewer Signature(s): _____ Date: 3/28/90

Technical Review QA Review Other: NHP Comments

REVIEWER'S COMMENTS			RESPONSE			REVIEWER DISPOSITION FOR MAJOR COMMENTS	
COMMENT NO. MAJOR/MINOR	PAGE NO.	COMMENTS	ACCEPT	REJECT	JUSTIFICATION	ACCEPT	* REJECT
22-cont'd.		necessary for conduct of a scientific activity: 1) largely requires professional judgement; 2) requires trial-and-error methods; 3) is beyond the state of the art, requiring development and experimentation.					
23-minor	4	Para 5.2: Line 2 and 4, upper case should be used for "Scientific Notebook Plan" and "Scientific Investigation Planning".			<i>DR</i> To be consistent, the lower case will be used throughout this procedure for scientific notebook system.		<i>SK</i>
24-major	4	Para 5.2: This entire paragraph needs to be clarified.	<i>DR</i>		See revised text.		
25-major	5	Para 5.2: What defines "qualified"?			<i>DR</i> No general qualifications can be specified. This communicates that in order to independently repeat the experiment, the worker needs to have the capability to perform the work.		<i>X</i> <i>Johnston for Wilmar</i>
26-major	5	Para 5.2: Line 3, "Achieve the same results"-- In many cases, even the same procedure exactly will yield different results.	<i>DR</i>		Its hard to argue the point here. The project uses this terminology to communicate that within the context of the given science, one should be able to retrace as best as possible how the data were obtained and to get equivalent		<i>Accept</i> <i>revised</i> <i>SK</i>

YMP-USGS REVIEW/COMMENT RESOLUTION FORM CONTINUATION SHEET

WBS #: 1.2.9.3

Document No. and Title: QMP-5.05, R2 Scientific Notebook Control of Technical Activities Page 6 of 16

Reviewer Name(s): See page 1 Governing Procedure: QMP-5.03, R4

Reviewer Signature(s): _____ Date: 3/28/90

Technical Review QA Review Other: NHP Comments

REVIEWER'S COMMENTS			RESPONSE			REVIEWER DISPOSITION FOR MAJOR COMMENTS	
COMMENT NO. MAJOR/MINOR	PAGE NO.	COMMENTS	ACCEPT	REJECT	JUSTIFICATION	ACCEPT	★ REJECT
26-cont'd.					results in the end. Judgement on equivalency obviously is a part in the case of some earth science investigations.		
27-major	5	Para 5.3: Numerous editorial changes needed to make this section say what it apparently is supposed to mean. Change to read "As controlled documents, scientific notebooks shall comply with the identification requirements of QMP-6.01. To distinguish a scientific notebook from a technical procedure, a "T" shall be placed after the document identification number of the scientific notebook. For example, a hydrologic scientific notebook might be designated as NWM-USGS-HP-181T, R0. The identifying number is obtained from the QA Office during preparation of the Scientific Notebook Plan and shown as Revision 0 during review, approval, and use. If the scientific notebook is subsequently upgraded to a technical procedure, the "T" shall be removed from the scientific notebook number but the revision numbers shall be incremented by one. The above example would become NWM-USGS-HP-181, R1 as a technical procedure.		<i>DP</i>	See revised text.		<i>SK</i>

YMP-USGS REVIEW/COMMENT RESOLUTION FORM CONTINUATION SHEET

WBS #: 1.2.9.3

Document No. and Title: QMP-5.05, R2 Scientific Notebook Control of Technical Activities Page 7 of 16

Reviewer Name(s): See page 1 Governing Procedure: QMP-5.03, R4

Reviewer Signature(s): See page 1 Date: 3/28/90

Technical Review QA Review Other: NHP Comments

REVIEWER'S COMMENTS			RESPONSE			REVIEWER DISPOSITION FOR MAJOR COMMENTS	
COMMENT NO. MAJOR/MINOR	PAGE NO.	COMMENTS	ACCEPT	REJECT	JUSTIFICATION	ACCEPT	★ REJECT
28-major	5	Para 5.4.1: "Initial Entry" needs to be defined in the definition section.		x	Initial entry is defined in the text describing how to accomplish the first step of the procedure.	✓	
29-major	5	Para 5.4.1: Does "Initial Entry" mean an entry in the notebook? If so, how can it be a controlled document? Should this really say "As Initial Step?"		x	The QARD states "Prior to initiation of the experiment or research the following entries..." The USGS has packaged all the "following entries" into a required-content format to be completed, reviewed, and approved as a first step. This could have been put directly into the notebook. Instead, the form completed by this procedure is put into the notebook after it has been completed, and approved. This approach was taken to help assure compliance with the requirements of the QARD, while not unduly burdening the PI with further research on the requirements in this area.	✓	
30-major	5	Para 5.4.1: Line 4, Change to management with a document to ..." Document is a more appropriate term than mechanism in this context.	x		See revised text.	✓	

YHP-USGS REVIEW/COMMENT RESOLUTION FORM CONTINUATION SHEET

WBS # 1.2.9.3

Document No. and Title: QMP-5.05, R2 Scientific Notebook Control of Technical Activities

Page 8 of 16

Reviewer Name(s): See page 1

Governing Procedure: QMP-5.03, R4

Reviewer Signature(s):

Date: 3/28/90

Technical Review QA Review Other: NHP Comments

REVIEWER'S COMMENTS			RESPONSE			REVIEWER DISPOSITION FOR MAJOR COMMENTS	
COMMENT NO. MAJOR/MINOR	PAGE NO.	COMMENTS	ACCEPT	REJECT	JUSTIFICATION	ACCEPT	* REJECT
31-major	6	Para 5.4.1: Line 1 and 2, change to "...following information shall be provided in the Scientific Notebook Plan to initiate...". Say what is meant in requiring filling out SNP completely.		<i>AB</i>	There are several ways to present the requirements of this procedure. To change the wording of this para. would necessitate a change in the way the procedure flows.	<i>AB</i>	
32-minor	6	Para 5.4.1: Delete "and tolerances" in 5th bullet	<i>AB</i>		See revised text.		
33-major	6	Para 5.4.1: Line 11, Suitable work environmental conditions is a meaningless hodge podge of words- say what is meant- better, say "Impacts on other Activities", a section heading in the SNP like all the other bullets.		<i>AB</i>	Suitable work environmental conditions" are words taken from the QARD.	<i>AB</i>	
34-minor	6	Para 5.4.1.1: Line 1, change to "A SNP shall..."	<i>AB</i>		See revised text.	<i>AB</i>	
35-minor	6	Para 5.4.1.1: Line 4, change to "...shall be permanently attached..." Permanently is a much more efficient way of communicating what is needed.	<i>AB</i>		See revised text.	<i>AB</i>	
36-minor	6	Para 5.4.1.2: Lines 3 and 4, Study Plan and Scientific Investigation Plan should be upper case.	<i>AB</i>		See revised text.	<i>AB</i>	
37-major	7	Para 5.4.1.2: 2nd sentence change to read "...from a reviewer, who is qualified..."	<i>AB</i>		See revised text.	<i>AB</i>	
38-major	7	Para 5.4.1.2: Line 1, "reviewer qualified and directed by the PI" meaning is unclear in this context.	<i>AB</i>		See revised text.	<i>AB</i>	

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NHP-USGS REVIEW/COMMENT RESOLUTION FORM CONTINUATION SHEET

WBS #: 1.2.9.3

Document No. and Title: QMP-5.05, R2 Scientific Notebook Control of Technical Activities Page 9 of 16

Reviewer Name(s): See page 1

Reviewer Signature(s): _____ Governing Procedure: QMP-5.03, R4

Technical Review QA Review Other: NHP Comments Date: 3/28/90

REVIEWER'S COMMENTS

RESPONSE

REVIEWER DISPOSITION FOR MAJOR COMMENTS

COMMENT NO. MAJOR/MINOR	PAGE NO.	COMMENTS	RESPONSE		REVIEWER DISPOSITION FOR MAJOR COMMENTS		
			ACCEPT	REJECT	ACCEPT	REJECT	
39-minor	7	Para 5.4.1.2: 2nd line, through the 4th line should read "All changes affecting Sections 1, 2, and 3 of the Scientific Notebook Plan (Purpose, Objectives, or Proposed Work Plan) shall be made in accordance with the review and approval requirements of this procedure.	<input checked="" type="checkbox"/>		See revised text.		
40-major	7	Para 5.4.1.2: 4th sentence change "Proposed Work Plan" to "Tentative" to be consistent w/ Att. 1.	<input checked="" type="checkbox"/>		See revised text.		
41-major	7	Para 5.4.1.2: Line 5, state section f of review and approval requirements.	<input checked="" type="checkbox"/>		See revised text. <i>DDP 11/4/90</i>		
42-major	7	Para 5.4.2: Line 1, Change to "5.4.2 IN PROCESS ENTRIES - The..." and In process entries needs to be defined.	<input checked="" type="checkbox"/>		See revised text. <i>NO quality effort, this is the normal work elsewhere.</i>		
43-minor	7	Para 5.4.2: Line 2, "in-process" and "as they occur" are redundant.	<input checked="" type="checkbox"/>		See revised text.		
44-major	7	Para 5.4.2: Activities covered by the SNS may be much more extensive than experiment/research - "work" would be more appropriate here (3 occurrences)	<input checked="" type="checkbox"/>		See revised text.		
45-minor	7	Para 5.4.2: Lines 4 and 5, change to "As appropriate, in-process entries shall provide..."	<input checked="" type="checkbox"/>		See revised text.		
46-major	7	Para 5.4.2: Line 9, unclear - what prerequisite What provisions?	<input checked="" type="checkbox"/>		This refers to Project prerequisites, which tend to change and therefore are not fixed for identification in a QMP.		<i>As changed</i>

ification in a QMP.

YMP-USGS REVIEW/COMMENT RESOLUTION FORM CONTINUATION SHEET

WBS #: 1.2.9.3

Document No. and Title: QMP-5.05, R2 Scientific Notebook Control of Technical Activities Page 10 of 16

Reviewer Name(s): See page 1 Governing Procedure: QMP-5.03, R4

Reviewer Signature(s): _____ Date: 3/28/90

Technical Review QA Review Other: NHP Comments

REVIEWER'S COMMENTS			RESPONSE			REVIEWER DISPOSITION FOR MAJOR COMMENTS	
COMMENT NO. MAJOR/MINOR	PAGE NO.	COMMENTS	ACCEPT	REJECT	JUSTIFICATION	ACCEPT	* REJECT
47-major	7	Para 5.4.2: Line 12, In science, samples are more often collected than used; what does used mean in this context?	<input checked="" type="checkbox"/>		See revised text.		
48-minor	8	Para 5.4.2.1: Line1, change to "...invoked in scientific...".	<input checked="" type="checkbox"/>		See revised text.		
49-minor	8	Para 5.4.2.2: Add the reference of the paragraph from the QMP-17.01.			It would not be wise to identify applicable paras from other procedures because of subsequent changes that would have to be carried into the referencing procedure.		
50-major	8	Para 5.4.2.2: 1st line insert "assigned by the QA Office" after the word "be". Also, in the 10th line the statement "No open space shall be left". This is not possible unless all pages are entirely blacked in. This doesn't achieve its purpose, as there is always a way to add, into margins, etc. if someone wanted to.	<input checked="" type="checkbox"/>		See revised text.		
51-major	8	Para 5.4.2.2: Sentence 2 makes no sense	<input checked="" type="checkbox"/>		The entire contents fo this para are requirements. Some editing was done to help with the communication of these requirements.		

YMP-USGS REVIEW/COMMENT RESOLUTION FORM CONTINUATION SHEET

WBS #: 1.2.9.3

Document No. and Title: QMP-5.05, R2 Scientific Notebook Control of Technical Activities Page 11 of 16

Reviewer Name(s): See page 1 Governing Procedure: QMP-5.03, R4

Reviewer Signature(s): _____ Date: 3/28/90

Technical Review QA Review Other: NHP Comments

REVIEWER'S COMMENTS			RESPONSE			REVIEWER DISPOSITION FOR MAJOR COMMENTS	
COMMENT NO. MAJOR/MINOR	PAGE NO.	COMMENTS	ACCEPT	REJECT	JUSTIFICATION	ACCEPT	* REJECT
52-major	9	Para 5.4.2.2: Sentence 3, at what point is bottom of page diagonalized off?	X		See revised text.	See	
53-major	8	Para 5.4.2.3: Is this mandatory hold point verified by any document? Is it stated in the SNP? Who establishes it?	X		This requirement will be deleted from this procedure. The requirement for including hold points is supposed to be addressed in the controlling document, which in this case is the Study Plan, as explained earlier in this procedure.		
54-major	8	Para 5.4.3: "Final Entries" needs to be defined in definition section.		X	The final entries were introduced in the first Para. of this procedure.		
55-major	8	Para 5.4.3: When are final entries made?		X	See revised text.		
56-major	8	Para 5.4.3: 2nd line "and the signature of a qualified technical reviewer." I don't feel that this is necessary. A Technical Report will be reviewed.		X	A technical review of the notebook is probably not as straightforward as a review of other technical documents. However, it is required by the QAPP and what it entails is indicated later in this procedure.		
57-major	8	Para 5.4.4: Last line, delete Parentheses.		X	See revised text.		
58-major	9	Para 5.5: line3, states the technical review will be in accordance with QMP-3.07, then gives the minimum review criteria in para 5.5.2. Change 5.5 to state "...in accordance with QMP-3.07 and section 5.5.2 of this QMP."		X	See revised text.		

J. S. [Signature]
 POC
 CHANGE PAGES
 10/25/90

MC
PC

YMP-USGS REVIEW/COMMENT RESOLUTION FORM CONTINUATION SHEET

WBS #: 1.2.9.3

Document No. and Title: QMP-5.05, R2 Scientific Notebook Control of Technical Activities Page 12 of 16

Reviewer Name(s): See page 1 Governing Procedure: QMP-5.03, R4

Reviewer Signature(s): _____ Date: 3/28/90

Technical Review QA Review Other: NHP Comments

REVIEWER'S COMMENTS			RESPONSE		REVIEWER DISPOSITION FOR MAJOR COMMENTS		
COMMENT NO. MAJOR/MINOR	PAGE NO.	COMMENTS	ACCEPT	REJECT	JUSTIFICATION	ACCEPT	REJECT
59-major	9	First line, substitute "work" for "experiment"	x		See revised text.	All ↓ X. W. [unclear] for [unclear]	
60-major	9	Para 5.5.1: Timing of SN review not stated.	x		See revised text.		
61-major	9	Para 5.5.1: last sentence, unclear that technical review is always appropriate. Why have a technical review of an entry that may be nothing more than two signatures.	x		See revised text.		
62-major	9	Para 5.5.2: line 1, specify what is being reviewed.	x		See revised text.		
63-major	9	Para 5.5.2: 1st bullet with this statement the reviewer is required to know the content of the SP or the SIP. This requirement may be impractical or impossible to comply with. This should be the responsibility of the PI, Section Chief, Program Chief, or the QA Manager.	x		See revised text.		
64-major	9	Para 5.5.2: 4th bullet-How can you reference procedures for a Scientific Notebook Plan? Supposedly, the procedure has not been determined yet.	x		The procedures referred to here are those independent procedures that might cover portions of the work being done.		
65-major	9	Para 5.5.2: 8th bullet-change to "environmental"	x		See revised text.		
66-major	9	Para 5.5: 1st line- the word "entries" may mislead an auditor into thinking the notebook itself is reviewed. This would be a data review, and should not be described here.	x		See revised text.		

YMP-USGS REVIEW/COMMENT RESOLUTION FORM CONTINUATION SHEET

WBS #: 1.2.9.3

Document No. and Title: QMP-5.05, R2 Scientific Notebook Control of Technical Activities Page 13 of 16

Reviewer Name(s): See page 1 Governing Procedure: QMP-5.03, R4

Reviewer Signature(s): _____ Date: 3/28/90

Technical Review QA Review Other: NHP Comments

REVIEWER'S COMMENTS			RESPONSE			REVIEWER DISPOSITION FOR MAJOR COMMENTS	
COMMENT NO. MAJOR/MINOR	PAGE NO.	COMMENTS	ACCEPT	REJECT	JUSTIFICATION	ACCEPT	* REJECT
67-major	9	Para 5.6: How is the QA representative "qualified"? This term is very vague and subject to wide interpretation.		<input checked="" type="checkbox"/>	The QA Program has definite training requirements to perform work under the auspices of the QA Office. Because the requirements for reviewing vary with the review, the matter of reviewer qualification is left to the QA Manager. To specify the qualifications in this procedure would be unnecessarily restrictive.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
68-major	10	Earlier comments re "Work environment conditions"	<input checked="" type="checkbox"/>		See revised text.	<input checked="" type="checkbox"/>	
69-minor	10	Line 4, not an appropriate part of SNP	<input checked="" type="checkbox"/>		See revised text.	<input checked="" type="checkbox"/>	
70-major	10	Line 5, Impacts to natural barriers very specialized consideration. Inappropriate to most studies.	<input checked="" type="checkbox"/>		See revised text.	<input checked="" type="checkbox"/>	
71-major	10	Para. 5.6, line 4 states the technical review be in accordance with QMP-3.07 then gives the minimum review criteria in section 5.6.2. Change 5.6 to state "...in accordance with QMP-3.07 and section 5.5.2 of this QMP".	<input checked="" type="checkbox"/>		See revised text.	<input checked="" type="checkbox"/>	
72-major	10	Para 5.6.1: Line 2, Change to "...by the preparer in cooperation with the YMP-USGS..." Resolution of problems should be a cooperative effort.	<input checked="" type="checkbox"/>		See revised text.	<input checked="" type="checkbox"/>	
73-major	10	Para 5.6.1: Responsibility for assembling review materials is unspecified.	<input checked="" type="checkbox"/>		See revised text.	<input checked="" type="checkbox"/>	

YMP-USGS REVIEW/COMMENT RESOLUTION FORM CONTINUATION SHEET

WBS #: 1.2.9.3

Document No. and Title: OMP-5.05, R2 Scientific Notebook Control of Technical Activities Page 14 of 16

Reviewer Name(s): See page 1 Governing Procedure: OMP-5.03, RA

Reviewer Signature(s): _____ Date: 3/28/90

Technical Review QA Review Other: NHP Comments

REVIEWER'S COMMENTS			RESPONSE			REVIEWER DISPOSITION FOR MAJOR COMMENTS	
COMMENT NO. MAJOR/MINOR	PAGE NO.	COMMENTS	ACCEPT	REJECT	JUSTIFICATION	ACCEPT	* REJECT
74-major	10	Para 5.6.2: Line 7, Its not stated what is being reviewed.	<input checked="" type="checkbox"/>		See revised text.	<input checked="" type="checkbox"/>	
75-major	10	Para 5.6.2: is a waste of time and space. All that needs to be said is that review needs to assure that the SMP is filled out completely and appropriately.	<input checked="" type="checkbox"/>		See revised text.	<input checked="" type="checkbox"/>	
76-major	10	Para 5.6.2 is maintained largely in its present form it requires much editing for clarity to say what it apparently is supposed to say.	<input checked="" type="checkbox"/>		See revised text.	<input checked="" type="checkbox"/>	
77-major	10	Para 5.6.2: 3rd bullet; further define "others".	<input checked="" type="checkbox"/>		See revised text.	<input checked="" type="checkbox"/>	
78-major	10	Para 5.9: Why 45 day intervals? Why not 90 day or 180 day intervals? Why not at the conclusion of the research? Last sentence of the request is unreasonable and unnecessary.	<input checked="" type="checkbox"/>		See revised text for most of this comment, The last sentence concerning further entries after the record is submitted is	<input checked="" type="checkbox"/>	
79-major	11	Line 1, earlier comments "Work Environment Conditions" apply her too. ^{Justification} Author rejects for same reason that was given to Comment # 33. ←	<input checked="" type="checkbox"/>		deemed necessary to preserve the accuracy of the record that has already been submitted to the LRC.	<input checked="" type="checkbox"/>	
80-major	11	Para 5.7: Line 2, delete "be used and"	<input checked="" type="checkbox"/>		See revised text.	<input checked="" type="checkbox"/>	
81-major	11	Para 5.7: Line 5, insert "if needed" before "with appropriate...", otherwise it implies that as one can ever do an acceptable job the first time around.	<input checked="" type="checkbox"/>		See revised text.	<input checked="" type="checkbox"/>	
82-major	11	Para 5.8: State clearly the qualities that make technical procedures appropriate.	<input checked="" type="checkbox"/>		The word "appropriate" does not appear in this paragraph.	<input checked="" type="checkbox"/>	

J. Wilcox
for Wilcox
 Also For PETERS
 475.
 MRS J.W.
 10/2/90

YMP-USGS REVIEW/COMMENT RESOLUTION FORM CONTINUATION SHEET

WBS #: 1.2.9.3

Document No. and Title: QMP-5.05, R2 Scientific Notebook Control of Technical Activities Page 15 of 16

Reviewer Name(s): See page 1 Governing Procedure: QMP-5.03, R4

Reviewer Signature(s): _____ Date: 3/28/90

Technical Review QA Review Other: NHP Comments

REVIEWER'S COMMENTS			RESPONSE			REVIEWER DISPOSITION FOR MAJOR COMMENTS	
COMMENT NO. MAJOR/MINOR	PAGE NO.	COMMENTS	ACCEPT	REJECT	JUSTIFICATION	ACCEPT	* REJECT
83-minor	11	Para 5.8: Lines 3, 4, and 5, several items need to be in upper case.			See revised text.	AK	
84-major	11	Para 5.8, Line 5, delete "implementing".			See revised text.		
85-major	11	Para 5.9, Line 1, Specify type of notebook, "of scientific notebook".			See revised text.		
86-major	12	Para 5.6: Investigators should not have to justify lack of activity at end of 45 days just state that there was none.			See revised text.		
87-major	12	Para 5.10, Line 1, specify what document.			See revised text.		
88-major	12	Para 5.10: Line 2, Editing clarifies meaning, "...shall either be the date of approval..."			See revised text.		
89-minor	12	Para 6.2: Line 2, specify the time period.			See revised text.		
90-major	12	Para 6.2: Line 4, Who will compile QA Record Package?			See revised text.		
91-major	13	Para 6.2: Line 1, delete "Individual Records: "; Line 3, change to "letter stating there are no entries"; line 5 change "experiment" to "work". These editorial changes have previously been justified.			See revised text.		
92-major	13	Para 6.2: delete 4th bullet; see previous comment			See revised text.		

12/90

YMP-USGS REVIEW/COMMENT RESOLUTION FORM CONTINUATION SHEET

WBS #: 1.2.9.3

Document No. and Title: OMP-5.05, R2 Scientific Notebook Control of Technical Activities Page 16 of 16

Reviewer Name(s): See page 1 Governing Procedure: OMP-5.03, R4

Reviewer Signature(s): _____ Date: 3/28/90

Technical Review QA Review Other: NHP Comments

REVIEWER'S COMMENTS			RESPONSE			REVIEWER DISPOSITION FOR MAJOR COMMENTS	
COMMENT NO. MAJOR/MINOR	PAGE NO.	COMMENTS	ACCEPT	REJECT	JUSTIFICATION	ACCEPT	REJECT
93-major	Att1	Para 4.0: If the author must include all personnel does the SNP need revision each time a new person gives input to the method. This would be very impractical and unnecessary.	<i>[Handwritten mark]</i>		No change needed here, because this procedure allows the type of change mentioned to be noted as an in-process entry. Except for the PI, rarely would a person's name be used.	<i>AK</i>	
94-major	Att1	Para 4.0: Lines 2 and 3, place a period after Investigator and delete the rest of the sentence.		<i>[Handwritten mark]</i>	The intent here is to communicate the scope of the workers and what type of workers are expected to be involved.	<i>AK</i>	
95-major	Att1	Para 5.2: This is inappropriate in an environment where the work is to set up equipment and develop procedures. The equipment should be calibrated before QA affecting work is started. The purpose of the work may be to develop calibration techniques-in this case the requirements can't be stated or complied with beforehand.	<i>[Handwritten mark]</i>		See revised text.		
96-minor	Att1	Para 5.2.2: Change to "Calibration procedure is (13).." to improve meaning.	<i>[Handwritten mark]</i>		See revised text.		
97-major	Att1	Para 8.0: Totally unclear what "work environment conditions" means.	<i>[Handwritten mark]</i>		See revised text.		
98-major	Att1	Para 9.0: SNP is not a technical procedure.	<i>[Handwritten mark]</i>		See revised text.		
99-major	Att1	Para 9.0: Insert "no document superseded" option in this paragraph.	<i>[Handwritten mark]</i>		See revised text.		

YMP-USGS REVIEW/COMMENT RESOLUTION FORM

Document Title: OMP-5.05, R2 Scientific Notebook Control of Technical Activities

Reviewer Name: Virginia M. Glanzman

WBS#: 1.2.9.3
QA: QA

Reviewer Signature: Virginia M. Glanzman

Date: 12/7/89

REVIEWER'S COMMENTS			RESOLUTION			* REVIEWER DISPOSITION FOR MAJOR COMMENTS	
COMMENT NO. MAJOR/MINOR	PAGE NO.	COMMENTS	ACCEPT	REJECT	REASONING	ACCEPT	REJECT
1-	all	This QMP is confusing. The text switches back and forth between descriptions of the Scientific Notebook Plan and the Scientific Notebook itself. It is doubtful that someone newly assigned to work on the Yucca Mountain project would be able to read through this procedure and know who to do.	AP		This comment will be kept in mind as future revisions are made.		
2-edit.	2-5-234	To make the first sentence grammatically correct, a comma should be inserted following "basis" in first line; "and is" should be inserted before "used" in the second line.	AP				
3-major		Section 5 and throughout the procedure: Change "technical implementing procedure" to "technical procedure". The two terms are used interchangeably throughout this procedure, which may be confusing to new personnel assigned to YMP work. Section 5 twice refers to the "technical implementing procedure". The definition under Section 3.7 defines "technical procedure".		x AP	Rejected because of QA Office determination that this procedure will immediately undergo another revision requiring a review at which time this comment will be considered.		AP
4-minor		Section 5.2: Add "...in this procedure" following "...as described" at the end of the third sentence. Delete comma following "results" in last sentence.	AP				

* Rejection of resolution is found to be justified:

NA

GD Branch/NHP Chief/TPO/QA Manager Date

GS-80.A.001629

YMP-USGS REVIEW/COMMENT RESOLUTION FORM

Document Title: QMP-5.05, R2 Scientific Notebook Control of Technical Activities

WBS#: 1.2.9.3
QA: QA

Reviewer Name: Virginia M. Glanzman

Reviewer Signature: See page 1 of 4

Date: 12/7/89

REVIEWER'S COMMENTS			RESOLUTION			* REVIEWER DISPOSITION FOR MAJOR COMMENTS	
COMMENT NO. MAJOR/MINOR	PAGE NO.	COMMENTS	ACCEPT	REJECT	REASONING	ACCEPT	REJECT
5-major		Section 5.4.1.2: Second sentence states that modifications will be approved by a reviewer "... qualified and directed by the PI...". This statement conflicts with Sections 4.4 and 5.5, which assign responsibility for certification and direction of reviewers to the GD Branch/NHP Chief.		DDP	See response to Comment #3.		Very
6-major		Section 5.4.2: Second line, change the word "procedure" to "experiment/research". The notebook records activities of the experiment not the procedure. Seventh bullet, add "interim" preceding the word location. The in-process entry will only show the interim location of the data prior to final submittal of the data to the LRC.	x	DDP			
7-major		Section 5.4.2.2: This section is very confusing. The second sentence (ninth line of paragraph) implies that the experiment will be signed off on a daily basis, however, section 5.4.2 does not discuss daily signoff of entries. If daily sign-off is to be required it should be stated under 5.4.2. The subject sentence is made additionally confusing because of the reference to the LRC.		DDP	See comment response for comment #3.		Very

* Rejection of resolution is found to be justified:

NA

GD Branch/NHP Chief/TPO/QA Manager Date

YMP-USGS REVIEW/COMMENT RESOLUTION FORM

Page 3 of 4

Document Title: OMP-5.95, R2 Scientific Notebook Control of Technical Activities

WBS#: 1.2.9.3

Reviewer Name: Virginia M. Glanzman

QA: QA

Reviewer Signature: See page 1 of 4

Date: 12/7/89

REVIEWER'S COMMENTS			RESOLUTION			* REVIEWER DISPOSITION FOR MAJOR COMMENTS	
COMMENT NO. MAJOR/MINOR	PAGE NO.	COMMENTS	ACCEPT	REJECT	REASONING	ACCEPT	REJECT
7-cont'd		One can understand the restriction to changes after the quarterly submittal to the LRC as outlined in Section 5.9, however, the sentence is ambiguous as to whether changes can be made after daily signoff. Furthermore, Section 5.9 requires submittal of copies to the LRC every 90 days, but does not specify that entries must be signed off for an on-going experiment. The last sentence does not belong in this section. It should be moved to section 5.4.3 FINAL ENTRIES.					
8-major		Section 5.4.4: The parenthetical statement "(or included in a technical report)" should be deleted. The statement can be misinterpreted to require discussion as outlined in the following sentence of the procedure to be included in a technical report (i.e., publication). Such discussion may not be appropriate in the publication, especially page restrictive journal articles.		PP	We had previously worded this paragraph to avoid any interpretation that such documentation might have to be done in a technical report. How can this parenthetical statement beginning with "or" be interpreted as requiring details of the final entry be put in a technical report?		
9-major		Section 5.5: This paragraph is also very confusing. It appears to be mixing technical review of the		PP			

For next revision, use statement in QA PP.

* Rejection of resolution is found to be justified:

CD Branch/NHP Chief/TPO/QA Manager

Date

NA

YMP-USGS REVIEW/COMMENT RESOLUTION FORM

Document Title: QMP-5.05, R2 Scientific Notebook Control of Technical Activities

WBS#: 1.2.9.3

Reviewer Name: Virginia M. Glanzman

QA: QA

Reviewer Signature: See page 1 of 4

Date: 12/7/89

REVIEWER'S COMMENTS			RESOLUTION			* REVIEWER'S DISPOSITION FOR MAJOR COMMENTS	
COMMENT NO. MAJOR/MINOR	PAGE NO.	COMMENTS	ACCEPT	REJECT	REASONING	ACCEPT	REJECT
9-cont'd.		<p>plan and technical review of the notebook. The first sentence refers to Scientific Notebook Plan final entries. The plan is signed off before the start of work, thus, there are no final entries to the plan. If "final entries" is deleted from the first sentence, the entire paragraph with the exception of the last sentence would apply to the plan. However, if "plan" is deleted from the sentence, the paragraph appears to go back and forth between discussing the plan and the notebook. As in my previous comments regarding this QMP (April 1989), I am disturbed by the requirement of a technical review for the notebook. In essence, a reviewer is being asked to review raw data. The verification activity required under section 5.4.2.3 will review the notebook "...to demonstrate that (1) the technical objectives of the investigation are being or have been adequately addressed by the work performed and (2) the investigation complies with all appropriate and applicable QA documentation requirements." (quote</p>					

from OMP-3.10). To require and additional technical review of the notebook is redundant.

* Rejection of resolution is found to be unjustified.

NA

GD Branch/NIIP Chief/TPO/QA Manager Date

97763 1521

YMP-USGS REVIEW/COMMENT RESOLUTION FORM

Document Title: YMP-USGS-QMP-5.05, R2 Scientific Notebook Control of Technical Activities

WBS#: 1.2.9.3

Reviewer Name: Joseph V. Barth

QA: QA

Reviewer Signature: Joseph V. Barth

Date: 11 April 90

REVIEWER'S COMMENTS			RESOLUTION			* REVIEWER DISPOSITION FOR MAJOR COMMENTS	
COMMENT NO. MAJOR/MINOR	PAGE NO.	COMMENTS	ACCEPT	REJECT	REASONING	ACCEPT	REJECT
		No comment for Barth (see Gray Glossary comments)					

* Rejection of resolution is found to be justified:

NA

GD Branch/NHP Chief/TPO/QA Manager Date

BB-50-A-0072B

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NHP-USGS REVIEW/COMMENT RESOLUTION FORM

WBS #: 1.2.9.3
QA: QA

Document No. and Title: QMP-5.05, R2 Scientific Notebook Control of Technical Activities

Page 1 of 3

Reviewer Name(s): Peggy Warner - Record Coordinator

Reviewer Signature(s): *Peggy Warner*

Date: 12/7/89

REVIEWER'S COMMENTS			RESOLUTION			* REVIEWER REPOSITIONS FOR MAJOR COMMENTS	
COMMENT NO. MAJOR/MINOR	PAGE NO.	COMMENTS	ACCEPT	REJECT	REASONING	ACCEPT	REJECT
Major #1	10	Para. 5.9 first line - fourth word delete "the", insert <u>entries</u> after "notebook" - insert before "at" at 45 day intervals following the first entry and the entire book ^{12/7/89} notebook - second line, place a period after "activity" and delete the remainder of the sentence - fourth line, insert after "and" subsequently by the RA Office	<i>JP</i>		<i>DP.</i> You have the full record via the periodic copy submitted. If you want the original, ask for it at the conclusion of the work.	<i>JPW</i>	
Major #2	10	Add a new sentence at the end of 5.9 should no entries be made during a 45 day interval, the PI shall send a letter to the RA Office which explains the reasons (eg. travel, weather, other activity priority).		<i>JP</i>		<i>JPW</i>	

NA

* Rejection of resolution is found to be justified:

GD Branch/NHP Chief/TPO/QA Manager Date

GS-90-A-001622

YMP-USGS REVIEW/COMMENT RESOLUTION FORM

Document Title: YMP-USGS-QMP-5.05, R2 Scientific Notebook Control of Technical Activities

WBS#: 1.2.9.3
QA: QA

Reviewer Name: Peggy J. Warner - Records Coordinator

Reviewer Signature: Peggy J Warner Date: 3/5/90

*Note: Acceptance actually conducted 5/9/90 the date below is the actual initial date.

REVIEWER'S COMMENTS			RESOLUTION		* REVIEWER DISPOSITION FOR MAJOR COMMENTS		
COMMENT NO. MAJOR/MINOR	PAGE NO.	COMMENTS	ACCEPT	REJECT	REASONING	ACCEPT	REJECT
Major 1	5	Para. 5.3 - all at the end of the paragraph "Note: "NWM" represents Nuclear Waste Management "HP" represents Hydrologic Procedure GP represents GCP represents GPP represents (fill in as appropriate) SP represents		DP	These details are given in QMP-6.01 + would not be particularly helpful here.		DP 5/9/90
Major 2	8	Para. 5.4.3 insert after "minimum," - "the date and"...		DP			DP 5/9/90
Major 3	8	Para. 5.4.4. insert in the third line, after "technical report" - "reference QMP-3.04"		DP	The reference to "technical reports" is in a general sense here. Comment is not applicable.		DP 5/9/90

* Rejection of resolution is found to be justified: NA
GD Branch/NHP Chief/TPO/QA Manager: _____ Date: _____

BS-90-A-001729

YMP-USGS REVIEW/COMMENT RESOLUTION FORM

Document Title: YMP-USGS-QMP-5.05, R2 Scientific Notebook Control of Technical Activities

Page 2 of 4

Reviewer Name: Peggy J. Warner - Records Coordinator

WBS#: 1.2.9.3

Reviewer Signature: Peggy J. Warner

QA: QA

Date: 3/5/90

REVIEWER'S COMMENTS			RESOLUTION			* REVIEWER DISPOSITION FOR MAJOR COMMENTS	
COMMENT NO. MAJOR/MINOR	PAGE NO.	COMMENTS	ACCEPT	REJECT	REASONING	ACCEPT	REJECT
Minor 4	9	Para. 5.5.1 - fifth line after "shall be" insert " <u>conducted</u> "		DP	This sentence was deleted from the Procedure.	DP 10/9/90	
Minor 5	10	Para. 5.5.2 - second bullet - place a comma after "conditions"		DP	this bullet line was deleted from the procedure.	DP 10/9/90	
Major 6	11	Para. 5.8 - last sentence, insert " <u>superseded</u> " after "corresponding" - place a period after "notebook" - delete the remainder of the line		DP		DP 10/9/90	

NA

* Rejection of resolution is found to be justified:

GD Branch/NHP Chief/TPO/QA Manager Date

Document Title: YMP-USGS-OMP-5.05, R2 Scientific Notebook Control of Technical Activities

WBS#: 1.2.9.3
QA: QA

Reviewer Name: Peggy J. Warner - Records Coordinator

Reviewer Signature: Peggy J. Warner Date: 3/5/90

REVIEWER'S COMMENTS			RESOLUTION			* REVIEWER DISPOSITION FOR MAJOR COMMENTS	
COMMENT NO. MAJOR/MINOR	PAGE NO.	COMMENTS	ACCEPT	REJECT	REASONING	ACCEPT	REJECT
Major 12	11	Para. 5.9 - title this paragraph - "Interim Technical Data Record Protection"	JP			JP	
Minor 13	12	Para. 5.9 first line - delete "for filing"	JP			JP	
Major 14	12	Para. 5.9 - last sentence, insert after the comma following "interim" - "it is recommended that" - delete the word "shall" - insert after letter "of explanation" - insert "in lieu of the notebook copy" after	JP	JP	This sentence has been deleted from the procedure.	JP	

* Rejection of resolution is found to be justified: NA
GD Branch/NHP Chief/TPO/QA Manager Date

MEETING ATTENDANCE ROSTER

Topic: OMP-5.05 R2 Concurrence Meeting Date 10/5/00

Location: SAR

Conducted by:

Subject: OMP-5.05 R2 DEMT

Printed Name	Signature	Employer (incl. Div.)	Title	Phone #
Marie E. Deussen	Marie E. Deussen	SAR/Jan OMP Coord.		239 7212
Virginia M. Glazant	Virginia M. Glazant	USGS/ED	Field	214-1247
Alan Riggs	Alan Riggs	USGS/WRD	Hydrologist	6-5182
Therap. Menden-Veg	Therap. Menden-Veg	USGS/WRD	AA	229-7212
Tam Cooney	Tam Cooney	USGS/WRD	Asst. Chief	6-1718
Marie E. Deussen	Marie E. Deussen	USGS/WRD	Asst. Chief	6-1718
Lee Barr	Lee Barr	USGS/WRD	QA Spec	6-1374
Tom Menden	Tom Menden	USGS/WRD	QA spec.	6-4547

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