

ROCKY FLATS PLANT
ERM ADMINISTRATIVE
PROCEDURES MANUAL
CATEGORY 1

Manual No.: 2-11000-ER-ADM
(a.k.a. 3-21000-ADM)
Procedure No.: Table of Contents, Rev 19
Page: 1 of 2
Effective Date: 07/15/94
Organization: Environmental Restoration

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FOR
ENVIRONMENTAL RESTORATION MANAGEMENT
ADMINISTRATIVE PROCEDURES MANUAL

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ADDITIONAL INFORMATION
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EG&G
SUPERSEDED
DOCUMENT

DOCUMENT CLASSIFICATION REVIEW WAIVER
PER R.B. HOFFMAN, CLASSIFICATION OFFICE
JUNE 11, 1991

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08.01	Control and Identification of Items, Samples, and Data	0	04/08/92
10.01	Inspections	0	04/08/92
12.01	Control of Measuring and Test Equipment	0	04/08/92
15.01	Control of Nonconforming Items and Activities	1	10/12/92
16.01	Corrective Action	0	04/08/92
17.01	Quality Assurance Records Management	0	02/28/92
94-DMR-000778	Text Addition and Section Number Modification	0	04/29/94
94-DMR-001200	Extension and Incorporation of DCN 93.02	0	06/23/94
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18.02	Surveillance Activities	1	04/08/92
18.03	Readiness Review	0	08/02/91
•18.05	2-G23-ER-ADM-18.05 Environmental Restoration Management Self Evaluation	0	07/15/94
AQD.08	Preparation of EPA Form R	1	10/10/91

ROCKY FLATS PLANT

2-G06-ER-ADM-05.10

REVISION 0

CONTROL OF SCIENTIFIC NOTEBOOK SYSTEMS

APPROVED BY: *S.G. Stiger* *S.G. Stiger* *15-19-94*
 Associate General Manager, Print Name Date
 EG&G Environmental Restoration Management

APPROVED BY: *K. Bentzen* *K. Bentzen* *10/18/94*
 Quality Assurance Program Manager, Print Name Date
 EG&G Environmental Restoration Management

CONCURRENCE BY: *NA NOT REQUIRED* */*
 Assistant Manager, Print Name Date
 Environmental Restoration Division
 DOE Rocky Flats Field Office

Environmental Protection Agency Approval Required: Yes No

Responsible Organization: Environmental Restoration Management Effective Date: *7-15-94 lmc*

CONCURRENCE BY THE FOLLOWING DISCIPLINES WILL BE DOCUMENTED IN THE PROCEDURE HISTORY FILE:

- ERM Remediation Project Management
- ERM Environmental Engineering and Technology
- ERM Environmental Operations Management
- ERM Environmental Quality and Document Systems
- ERM Solar Pond Project
- ERM Sample Management
- ERM Program Integration and Reporting
- ERM Geosciences
- Standards, Audits, and Assurance

USE CATEGORY 4

ORC review not required

Periodic review frequency: 1 year from effective date

DOCUMENT CLASSIFICATION REVIEW WAIVER
PER R.B. HOFFMAN, CLASSIFICATION OFFICE
JUNE 11, 1991

LIST OF EFFECTIVE PAGES

<u>Pages</u>	<u>Effective Date</u>	<u>Change Number</u>
1-24	<u>07 / 15 / 94</u> <i>lme</i>	n/a

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1. PURPOSE

This procedure defines the requirements for identification, review, approval, modification, and documentation of the Scientific Notebook System (SNS) in experimental and research work. The SNS provides for the development of a Scientific Notebook Plan and the use of a Scientific Notebook to record methods and data in support of Environmental Restoration Management (ERM) activities in lieu of procedures.

2. SCOPE

This procedure applies to ERM quality-affecting experimental or research activities such as those requiring professional judgement, trial-and-error methods, or developing methodology. This procedure does not apply to activities that can be conducted effectively through utilization of procedures or instructions. This procedure does not apply to the field logbooks or notebooks used throughout the program but only to those Scientific Notebooks that use the controls of this SNS in lieu of other procedures and that are generated in accordance with this procedure. Subcontractors with approved Quality Assurance (QA) programs may operate to their own requirements rather than to this procedure.

This process may only be implemented under an existing ERM work plan (2-E20-ER-ADM-05.09, Work Plan Development to be issued) and the project-specific health and safety plan. All activities fall within the scope of the project-specific health and safety plan. Modifications to or deviations from the health and safety plan cannot be made under this procedure.

This procedure addresses the following topics:

- Selection of procedure approach
- Scientific Notebook Plan
- Scientific Notebook preparation
- Scientific Notebook review
- Conversion from the SNS
- Technical data record protection

3. DEFINITIONS

Experiments. Operations carried out under controlled conditions to establish characteristics or values not previously known.

Hold Point. A point in the procedure requiring independent verification (normally by quality control) before proceeding to the next step. This independent verification is normally documented on the applicable data sheet or notebook.

Quality Assurance Program Manager (QAPM). The manager designated by the Associate General Manager (AGM) for ERM who is responsible for the implementation of the ERM QA program.

Research. A systematic inquiry or extensive investigation into a subject area in order to discover, revise, or prove theories, knowledge, etc. Research often requires the development of new methodologies.

Scientific Notebook. A QA record maintained by an investigator and used to record the details of events, activities, and pertinent assessments made of an investigation in accordance with this procedure. The system may include computer-based files and bound records.

Scientific Notebook Plan. A controlled document that describes the experimental or research approach and requirements that are applicable to projects.

Scientific Notebook System (SNS). The flexible documentation of technical activities used in lieu of a technical procedure or instruction. The SNS is used to provide a record of the methodologies and results of scientific investigations and experiments when work involves professional judgement, trial-and-error methods, or emerging technologies developed as an investigative activity progresses.

Work Plan. A document that describes the technical nature of the work to be accomplished and that incorporates the appropriate QA requirements and methods.

4. RESPONSIBILITIES

4.1 ERM Document Control

Ensures that control numbers and an inventory of controlled documents are maintained.

Maintains control of the Scientific Notebook Plan.

4.2 Principal Investigator (PI) or Designee

Identifies the need for using the SNS, including the type of notebook.

Prepares the appropriate Scientific Notebook Plan and Scientific Notebook in accordance with this procedure.

Determines and documents the need for a revision or modification of the Scientific Notebook Plan.

Coordinates the review and approval process.

4.3 Project Manager (PM)

Concurs with the use of the SNS and signs the Scientific Notebook Plan.

Assigns the technical reviewer for the Scientific Notebook Plan and the notebook when the investigation is completed.

Resolves conflicts between the reviewer(s) and the PI.

Selects the PI for an activity, in conjunction with the Responsible Manager, based on the training and qualification requirements.

Ensures that all personnel working under the SNS are trained in the applicable requirements of this procedure and any procedures or instructions associated with the implementation of this activity.

Ensures that all personnel have read the applicable Scientific Notebook Plan.

4.4 QAPM

Reviews and approves the use of the SNS and the Scientific Notebook Plan.

4.5 Technical Reviewer

Conducts and documents a peer review of the Scientific Notebook Plan and the contents of the Scientific Notebook.

4.6 Responsible Manager

Provides management support to the PM in the implementation of this procedure, including:

- Preparation of documentation.
- Conflict resolution.
- Training and qualification of personnel.
- Other support, as necessary.

4.7 Environmental Operations Management (EOM)

Reviews the Scientific Notebook Plan.

5. INSTRUCTIONS

5.1 Selection of Procedure Approach

NOTE *Three systems may be used for the quality assurance documentation and control of scientific work implemented as specified in the applicable ERM work plan:*

- *The procedure as described in 2-E95-ER-ADM-05.01, Procedure Development*
- *The instructions as described in 2-G07-ER-ADM-05.11, Preparation of Instructions*
- *The SNS*

This procedure addresses the SNS system. Even when implementing the SNS system, existing or new procedures or instructions are used to the extent practicable to implement the activities.

PM and Responsible Manager

- [1] Select a PI for the activity based on the qualification requirements.

Qualification requirements include:

- A college degree (BS, MS, or PhD) and at least 1 yr of field experience relating to the area of scientific investigation being addressed by the SNS.
- Training in the implementation of this procedure before initiating the SNS process.

PI

- [2] Evaluate the activity before beginning technical work on quality-related activities to determine which type of documentation and control system will be used for the technical work.

The evaluation is based on the work plan and/or other available information.

5.1 Selection of Procedure Approach (continued)

PI(continued)

- [3] Identify the decision to use the SNS process in the work plan or in a modification of the work plan.

Such a modification requires a review by the applicable regulatory oversight agencies (U.S. Department of Energy [DOE], U.S. Environmental Protection Agency [EPA], or the Colorado Department of Health [CDH]) in accordance with

2-E04-ER-ADM-05.07, Preparation of Document Modification Requests or 2-E20-ER-ADM-05.09, Work Plan Development.

5.2 Scientific Notebook Plan

PI

- [1] Prepare a Scientific Notebook Plan.

An example is provided in Appendix 1, ERM Scientific Notebook Plan. As appropriate, the topics listed below will be addressed to justify the use of the SNS process and to document the necessary planning for implementation. The topics will be addressed by reference to existing documents. The detail to which topics are addressed is limited to the information existing during the planning process, as follows:

- Title of the experiment or research
- Description of the experiment's purpose and objectives (Section 1, Appendix 1)
- Description of the proposed approach or methods and required prerequisites to the activity (Section 2, Appendix 1) (The description may include references to the appropriate work plan and other implementing documents and may identify exceptions taken to existing control system such as those for sample control.)
- The analytical models which are currently identified for use in this investigation (Section 2, Appendix 1) (2-G03-ER-ADM-03.01, Verification and Control of Calculations and Technical Reports.)
- Applicable hold points, if any (Section 2, Appendix 1)
- Ongoing table of contents of the SNS, such as which portions of the SNS are computerized and/or digital file directories/subdirectories in 3-ring binders. (Section 2, Appendix 1)
- Name(s) of qualified individual(s) performing the work activity (Section 3, Appendix 1)
- Special personnel qualifications or training requirements (Section 3, Appendix 1)

5.2 Scientific Notebook Plan (continued)

PI (continued)

- Equipment and materials to be employed during the experiment or research, including any necessary fabrication of experimental equipment and any other needed materials (Section 4, Appendix 1)
- Calibration requirements (Section 4, Appendix 1)
- Potential sources of uncertainty and error in data or measurements (Section 5, Appendix 1)
- Historical data that are suspect or whose quality is beyond the control of the PI (Section 6, Appendix 1)
- The data reduction and qualification procedures to be used based on available data (2-G03-ER-ADM-03.01), (Section 6, Appendix 1)
- Required levels of precision and accuracy in data and measurements (Section 6, Appendix 1)
- Documentation of suitable and controlled environmental conditions (Section 7, Appendix 1)
- Dated signature of the preparer of the plan

QAPM, EOM, and Technical Reviewer

- [2] Review and approve the Scientific Notebook Plan, in accordance with 2-E02-ER-ADM-05.05, Document Review.

The reviewers address the applicability of the SNS and the adequacy of the Scientific Notebook Plan.

PM

- [3] Resolve conflicts between the reviewer(s) and the PI.

In some cases the PI and the PM may be the same individual. When this occurs, the Responsible Manager will resolve conflicts between the reviewer(s) and the PI. The Responsible Manager's concurrence is required to use the SNS.

ERM Document Control

- [4] Issue the approved Scientific Notebook Plan as a controlled document in accordance with 2-G01-ER-ADM-06.01 to the user, the QAPM, and the PI and/or the PM before commencing technical work.

5.2 Scientific Notebook Plan (continued)

PM

- [5] Ensure that all personnel are trained in the use of this procedure and the applicable Scientific Notebook Plan.

PI

- [6] Place a controlled copy of the approved Scientific Notebook Plan and the Scientific Notebook in the work area or in another accessible location.
- [7] Implement the task as described in the Scientific Notebook Plan and document the tasks in the Scientific Notebook.
- [8] Reference in the Scientific Notebook any applicable documents supplementing the activity.
- [9] Document modifications to the process described in the Scientific Notebook Plan while the investigation is in progress.
- [A] Record the full details of the modification in the Scientific Notebook, including justification for this change.
- [B] **IF** the in-process modification is **NOT** within the scope of any applicable work plan which establishes the applicable requirements,
THEN revise the work plan in accordance with 2-E04-ER-ADM-05.07 before implementing the change.

5.3 Maintenance of Scientific Notebooks

PI

- [1] Ensure that computer-based portions of the Scientific Notebook have an access control system accessible only to trained and authorized personnel.
- [2] Provide the following information to all activity personnel:
- Location and, if applicable, access procedures for the Scientific Notebook
 - Location of the Scientific Notebook Plan and any supplemental documents
- [3] Number pages of bound portions of the Scientific Notebook consecutively up to the last page used.

5.3 Maintenance of Scientific Notebooks (continued)

PI(continued)

- [4] Ensure that the control number (Section 6, Step [2]) and the title are displayed on the first page of each volume of the Scientific Notebook or within each individual file for computerized data as the header or footer information.

- [5] **IF** more than one volume is required,
THEN obtain the additional control number from the ERM Document Control Center (DCC).

DCC

- [6] **WHEN** the PI indicates that more than one volume is required for a Scientific Notebook,
THEN assign each volume the original control number followed by -V and the volume number.

PI

- [7] Reference the new volume in the last entry of the old volume, and the old volume in the first entry on the new volume.

- [8] Retain all volumes as a single document until they are returned to the ERM DCC.

- [9] Record the following information in the Scientific Notebook, as appropriate (reference existing documents to provide this information where feasible):
 - Date and signature of the individual making the entry
 - Detailed, step-by-step description of the experiment or research being performed followed by either a reference to an implementing procedure or instruction or by an actual entry into the notebook
 - The basis for ensuring that prerequisites have been met
 - Conditions which may adversely affect the results of the experiment or research investigation
 - Identification of the samples collected or used;
 - Identification of the additional quality-affecting equipment and materials, that are not included as part of the initial entries
 - Computer software used
 - Interim conclusions

5.3 Maintenance of Scientific Notebooks (continued)

PI (continued)

- Documentation of the disposition of facilities and equipment after completion of the activity/project, particularly any contaminated equipment, facilities, or wastes
- A reference in the physical notebook of computer-based entries
- Unique identification for unbound documentation

[10] Document activities in sufficient detail to allow another qualified researcher to:

- Retrace the investigation
- Confirm the results
- Repeat the experiment and achieve the same results without recourse to the PI

[11] Make any changes to entries in the notebook in accordance with 2-G18-ER-ADM-17.01, Quality Assurance Records Management.

[12] Make ongoing entries continuous on the page with no open spaces left for subsequent entries.

Tables or similar formats used to record ongoing data are exempted from the requirement for continuous entries in Step 5.3[12].

[13] Draw lines or use a similar method to fill any blank sections in the continuous entries caused by tables or other entries in similar format, including table entries once the table is completed.

NOTE *Open space in the text could allow undetected alteration of this legal record. Steps 8 and 9 do not apply to computer-based Scientific Notebooks.*

[14] Record all entries in the Scientific Notebook (not computer based) in permanent black ink.

Permanent colored ink pens may be used for drawing schematic diagrams.

5.3 Maintenance of Scientific Notebooks (continued)

PI (continued)

- [15] **WHEN** the work described in the Scientific Notebook Plan has been completed, **THEN** close out the notebook by adding a brief summary of the work, or a statement that this concludes the Scientific Notebook, including:
- The name of the designated technical reviewer (Section 5.4).
 - The date and signature of the PI.
 - Technical review as described in Section 5.
- [16] Print the contents of computer-based Scientific Notebooks upon completion of the task for use in the review process.
- [17] Sign and date all the components of the Scientific Notebook before it is distributed for peer review.

5.4 Scientific Notebook Review

NOTE *The reviews specified below are those specifically related to Scientific Notebooks and do not replace any other reviews required under other Rocky Flats Plant (RFP) procedures or policies e.g., classification and patent office.*

Technical Reviewer

- [1] Review the completed Scientific Notebook for technical adequacy.

NOTE *Reviewers will not write in the Scientific Notebook except to:*

- *Indicate that the reviewer has reviewed the documents.*
 - *Concur that the Scientific Notebook is consistent with the requirements established in this procedure and is technically correct.*
 - *Document concerns (via signatures and dates).*
- [2] Determine if the notebook adequately documents the investigations as required by this procedure and as specified in the Scientific Notebook Plan.
- [3] Verify that the contents of Section 5.3 have been appropriately addressed.

PI and Technical Reviewer

- [4] Discuss the comments and establish a consensus markup of the notebook.

5.4 Scientific Notebook Review (continued)

PI

- [5] Document markups in the notebook with an annotation indicating the source and the basis of the change.
- [6] Ensure that any corrections made to the Scientific Notebook with concurrence by the reviewer are completed in a manner consistent with 2-G18-ER-ADM-17.01.

Technical Reviewer

- [7] **IF** the reviewer and the PI do **NOT** agree on the resolution,
THEN document the point of disagreement and sign and date the entry.

PM or Responsible Manager

- [A] Determine resolution of the discrepancies.
- [B] Sign and date the entries.
- [8] Arrange a QA review and approval of the SNS with the QAPM.

QAPM

- [9] Review and approve the SNS.

PI

- [10] Submit the reviewed and completed Scientific Notebook to ERM DCC in accordance with 2-G18-ER-ADM-17.01.

ERM Document Control

- [11] Document closure of the controlled SNS as a field document.
- [12] Submit the document to the ERM Central Records Center (CRC) in accordance with 2-G01-ER-ADM-6.01.

5.5 Conversion from the SNS (as necessary)

The SNS may be used throughout the activity. However, if the activity or an individual process within the activity has reached a mature stage, i.e., the methods will be adopted for routine use, this system will be converted to an instruction or procedure.

PI

- [1] Determine the stage at which the SNS can be converted to a technical procedure or instruction.
- [2] **IF** the activity or a significant associated process can be established as a routine, activity or process,
THEN request that the Responsible Manager generate an instruction or procedure for the activity.

Responsible Manager

- [3] Prepare the procedure or instruction in accordance with 2-E95-ER-ADM-05.01 or 2-G07-ER-ADM-05.11.
- [4] Arrange for the review and approval of the procedure or instruction in accordance with 2-E02-ER-ADM-05.05.
- [5] Reference the superseded Scientific Notebook in the new procedure or instruction.
- [6] Reference the new procedure or instruction as the final entry of the Scientific Notebook.

5.6 Technical Data Record Protection

ERM DCC

- [1] Maintain the Scientific Notebook(s) in bound hardcopies.
- [2] Maintain the Scientific Notebook Plan as a controlled document.
- [3] Ensure that the Scientific Notebook Plan and the Scientific Notebook are identified with unique numbers issued by DCC.

5.6 Technical Data Record Protection (continued)

ERM DCC (continued)

A specific unique number may be requested by the Project Manager; otherwise, these numbers will be in the form of:

- ERM-SNBP-YY-### for the plan and ERM-SNB-YY-### for the notebook, where YY is the year of issuance and ### is a unique number for the plan/notebook set.
- The existing Rocky Flats Plant data book system number may also be used to establish the control number of the notebook.

PI

- [4] Make a copy (electronic backup for computer-based SN) of the Scientific Notebook entries quarterly following the first entry or more frequently when required by the Scientific Notebook Plan.

Closed notebooks do not need to be recopied, as discussed in Step 5.6[4].

- [5] Ensure that the copies are stored in a physically separate location from the ERM CRC in accordance with 2-G18-ER-ADM-17.01.

6. RECORDS

Management of all records is consistent with 1-77000-RM-001, Records Management Guidance for Records Sources.

The Scientific Notebook Plan, the Scientific Notebooks, and any related document modifications to the SNS generated as a result of this procedure are considered quality records. These records are managed in accordance with 2-G18-ER-ADM-17.01.

When the activity being addressed by the Scientific Notebook is an IAG activity, then the corresponding Scientific Notebook records are part of the Administrative Record

In addition to 2-G18-ER-ADM-17.01, administrative records are managed in accordance with 3-21000-ADM-17.02, Administrative Records Screening and Processing.

6.0 RECORDS (continued)

PI

- [1] Ensure that the following quality-related records are transmitted to the ERM CRC in accordance with 2-G18-ER-ADM-17.01:
- Scientific Notebook Plan
 - Scientific Notebook and revisions
 - Documented modifications to the SNS
- [2] **IF** the activity being addressed by the Scientific Notebook is an IAG activity, **THEN** ensure that the associated records listed below are managed in accordance with 3-21000-ADM-17.02, **AND** transmitted to the ERM CRC in accordance with 2-G18-ER-ADM-17.01:
- Scientific Notebook Plan
 - Scientific Notebook and revisions
 - Documented modifications to the SNS

7. REFERENCES

2-G03-ER-ADM-03.01, Verification and Control of Calculations and Technical Reports
(Until issued, use 3-21000-ADM-03.01.)

2-E95-ER-ADM-05.01, Procedure Development

2-E02-ER-ADM-05.05, Document Review

2-E04-ER-ADM-05.07, Preparation of Document Modification Requests

2-E20-ER-ADM-05.09, Work Plan Development (Until issued, use 3-21000-ADM-05.09.)

2-G07-ER-ADM-05.11, Preparation of Instructions (Until issued, use 3-21000-ADM-05.11.)

2-G01-ER-ADM-06.01, Document Control (Until issued, use 3-21000-ADM-06.01.)

2-G18-ER-ADM-17.01, Quality Assurance Records Management (Until issued, use 3-21000-ADM-17.01.)

3-21000-ADM-17.02, Administrative Records Screening and Processing

APPENDIX 1

Page 1 of 6



**ERM Scientific Notebook
Plan**

ERM ID No.: _____
Page ____ of ____
Prepared by: _____
Date: _____

Title: _____

1. Description:

- Notebook Plan Title _____

- Governing Work Plan No. _____
- Governing Work Plan Title _____

- Scientific Notebook Plan purpose and objective (Provide sufficient detail to permit reviewers and others to understand what the work is to accomplish.)

