Distribution
~~WM s/f 3405~~
WMRP r/f 102
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CF
REBrowning
MJBell
PAltomare
HJMiller
JLinehan
JKennedy
RJohnson
RWright
KStablein
RBoyle
SCoplan
RCook
PPrestholt
TVerma
SBilhorn & r/f
WAltman
CWalenga
FForscher
MDelligatti
PDR
LPDR

See Pocket 3 for encl.

APR 11 1985

MEMORANDUM TO: Hubert J. Miller, Chief
Repository Projects Branch,
Division of Waste Management

THRU: James E. Kennedy, Section Leader
Repository Projects Branch,
Division of Waste Management

FROM: Susan Bilhorn
Repository Projects Branch,
Division of Waste Management

SUBJECT: REPORT FROM MARCH 1-7, 1985, TRIP TO NNWSI PROJECT OFFICE

The purpose of the subject trip was to attend, as an observer, two quality assurance activities: (1) a meeting to discuss a draft procedure for the acceptance of data or interpretations of data not generated under the NNWSI Project QA program; and (2) a QA audit of the NNWSI Project Office by DOE/OCRWM. Both activities provided an opportunity to acquire a better understanding of the direction and status of the NNWSI QA program which will support NRC staff efforts during prelicensing consultation. Information on the repository projects' QA programs is needed to provide material to comment on, to support development of staff positions, and to use with resolving site specific licensing issues in a timely manner (i.e., prior to issuance of the SCP). The purpose of the following report is to describe these two QA activities and to summarize my observations.

(1) Standard Operating Procedure (SOP) for Acceptance of Data and Interpretations Not Generated Under the NNWSI QA Plan

One of the issues raised during the December, 1984 NRC site visits concerned use of data not generated under an approved Project Office QA Plan. To address this issue a group of Project QA and participant technical personnel developed a draft SOP detailing the method for acceptance of such data (see enclosure 1). The subject SOP applies to the acceptance of data or data interpretations to be used in licensing (Quality Level I) which meet any of the following conditions: (a) were generated by NNWSI Project participants involved in siting the NNWSI HLW repository prior to implementation of the NNWSI QA Plan; (b) are derived from technical (referred) journals which a NNWSI Project participant would like to use; or (c) are derived from unpublished reports, theses or books. This procedure describes the number, level(s) and types of review to be performed for acceptance of data/interpretations falling in these categories and the concurrence and documentation necessary for each.

WM Record File 102
WM Project 11
Docket No.
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(Return to WM, 623-SS) L3

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NNWSI scheduled the March 1, 1985 meeting to discuss the draft SOP and invited the NRC Staff (NMSS and IE) to attend as observers (letter from Dr. Vieth to Mr. Browning, 2/28/85). Since I was to be in Nevada the following week, my trip was extended to include the March 1 meeting. IE was unable to make the scheduled date due to prior commitments and the late meeting notice.

In preparation for the meeting, J. Kennedy, F. Forscher (IE), Bill Bland (contractor to WMPC) and myself reviewed the draft SOP which we received 2/26/85. In addition, since IE is assigned the lead for developing a draft technical position on qualifying existing data and interpretations (those not developed under the NNWSI QA program), W. Altman (IE), F. Forscher (IE), J. Kennedy and I met on 2/27 to discuss the approach and philosophy of qualifying old data.

The NNWSI meeting was conducted from 9:00AM to 12:30 and 1:30PM to 3:30, Friday March 1. Those in attendance were:

James Blalock - DOE-NVO (QA)
Steve Metta - SAIC (QA)
Gerald DePoorter - Los Alamos (Technical)
Gene Rush - USGS (Technical)
Barry Schwartz - Sandia (Technical)
Paul Prestholt - NRC (OLR).

A large portion of the morning was spent discussing acceptance of data and interpretations published in technical journals by non-NNWSI Project participants. Included in the discussions were: types of technical journals which Project participants may want to use and the technical review they require for publication; types of information from technical journals which project participants may desire use of; number and qualification of persons who should be responsible for implementing the acceptance reviews; concurrence requirements and documentation on acceptance reviews; and review of information supporting and/or rebutting publications. The remaining discussion focused primarily on expansion of the draft SOP to include data and interpretations presented in unpublished reports, theses, and books. At the conclusion of the meeting the participants indicated that another review of the draft SOP would be necessary following submittal of the revision.

This SOP will be considered by IE and DWM in development of the staff technical position on data qualification. Additional guidance on the SOP will be provided to DOE if appropriate.

(2) DOE Headquarters QA Audit of the NNWSI Project Office

OFC	:WMRP:mkg	:WMRP	:	:	:	:	:
NAME	:SBilhorn	:JKennedy	:	:	:	:	:
DATE	:04/ /85	:04/ /85	:	:	:	:	:

The DOE-HQ Office of Geologic Repositories (OGR) is responsible for overseeing development and implementation of the Project Offices QA programs. Prior to the end of FY84, DOE QA personnel were primarily involved in developing the QA programs needed to meet licensing requirements. In early FY85 the Project Offices submitted these QA plans and procedures to the participating organizations for implementation and to OGR for review. To evaluate the implementation status of the Project Office QA Plans and to verify compliance with the requirements of the OGR QA Plan, OGR has scheduled audits of each Project Office (NNWSI, BWIP, SRPO). The first of these audits was conducted at the NNWSI Project Office March 7 through 9, 1985. The NRC staff (DWM) was invited to observe the OGR audits in an effort to keep the staff apprised of all QA activities and to help NRC develop a better understanding of each project's program. Arrangements were made for myself to attend the first audit. Future DOE audits of the Project Offices and their contractors will also be attended by other NRC staff (DWM and IE).

In preparation for the audit of the NNWSI Project Office, J. Kennedy, W. Bland and myself reviewed an OGR prepared audit notebook received 2/25/85. The scope of this initial audit was to examine all activities related to quality assurance. The requirements and applicable documents referenced in the audit were: WMPO QA Program Plan - Revision 2; WMPO Implementing Procedures; ANSI/ASME NQA-1, 1983; 10 CFR 60, Section 60.21(c)(4); 10 CFR 50, Appendix B; DOE Order 5700 6A; DOE OGR Quality Assurance Plan, September 1984; and NRC Review Plan, June 1984.

The interviews scheduled on the audit agenda were outlined to address the 18 criteria of 10 CFR 50 Appendix B that DOE believes to be applicable during this stage of the HLW program. These are criteria 1-7 and 15-18, which address the programmatic areas of: QA Organization; QA Program; Design Control; Procurement Document Control, Instructions, Procedures, and Drawings; Document Control; Control of Purchased Services; Non-conformances; Corrective Action; QA Records; and Audits. The Appendix B criteria not included on this agenda are 8 through 14 which address QA activities associated with hardware and construction not applicable during this stage of the program, and technical work not conducted at the NNWSI Project Office.

The checklist was composed of questions which were developed using (and referencing) sections of the requirements and documents listed above. The questions were aimed at evaluating programmatic points, as opposed to technical, within each criteria. The checklist appeared relatively comprehensive if the questions cited were used to lead into detailed discussions and reviews of the program.

The audit was generally conducted as outlined in the agenda (enclosure 2) with the following individuals as team members:

Carl Newton, OGR, Lead Auditor
Ed Sulek, Weston
Nancy Voltura, NVO
John Rinaldi, NVO - Observer
John Malvin, Weston
Susan Bilhorn, NRC - Observer

A generally cooperative attitude was evident among all audit participants. The persons interviewed are listed in enclosure 2, most of whom were individuals in the NNWSI Project QA organization.

The report compiled and transmitted to the NNWSI Project Manager is presented as enclosure 3. Four findings and five observations were documented in the audit report, each of which need to be addressed by NNWSI Project personnel. In summary, the four findings were: 1) absence of clear (documented) management control between NNWSI and its contractors to assure direction of the QA Program; 2) absence of a records management system and procedures for control of computer programs; 3) absence of defined provision(s) for resolution of quality disputes and responsibilities of the project QA manager; and 4) use of uncertified lead auditors (i.e., LANL and SNL). These represent areas which is left uncorrected could have a significant impact on the program. Findings 1, 3 and 4 were identified by the NRC, during the December 1984 site visits, as problem areas. The NRC staff is currently preparing to discuss with the DOE and developing guidance on independence of the QA organization and computer code QA, both issues covered in these findings. The observations reported address: adequacy of QA documents/distribution to assure knowledge of and compliance with QA requirements; completeness of QA files on WMPO personnel qualifications; frequency of audits to assure effectiveness of prime contractor audit programs; description of yearly management assessment of QA program; and performance of internal audits. Most of these are detailed procedural concerns involving interpretation of the requirements that will need to be more clearly addressed in the QA program to assure adequate compliance.

OFC	:WMRP:mkg	:WMRP	:	:	:	:
NAME	:SBilhorn	:JKennedy	:	:	:	:
DATE	:04/ /85	:04/ /85	:	:	:	:

The audit provided me with a better understanding of multiple aspects of the QA program as well as of the NNWSI project structure and operation. The knowledge and information gained will provide a useful basis for conducting future interactions, development of staff positions, and evaluation of the Project status.

Susan G. Bilhorn
Repository Projects Branch
Division of Waste Management

OFC	:WMRP:mkg	:WMRP	:	:	:	:
NAME	:SBilhorn	:JKennedy	:	:	:	:
DATE	:04/10/85	:04/11/85	:	:	:	:

ENCLOSURE 1 102

Encl. to memo to Miles from Bilhorn 4/11/85

NON-NNWSI QA PLAN

DATA OR INTERPRETATION ACCEPTANCE

Originated by: _____ Approved by/date: _____
WMPO Director

Effective date: _____

_____
DOE/NV Director

To
Nancy Voltura
Mitch Kunich
Miles

Please review this draft

Thanks
Steve Metta

Draft

1.0 PURPOSE AND SCOPE

This procedure describes the methods to be used by all Nevada Nuclear Waste Storage Investigation (NNWSI) Project participating organizations and Nevada Test Site (NTS) support contractors for the acceptance in current licensing activities of data or interpretation that was not generated under the controls of an NNWSI QA program.

2.0 APPLICABILITY

2.1 This procedure applies to the acceptance of data or interpretation to be used in current licensing Quality Level I activities or items which meet either of the following conditions: (a) data or interpretation that was generated by the NNWSI Project participants, predecessor organizations, or their subcontractors involved in siting the NNWSI high-level waste (HLW) repository prior to the NNWSI QA Plan implementation; or, (b) data or interpretation from a technical journal which a NNWSI Project participant would like to use.

2.1.1 If the data or interpretations can fall in condition (a), they must be processed in accordance with this procedure within two years of the effective date of the procedure.

2.1.2 If the data or interpretations can fall in conditions (a) and (b), they shall be processed for acceptance by condition (a).

2.2 This procedure is not intended to cover data or interpretation that were generated by the NNWSI participants post NNWSI QA Plan where the activity was not funded by the NNWSI or the QA Plan was not implemented. In this case the data or interpretation shall be processed as a nonconformance in accordance with NNWSI-SOP-15-01.

3.0 DEFINITIONS

3.1 ACTIVITY

An activity is the time consuming effort (operation, task, functions, or services) which influence or affect the achievement or verification of the objectives of the NNWSI as depicted in the WBS Dictionary.

3.2 APPENDIX A, DEFINITIONS OF NNWSI SOP-02-01

Appendix A, Definitions of NNWSI-SOP-02-01 is a list of general definitions used in conjunction with the NNWSI Project.

3.3 ITEM

An item is an all-inclusive term that is used in place of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, unit, data, sample, and prototype hardware.

3.4 NNWSI PROJECT PERSONNEL

NNWSI Project personnel refers to all U. S. DOE participating organizations and NTS support contractor personnel involved in NNWSI Project activities.

3.5 PRINCIPAL INVESTIGATOR

Principal Investigator (PI) may be synonymous with task leader or project engineer depending upon the NNWSI Project participant. The PI is the individual who has the technical responsibility for an assigned task including, but not limited to planning and cost control, day-to-day technical direction and quality control of the item or activity, and assembling a support team to accomplish the item/activity.

3.6 TECHNICAL JOURNAL

A technical journal is a serial publication of a recognized nationally or internationally scientific organization.

4.0 RESPONSIBILITIES

4.1 It is the responsibility of all NNWSI Project participant PIs to ensure that this procedure is followed for the acceptance of data/interpretation that was not generated under the controls of an NNWSI Quality Assurance program.

4.2 It is the responsibility of WMPO to ensure that this procedure is followed prior to approving the information for use.

4.3 Detailed responsibilities for NNWSI Project and WMPO personnel are outlined in Section 5 of this procedure.

5.0 PROCEDURE

5.1 When an NNWSI Project participant PI identifies a need to accept data or interpretation for use in current licensing Quality Level I activities, the PI shall coordinate the acceptance process for the data or interpretation.

5.1.1 If the data or interpretation was originated by an NNWSI participant, a predecessor organization, or a subcontractor, the PI shall collect any available supporting documents which can be used during the acceptance process such as:

1. Statement Of Work
2. Log Books

3. Technical Procedures

4. Documented Reviews

5. Calibration Records.

5.1.2 If the data or interpretation is from a published technical journal, the PI shall perform a reference search and collect:

1. additional published technical journals supporting the information under review

2. published technical journals rebutting the information under review

3. any documentation of an independent verification.

5.2 The PI shall initiate a Data/Interpretation Acceptance Review Sheet (Exhibit 1) or Technical Journal Acceptance Review Sheet (Exhibit 2).

5.2.1 For a Data/Interpretation Acceptance Review Sheet, the PI shall complete Part I of the form indicating the following:

1. name and location of the coordinating PI

2. name and location of the original investigator or organization

3. detailed description of the unit data and all constituent parts, and its relationship to the current activity or item for which it will be used

4. technical justification explaining in detail why the subject data/interpretation should be used, and why the process cannot be repeated under NNWSI QA Plan controlled conditions

5. detailed description of the quality assurance methods (procedures, reviews, approvals, etc.) that may have been used during the generation of the subject data or interpretation, including the manner in which the data was collected and the tools, resources, computer programs, etc. used in its collection.

5.2.2 For a Technical Journal Acceptance Review Sheet, the PI shall complete Part I of the form indicating the following:

1. complete reference of the subject technical journal to include the following: journal date and issue, article title, author, date tests or experiments were conducted, and other relevant references if the article is part of a series

2. detailed description of the information in the article and its relationship to the current activity or item for which it will be used

3. technical justification explaining in detail why the subject technical journal information should be used, and why the process cannot be repeated under NNWSI QA Plan controlled conditions

4. attached list of known supporting published technical journals indication

5. attached list of rebuttal published technical journals indication

6. completed reference of any known independent verification of the data or interpretation including who performed it and how (reconstruction or review) indication.

5.3 The PI, with concurrence from the Technical Project Officer (TPO), shall assign two technical individuals and a QA individual (only for data or interpretation acceptance) to perform separate and independent reviews of the subject information. The reviewers shall be familiar with the subject matter, but shall not have had involvement with the data collection or interpretation.

5.3.1 The PI shall record the assigned individuals' names on Part II of the review sheet.

5.3.2 The PI shall forward, to the reviewers, a copy of the review sheet with appropriate Appendix Sheet (Exhibits 3 and 4), and any additional documented information to assist the reviewers when performing their review.

5.4 Upon receipt of the Appendix Sheet, the reviewers shall perform and document their reviews independently of each other.

5.4.1 As a minimum the review shall take into account the attributes listed on the supplied Appendix Sheet.

5.4.2 The reviewers shall document their comments for each attribute, identify failures to meet, evaluate importance of attribute and importance of any discrepancy; if the information is not good, the reviewers shall identify any other related issues and indicate other ways of possibly securing controlled data on the Appendix Sheet, and then forward it to the coordinating PI.

5.4.3 Upon completion, the reviewers shall sign and date the Appendix Sheet and return all documents to the coordinating PI.

5.5 Upon receipt of the completed Appendix Sheet, the PI shall review it for clarity and completeness. It shall be the responsibility of the PI to resolve any open issues with the reviewer (if possible), and document resolutions. If comments are appropriate, they shall be documented by the PI on Part III of the review sheet. Upon completion, the complete package of documents shall be sent to the TPO for approval.

5.6 Upon approval of the review sheet by the TPO the package shall be submitted to the WMPO for approval. Approvals shall be documented on Part IV of the review sheet.

TECHNICAL JOURNAL ACCEPTANCE REVIEW SHEET

PART I: (BACKGROUND INFORMATION)

COORDINATING PI _____ _____
NAME ADDRESS

SUBJECT TECHNICAL JOURNAL:

DATE: _____ ISSUE _____

ARTICLE TITLE: _____

AUTHOR: _____

DATE CONDUCTED: _____

RELEVANT REFERENCES: _____

DESCRIPTION OF SUBJECT DATA/INTERPRETATION: _____

TECHNICAL JUSTIFICATION - WHY THE DATA/INTERPRETATION SHOULD BE USED: _____

LIST OF SUPPORTING TECHNICAL JOURNALS ATTACHED ☐

LIST OF REBUTTING TECHNICAL JOURNALS ATTACHED ☐

DOCUMENTATION OF INDEPENDENT VERIFICATION ☐

PART II: (REVIEW INFORMATION)

	NAME	AFFILIATION
TECHNICAL REVIEWER #1	_____	_____
TECHNICAL REVIEWER #2	_____	_____

NOTE: REVIEWER'S COMMENTS DOCUMENTED ON APPENDIX SHEETS.

PART III: PI COMMENT ON REVIEW. (USE ATTACHMENTS IF NECESSARY)

PART IV: MANAGEMENT APPROVALS

TPO _____ DATE _____

WMPO _____ DATE _____

N-QA-002 (2/85)

Exhibit 2 Technical Journal Acceptance Review Sheet

DATA/INTERPRETATION ACCEPTANCE REVIEW SHEET - APPENDIX SHEET

1.	Were experiments and tests associated with the data conducted in accordance with documented plans, procedures, etc., and was the documentation of such sufficient?	TQ
2.	Were the methods, practices, techniques, and experiments used to obtain and treat the data technically sound, objective and properly selected?	T
3.	Are data calculations (including statistical analysis) correct?	T
4.	Were measuring and testing equipment calibrated to known standards before and after the test or experiment of concern was run?	TQ
5.	Did conclusions take into account deviations (sensitivity) in the measuring and testing equipment?	T
6.	Were samples, specimens, and data adequately identified and controlled for use within the test or equipment?	TQ
7.	Are original samples or specimens available for further tests or experiments?	TQ
8.	Was the operating procedure stated in sufficient detail so that the test or experiment can be reconstructed?	TQ
9.	Is the raw data sufficiently recorded and retrievable?	Q
10.	Was the data input sufficient to make a reasonable interpretation, supported by documented analysis, when compared to the input data?	T
11.	Were the results of the data or interpretation presented in an understandable format consistent with obtaining the desired results?	T
12.	Were assumptions used in the data or interpretation adequately identified and reasonable, and were all possible assumptions taken into account?	T
13.	Based on your review, do you concur with the use of the subject information for its intended purpose?	TQ

T = Technical Reviewer Attributes Q = QA Reviewer Attributes

Reviewer's Comments: (Attach additional sheets as necessary)

Reviewer's Name and Signature Date

Location Phone Number

Exhibit 3

DATA/INTERPRETATION ACCEPTANCE REVIEW SHEET - APPENDIX SHEET

1. Are there additional (other than those procvided) published technical journals supporting the technical conclusions of the work undergoing the acceptance review? (Provide a complete reference)

2. Are there additional (other than those provided) published technical journals rebutting the work undergoing acceptance review? (Provide a complete reference)

3. Of the known published rebuttals document and address (agreement or disagreement) the points of significant difference?

4. In your opinion do you technically concur with the use of the information in this technical publication for its intended purposes?

Reviewers Comments: (Attach additional sheets as necessary)

Reviewer's Name & Signature _____ Date _____

Location _____ Phone Number _____

Exhibit 4

5.7 After the review sheet is approved or disapproved by WMPO (if disapproved, WMPO shall state justification), the package shall be returned to the coordinating PI. The PI shall ensure that all review sheets and associated document packages are properly dispositioned in accordance with the organization's QA Records Control System.

6.0 REFERENCES

NVO-196-17	NNWSI Project Quality Assurance Plan
NNWSI-SOP-02-01	QAPP Requirements
NNWSI-SOP-15-01	Nonconformance Control

DATA ACCEPTANCE REVIEW SHEET

PART I: (BACKGROUND INFORMATION)

COORDINATING PI _____ _____
NAME ADDRESS

ORIGINAL INVESTIGATOR _____ _____

DESCRIPTION OF SUBJECT AREA:

_____

_____

_____

_____

TECHNICAL JUSTIFICATION - WHY DATA SHOULD BE USED:

_____

_____

_____

_____

PROCEDURES/RESOURCES UTILIZED DURING DATA COLLECTION:

_____

_____

_____

_____

PART II: (REVIEW INFORMATION)

	REVIEWER'S NAME	AFFILIATION
TECHNICAL REVIEWER #1		
TECHNICAL REVIEWER #2		
QA REVIEWER		

NOTE: REVIEWER'S COMMENTS DOCUMENTED ON APPENDIX SHEETS

PART III: PI COMMENTS ON REVIEW. (USE ATTACHMENTS IF NECESSARY)

_____

_____

_____

_____

TECHNICAL APPROVAL. PI _____
SIGNATURE/DATE

PART IV: MANAGEMENT APPROVALS

TPO _____ DATE _____

WMPO _____ DATE _____

N-QA-001 (2/85)

Exhibit 1 Data Acceptance Review Sheet

ENCLOSURE 2

AGENDA
HQ/OGR QA Audit #85-N-1
NNWSI Project Office
March 4-7, 1985

March 4

Time	Activity	Team
1:00/5:00	Audit Team Meeting.	A&B

March 5

8:00/~~9:00~~ 8:15	Pre-Audit Conference	
~~9:00~~ 8:15/11:30	Organization.	A Steve Metta (SAIC-QA)
	Design Control/Peer Reviews (T.D. & E. Branch).	(B) Vern Witherall, (Chief-TDE/NNWSI)
11:30/12:30	Lunch	
12:30/2:30	QA Program.	A Metta/Klein (SAIC-QA)
	Site Characterization Activities/Peer Reviews (G. I. Branch).	(B) Max Blanchard (Chief-GI/NNWSI)
2:30/3:30	Procurement Document Control.	A Metta
	Nonconformances	(B) Blalock (NVO/NNWSI QA)
3:30/4:15	Caucus	
4.:15/5:00	Brief PQAM on findings and observations - prepare for continuation → J. Blalock (and S. Metta)	

March 6

8:00	Findings/observations submitted to Blalock for typing.	
8:00/10:00	Procurement Document Control.	(A) Metta (*)
	Corrective Action	B Blalock
10:00/11:30	Control of Purchased Services	(A) Metta, Klein
	QA Records.	B Blalock/ Brogan (SAIC-QA)
11:30/12:30	Lunch	
12:30/2:00	Instructions-Procedures-Drawings.	(A) Metta
	QA Records.	B Blalock/Klein
2:00/3:30	Document Control.	(A) Klein
	Audits.	(B) S. Singer (SAIC-QA)
4:30	Brief PQAM	

(*) Mitch Kunich and Don Vieth were interviewed, in addition, to clarify a question on procurement of National Laboratory Services – Contractural Documentation.

March 7

8:00/11:30	Prepare Audit Report.	A&B
11:30/12:30	Lunch	
12:30/1:30	Complete Audit Report	A&B

Time	Activity	Team
1:30/2:00	Brief PQAM.	A&B
2:00/3:00	Brief Project Director	A&B
3:00/4:00	Exit Meeting	

0003Q

ENCLOSURE 3

DOE F 1325.8
(12-84)

United States Government | Department of Energy

memorandum

WM DOCKET CONTROL CENTER

'85 APR -5 P2:16

DATE: MAR 27 1985

REPLY TO ATTN OF: RW-23

SUBJECT: Report of March 5-7, 1985 Audit

TO: Don Vieth, NV

Attached is the report of the quality assurance audit conducted by the HQ-OGR of the Waste Management Project Office. The report contains four findings and five observations; your response to both findings and observations should be furnished to this office within 30 days of the date of this memo.

J. W. Bennett, for

William J. Purcell
Associate Director
for Geologic Repositories
Office of Civilian Radioactive
Waste Management

Attachment

cc: w/attachment: Ed Sulek, Weston
John Malvia, Weston
John Rinaldi, NV
Nancy Voltura, NV
~~Susan~~ Billhorn, NRC

AUDIT REPORT

REPORT NO. 85-N-1

AUDIT TYPE External

DATE OF AUDIT 3/5 - 3/7/85

PROJECT NAME NNWSI

ORGANIZATION/ACTIVITY AUDITED WMPO (Name) Las Vegas, NV (Location)

AUDIT SCOPE Verify implementation of the WMPO QAPP NVO-196-18, Rev 2

AUDIT TEAM (NAME AND TITLE)

SEE ATTACHED SHEETS

PERSONS CONTACTED (NAME AND TITLE)

SEE ATTACHED SHEETS

AUDIT SUMMARY AND EVALUATION

A preaudit meeting was conducted at 8:00AM on Tuesday, March 5, 1985 to advise WMPO of the purpose and scope of the audit, introduce the audit team, identify project counterparts and establish lines of communication. Attendees are identified on the attached attendance sheet.

Audit Team Members:

E W Sulek 3/7/85

J H Malvin J. H. Malvin 3/7/85

J R Rinaldi 3-7-85

N A Voltura 3/7/85

Carl Newton 3-7-85

AUDIT TEAM LEADER DATE

0005Q
2/15/85

The purpose of the audit was to assess the status and adequacy of the WMPO QA Program and effectiveness of its implementation. The audit specifically covered the activities falling under the following QA criteria of Appendix B to 10CFR50:

I - Organization
II - Quality Assurance Program
III - Design Control
IV - Procurement Document Control
V - Instructions, Procedures & Drawings
VI - Document Control
VII - Control of Purchased Material, Equipment, and Services
XV - Nonconforming Materials, Parts and Components
XVI - Corrective Action
XVII - Quality Assurance Records
XVIII - Audits

All WMPO and QASC persons contacted by the audit team were knowledgeable, courteous and professional in their replies to auditor's questions. At the time of the audit, the development and issuance of the Quality Assurance Program Plan, and Quality Management Procedures were complete with the exception of the procedure for Records Management which is under study and development. Implementation of the program was initially underway and could not be fully evaluated.

The Audit Team observed a number of positive features in the WMPO QA Program. One such feature is the establishment of program wide QA Program Requirements through the issuance of NVO-196-17, Rev. 3. Also, the WMPO requirement for the review and approval of the QA Plans and procedures of the Participating Organizations provides an effective initial step in the overview of their activities. Issuance of procedures for the control of Computer Programs is currently under study and development.

Considerable progress has been made in that a procedure for identifying items

and activities important to safety and barriers important to waste isolation has been issued. Also, the plans to initiate an overview of participating organizations through audits and surveillances is to be commended. The Director and his staff are to be congratulated for their efforts in these areas of QA Program development and implementation.

Four findings and five observations were identified during the audit and are attached to this report. The Project Quality Manager was briefed daily on the audit results and was given a summary briefing on the last day of the audit.

The Audit Team Leader briefed the Project Director immediately prior to the exit meeting.

The post audit meeting was held at 3:00 p.m. on March 7, 1985. Attendees are identified on the attached attendance sheet. The findings and observations were presented and discussed at the Audit exit meeting. A copy of the Audit Report with findings/observations was provided for each attendee.

APPENDIX D

AUDIT ATTENDANCE SHEET

	DATE	TIME
(A) PRE-AUDIT CONFERENCE	3-5-85	8:00 am
~~B. PERSONNEL CONTACTED DURING AUDIT~~		
~~C. POST-AUDIT CONFERENCE~~		

	NAME	ORGANIZATION	TITLE
1.	CARL NEWTON	DOE-HQ	OGR QA MANAGER
2.	EDWARD SULEK	WESTON	QA MGR
3.	John H Malvin	Weston	QA
4.	[illegible]	NRC	[illegible]
5.	[illegible]	WMPO/NV	Chief Tech [illegible]
6.	Maxwell Blanchard	WMPO	[illegible]
7.	Stephen Metta	SAIC	QA
8.	Mitchell P Kunich	DOE/NV	Asst. Director WMPO
9.	Nancy Valtura	DOE/NV	QA Spe[illegible]
10.	JOHN RINALDI	DOE-NV	QAD-DIRECTOR
11.	Jim Blaylock	DOE	PQM-WMPO
12.	Stan Klein	SAIC	QA Manager
13.			
14.			
15.			
16.			
17.			
18.			
19.			
20.			

APPENDIX D

AUDIT ATTENDANCE SHEET

		DATE	TIME
A.	~~PRE-AUDIT CONFERENCE~~		
(B)	PERSONNEL CONTACTED DURING AUDIT	3-5&3-6/85	
C.	~~POST AUDIT CONFERENCE~~		

	NAME	ORGANIZATION	TITLE
1.	Max Blanchard	WMPO	Branch Chief - Geologic In
2.	Vern Witherill	WMPO	Branch Chief - DEE Gro
3.	Steve Mehta	SAIC	QA
4.	Jim Blaylock	WMPO	PQM - WMP
5.	Sam Singer	SAIC	QA
6.	John Rinaldi	WMPO	CAD - Director
7.	Mitch Kunich	WMPO	Assistant Director
8.	Don Vieth	WMPO	Director
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APPENDIX D

AUDIT ATTENDANCE SHEET

	DATE	TIME
A. ~~PRE-AUDIT CONFERENCE~~		
B. ~~PERSONNEL CONTACTED DURING AUDIT~~		
C. POST-AUDIT CONFERENCE	3-7-85	3:00 pm

	NAME	ORGANIZATION	TITLE
1.	Carl Newton	DOE-HQ	OGR QA Mgr
2.	E.W. SULEK	WESTON	QA MGR
3.	S.G. Bilhorn	NRC	QA S[illegible]
4.	John H. Malvin	Weston	QA Spec.
5.	Paul Prestwitt	NRC	OLR - [illegible]
6.	Bob Taft	DOE NV	AM/ES
7.	JOHN RINALDI	DOE-NV	DIRECTOR-QAD
8.	Vern F. Witherill	WMPO/NV	[illegible]
9.	Mitchell P Kunich	WMPO/NV	Asst Dir WMPO
10.	Jim Blaylock	WMPO/NV	PQM WMPO
11.	Stephen Mette	SAIC	QA
12.	DONALD L. VIETH	WMPO/NV	DIRECTOR WMPO
13.	Nancy Voltura	DOE/NV	QA SPECIALIST
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APPENDIX C

AUDIT FINDING REPORT

REPORT NO. 85-N-1
DATE OF AUDIT 3/5-7/85

AUDITOR E. Sulek/J. Rinaldi/N. Voltura FINDING/[redacted] NO. 1

FINDING/OBSERVATION DISCUSSED WITH D. Vieth (Name) Director, WMPO (Title)

SIGNED BY /Donald K. Vieth/ (Name) /Director WMPO (Title) 5/7/85 (Date)
(Audited Project Manager)

REQUIREMENT:

NRC Review Plan, Appendix A, Para. 1.6, requires that clear management controls and effective lines of communications exist for QA activities between DOE and its contractors to assure direction of the QA Program.

FINDING/[redacted]

Management controls have been established but are not fully documented between the project and the following participating organizations:

a) National Laboratories (SNL, LANL and LLNL)

b) USGS

c) NTSSO contractors (H&N and REECo)

(The WMPO Director is fully aware of the finding and has taken and is taking considerable action to resolve the issues involved.

AUDITOR RECOMMENDATION/[redacted]

a) Establish clearly documented management controls between WMPO and the national labs through a memorandum of understanding, a project charter in accordance with DOE 5700.4 or other effective vehicle between the Nevada, Albuquerque and San Francisco Operations Offices. These controls should provide the Director, WMPO, with authority to direct work, officially specify QA Program requirements, stop unsatisfactory work and lead QA audits of the laboratory activities.

b) The existing interagency agreement between DOE and the USGS does not provide the Director, WMPO, the full extent of management controls required by NRC regulations. Ongoing communications between the Director, WMPO, and the USGS should be continued until regulatory QA Program Requirements are met and a satisfactory agreement implemented.

Audit Finding Report (Continued)

AUDIT RECOMMENDATION/COMMENT

c) The Director, WMPO, has been officially designated as the contracting officers technical representative, COTR, for the contracts with SAI, Westinghouse and Fenix & Scisson, similar authority should officially be provided to the Director, WMPO, for the Holmes & Narver as well as for REECo contracts.

APPENDIX C

AUDIT FINDING REPORT

REPORT NO. 85-N-1
DATE OF AUDIT 3/5-7/85

AUDITOR C. Newton/J. Rinaldi/J. Malvin FINDING/[redacted]. 2

FINDING/OBSERVATION DISCUSSED WITH Jim Blaylock (Name) POM (Title)

SIGNED BY Donald L. Keith (Name) Director WMPO (Title) 3/7/85 (Date)
(Audited Project Manager)

REQUIREMENT:

NRC Review Plan, Appendix A, Para. 17.1, 17.2 and ANSI/ASME NQA-1, 1983 Section 17 state in part "The scope of the records programs is described." "QA and other organizations are identified and their responsibilities are described for the definitic and implementation of activities related to QA records."

NRC QA Review Plan, Appendix A, Para. 2.2 requires the QA Program to include a commitment that development, control, and use of computer programs will be in accordance with QA Program.

FINDING/[redacted]

Contrary to the requirements, WMPO has not established a Records Management System. The WMPO Director was fully aware of this situation before this audit and in a December 13, 1984, memo to Ralph Stein advised HQ that a procedure is being developed and will be issued after completion of a study by Effective Solutions, Incorporated.

Procedures for the control of computer programs have not been finalized and issued. The WMPO has drafted SOP-02-02 to establish program controls of computer programs in accordance with the guidance in NUREG-0856.

AUDITOR RECOMMENDATION/[redacted]

Develop a Records Management System. The system should also describe how records generated before the system is implemented will be collected and placed in the records system.

Establish a schedule for the completion, issuance and implementation of QMP 02-02 and for a review of controls being applied to computer programs presently being used to verify their adequacy.

APPENDIX C

AUDIT FINDING REPORT

REPORT NO. 85-N-1
DATE OF AUDIT 3/5-7/85

AUDITOR E. Sulek/J. Rinaldi/N. Voltura FINDING ~~OBSERVATION~~ NO. 3

FINDING/OBSERVATION DISCUSSED WITH Jim Blaylock (Name) QA Project Manager (Title)

SIGNED BY Donald L. Vieth (Name) (Audited Project Manager) Director WMPO (Title) 3/7/85 (Date)

REQUIREMENT:

a) NRC QA Review Plan, Appendix A, Para. 1.13, requires that provisions be established for the resolution of disputes involving quality.

b) NRC QA Review Plan, Para. 1.10 requires the DOE to identify a management position within each organization that retains overall authority and responsibility for the QA Program...(d) and has no other duties or responsibilities unrelated to QA.

FINDING/~~OBSERVATION~~:

a) The QA Program does not adequately describe provisions for the resolution of disputes involving quality.

b) Although the PQM position has been established in WMPO, the responsibilities of the PQM are not defined in Section 4 of QMP-01-01.

AUDITOR RECOMMENDATION/~~COMMENT~~

a) Provisions for resolution of disputes are described in Note #7 to WMPO's "Comparison of the NRC Review Plan to the implementing methods of the NNWSI Project." These provisions should be incorporated in NVO-196-18 when it is revised.

b) Provisions for defining the responsibilities of the PQM position should be addressed within the WMPO QA Program.

APPENDIX C

AUDIT FINDING REPORT

REPORT NO. 85-N-1
DATE OF AUDIT 3/5-7/85

AUDITOR C. Newton/J. Rinaldi,J. Malvin FINDING/OBSERVATION NO. 4

FINDING/OBSERVATION DISCUSSED WITH J. Blaylock (Name) PQM (Title)

SIGNED BY Donald L. Keith (Name) Director WMPO (Title) 3/7/85 (Date)
(Audited Project Manager)

REQUIREMENT:

ANSI/ASME NQA-1, 1983 Supplement 2S-3 states in part "This supplement provides amplified requirements for the qualification of an audit team leader..."

FINDING

The audit team leader on the LANL audit and the SNL conducted by the Albuquerque, NM Field Office, was not certified to the requirements of NQA-1.

(The WMPO Director was aware of this situation before this audit and was taking action to correct it).

AUDITOR RECOMMENDATION/COMMENT

Attempts are now being made to try to revise the ALO/NV Memorandum of Agreement (MOA) on the conduct of QA audits of ALO and LANL to include the certification of Audit Team Leaders to the requirements of ANSI/ASME NQA-1, 1983. The revision of the MOA's was in the early stages at the time of the audit. A similar situation potentially exists at the SAN Office with the LLNL contractor.

APPENDIX C

AUDIT FINDING REPORT

REPORT NO. 85-N-1
DATE OF AUDIT 3-5-85

AUDITOR C. Newton/J. Malvin [redacted]/OBSERVATION NO. 1

FINDING/OBSERVATION DISCUSSED WITH V. Witherill/M. Blanchard WMPO Branch Chiefs
Name Title

SIGNED BY [signature] Director WMPO 3/7/85
Name Title Date
(Audited Project Manager)

REQUIREMENT: (1) Page 1-4 of OGR/B-2 states: "The OGR projects will use the GR document:

- as the generic basis for site-specific design requirements;
- as the starting point for site-specific system requirements documents;
- as a basis for evaluating the adequacy of the project designs;
- to assist in project control of the site-specific design."

(2) NRC Review Plan, Appendix A, Paragraph 3.2, requires the design control...(cont'd)

[redacted]/OBSERVATION:

Copies of the five OGR baseline documents released by HQ to date were not all readily available in either of the WMPO branch chief offices and the branch chiefs did not seem familiar with the documents. The program does not describe design interface controls to ensure that the requirements in these documents had been passed on (as requirements) to participants.

AUDITOR [redacted]/COMMENT

The Generic Requirements Document (OGR/B-2) was in the TD&E Branch Chief's Office and he was familiar with the document. He was also able to produce a memo showing that these requirements had been transmitted to participating organizations (but only for information).

OBSV 1

... program to provide for the correct translation of applicable regulatory requirements and design bases into design, procurement, and procedural documents.

NRC Review Plan, Appendix A, Paragraph 3.5, requires that Interface controls among organizations or groups involved in design activities be described.

NQA-1, Supplement 3S-1 states, Design interfaces shall be identified and controlled and the design efforts shall be coordinated among the participating organizations... Design information transmitted across interfaces shall be documented and controlled."

APPENDIX C

AUDIT FINDING REPORT

REPORT NO. 85-N-1
DATE OF AUDIT 3/5-7/85

AUDITOR E. Sulek/J. Rinaldi/N. Voltura [redacted]/OBSERVATION NO. 2

FINDING/OBSERVATION DISCUSSED WITH J. Blaylock (Name) POM (Title)

SIGNED BY Donald K. Keith (Name) Director WMPO (Title) 3/7/85 (Date)
(Audited Project Manager)

REQUIREMENT:

a) NQA-1, Basic Requirement 2 requires the QA Program to provide for the indoctrination and training as necessary of personnel performing activities affecting quality.

b) QMP-02-01 requires a documented evaluation of individuals performing quality Level 1 activities to assure that the proficiency of the individual to perform the activity is achieved. Records are to be sent to the QA Records File.

[redacted]/OBSERVATION:

a) Initial proficiency evaluation as required by QMP-02-01 for WMPO personnel are not in the QA files.

b) The training records reviewed do not adequately describe the scope of training that was conducted.

AUDITOR RECOMMENDATION/[redacted]

Establish an action plan for completing the initial proficiency evaluations of WMPO personnel. Provide an adequate description of the scope of training conducted on the training forms.

APPENDIX C

AUDIT FINDING REPORT

REPORT NO. 85-N-1
DATE OF AUDIT 3/5-7/85

AUDITOR C. Newton/J. Rinaldi/J. Malvin [redacted]/OBSERVATION NO. 3

FINDING/OBSERVATION DISCUSSED WITH J. Blaylock (Name) POM (Title)

SIGNED BY Donald L. Vieth (Name) Director WMPO (Title) 3/7/85 (Date)
(Audited Project Manager)

REQUIREMENT: NRC Review Plan, Appendix A, Paragraph 18.1, states "DOE should perform audits of the prime contractor and representative subcontractors, consultants, vendors, and laboratories to assess the effectiveness of the prime contractor's audit program."

[redacted]/OBSERVATION:

WMPO does not, to a reasonable representative degree, perform audits of representative subcontractors, consultants, or vendors as required.

AUDITOR RECOMMENDATION/[redacted]

The only subcontractor actually audited by WMPO to date is USGS in Menlo Park (subcontractor to LLNL). No other audits by WMPO of subcontractors, consultants, and vendors are planned except for an audit of USGS in Menlo Park. QASC personnel once participated in an audit of Bechtel led by Sandia. It is recommended that WMPO explain in their program plan how they intend meeting this NRC requirement.

APPENDIX C

AUDIT FINDING REPORT

REPORT NO. 85-N-1
DATE OF AUDIT 3/5-7/85

AUDITOR E. Sulek/J. Rinaldi/N. Voltura [redacted]/OBSERVATION NO. 4

FINDING/OBSERVATION DISCUSSED WITH J. Blaylock (Name) PQM (Title)

SIGNED BY Donald L. Vieth (Name) Director WMPO (Title) 3/7/85 (Date)
(Audited Project Manager)

REQUIREMENT:

a) NRC QA Review Plan, Appendix A, Para. 2.7, requires a description of how management (above or outside QA organization) regularly assesses the scope, status, adequacy, and compliance of the QA Program.

b) NV 196-18, Section 1.0, states that the Director, WMPO, is responsible for a yearly assessment of the NNWSI Project QA Plan.

[redacted]/OBSERVATION:

The WMPO QA Plan does not describe how the yearly management assessment of the scope, status, adequacy and compliance of the QA Program is performed by persons or organizations above or outside the QA organization.

AUDITOR RECOMMENDATION/[redacted]

Provide a description of how yearly management assessments above or outside the QA organization of the status and adequacy of the QA Program are performed and documented.

APPENDIX C

AUDIT FINDING REPORT

REPORT NO. 85-N-1
DATE OF AUDIT 3/5-7/85

AUDITOR E. Sulek/J. Rinaldi/N Voltura ~~FINDING~~/OBSERVATION NO. 5

FINDING/OBSERVATION DISCUSSED WITH J. Blaylock (Name) PQM (Title)

SIGNED BY Donald L. Keith (Name) Director WMPO (Title) 3/7/85 (Date)
(Audited Project Manager)

REQUIREMENT:

a) NRC QA Review Plan, Appendix A, Para. 1.1, states in part "... While the line organization is responsible for performing quality affecting activities properly, the QA organization shall verify the performance of work through implementation of appropriate QA controls."

b) QMP's 07-01 and 18.01 have been developed to establish verification of internal activities through audits and/or surveillances respectively.

~~FINDING~~/OBSERVATION:

Performance of internal audits have been scheduled but have not commenced. The program is not clear, as evidenced by interviews, as to whether surveillances of internal activities will be performed.

AUDITOR ~~RECOMMENDATION~~/COMMENT

Clarification is needed as to program plans for performing internal surveillances.