

UNITED STATES NUCLEAR REGULATORY COMMISSION WASHINGTON, D. C. 20555

> Reply to: 1050 East Flamingo Road Suite 319 Las Vegas, Nevada 89119 Tel: (702) 388-6125 FTS: 598-6125

TO: James E. Kennedy, M/S 4-H-3

FROM: Paul T. Prestholt, Sr. On-Site Licensing Representative

DATE: July 29, 1988

SUBJECT: NNWSI PROJECT QA LIMITED STOP WORK ORDER ISSUED; CORRESPONDENCE REGARDING USGS

Please find enclosed the above-referenced information.

PTF:nan cc: J. J. Linehan w/o enc.



102.7 WM-11 NHØ3

# NNWSI PROJECT QUALITY ASSURANCE LIMITED STOP WORK ORDER ISSUED

PRESENTED BY

Carl Gertz PROJECT MANAGER

### JULY 27, 1988

UNITED STATES DEPARTMENT OF ENERGY NEVADA OPERATIONS OFFICE/WASTE MANAGEMENT PROJECT OFFICE

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QAUPDAT 9/7-27-88

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## NNWSI PROJECT QUALITY ASSURANCE LIMITED STOP WORK ORDER ISSUED

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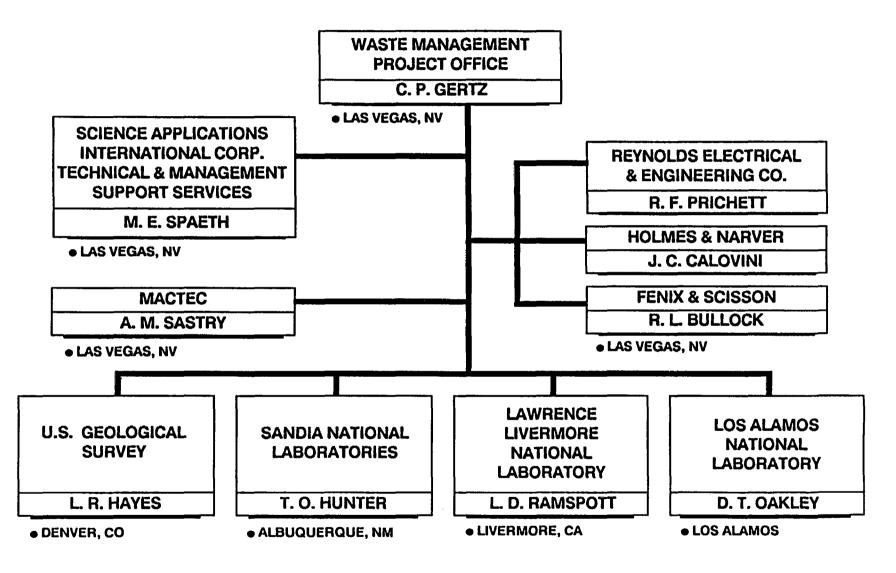
QAUPDAT

7-27-88

# WORK ON YUCCA MOUNTAIN PROJECT CONTINUES

1.4.2

# **DOE/NV ORGANIZATION**



DOENV.PUB:6-17-88 3

PROJECT DIRECTION

## DOE PROJECT OFFICE ISSUED THE USGS A STOP WORK ORDER (SWO) ON JULY 26, 1988, TO DISCONTINUE THE ANALYSIS, INTERPRETATION, AND PUBLICATION OF RESULTS IN FIVE TECHNICAL AREAS

- SITE WATER TABLE LEVEL EVALUATION
- CURRENT SEISMICITY MEASUREMENTS
- SURFACE WATER RUNOFF MONITORING
- TRANSPORT OF DEBRIS BY SEVERE RUNOFF
- STUDIES OF CALCITE AND OPALINE SILICA VEIN DEPOSITS
- 20 DEFICIENCIES WERE IDENTIFIED DEALING WITH PROCEDURAL INCONSISTENCIES
- DATA COLLECTION ASSOCIATED WITH ALL AREAS EXCEPT CALCITE AND OPALINE SILICA STUDIES WILL CONTINUE

## SWOS DIRECTLY AFFECT APPROXIMATELY 10 PERCENT OF THE WORK BEING DONE ON THE PROJECT BY THE USGS

- FINDINGS BY DOE AUDIT TEAM AT THIS TIME INDICATE THAT DEFICIENCIES HAVE NO MAJOR IMPACT ON DATA COLLECTED BY USGS
- USGS WILL SUBMIT A PLAN TO DOE IN FOUR WEEKS TO ASSESS THE IMPACT OF THE DEFICIENCIES ON THE OTHER SCIENTIFIC ACTIVITIES CONDUCTED BY THE USGS ON THE PROJECT
- AFTER USGS PLAN IS REVIEWED, FURTHER EVALUATIONS OF IMPACTS MAY BE MADE

## NNWSI PROJECT QA AUDIT SCHEDULE FOR FY 1988

### COMPLETED AUDITS

FENIX & SCISSON (TULSA)	2/28 - 3/02
HOLMES & NARVER	3/23 - 4/01
U.S. GEOLOGICAL SURVEY (MENLO PARK)	4/26 - 4/29
U.S. GEOLOGICAL SURVEY (DENVER)	6/09 - 6/24
SCHEDULED AUDITS	
LAWRENCE LIVERMORE NATION	AL 10/24 - 10/28
SANDIA NATIONAL LABORATORIE	ES 7/25 - 7/29
REYNOLDS ELECTRICAL & ENGINEERING CO.	8/22 - 8/26
LOS ALAMOS NATIONAL LABORATORY	10/03 - 10/07
FENIX & SCISSON (LAS VEGAS)	9/07 - 9/09
	QAUPDATE.CPG/7-27-Ն



### **Department of Energy**

Nevada Operations Office P. O. Box 98518 Las Vegas, NV 89193-8518

JUL 26 1988

Larry R. Hayes Technical Project Officer for NNWSI U.S. Geological Survey Mail Stop 421 P.O. Box 25406 Denver, CO 80225

WASTE MANAGEMENT PROJECT OFFICE (WMPO) STOP WORK ORDER FOR THE U.S. GEOLOGICAL SURVEY (USGS) NEVADA NUCLEAR WASTE STORAGE INVESTIGATIONS (NNVSI) PROJECT SUPPORT

During the course of WMPO Quality Assurance (QA) Audit 88-04 of USGS, the audit team reviewed sufficient objective evidence and generated numerous Standard Deficiency Reports to conclude the following based on the sample taken:

- The QA program currently in place <u>is not</u> being properly implemented in all areas.
- 2. In specific areas the effectiveness of the QA program is questionable.

As a result of these findings, the following actions are ordered:

- 1. A stop work order is hereby placed on the analysis, interpretation, publication, and dissemination of data and information generated from the following activities:
  - a. 8.3.1.2.3.1.2, Site Potentiometric Level Evaluation
  - b. 8.3.1.5.2.1.5, Studies of Calcite and Opaline Silica Vein Deposits
  - c. 8.3.1.17.4.1.2, Current Seismicity
  - d. 8.3.1.2.1.2.1, Surface Water Runoff Monitoring
  - e. 8.3.1.2.1.2.2, Transport of Debris by Severe Runoff

All other tasks, including data collected for the preceding monitoring activities, will continue. The sole exception to this provision is the Calcite and Opaline Silica Vein Deposits study, for which sample collection is not authorized.

This stop work order will remain in effect until a readiness review, in which the U.S. Department of Energy is a direct participant, determines that the affected activities have been brought into full compliance with the provisions of the USGS NNWSI Project QA program.

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Larry R. Hayes

2. Further, an in-depth investigation shall be undertaken to determine the extent to which the identified deficiencies in the QA program noted above apply to the balances of the QA Level I and II monitoring activities being conducted by the USGS. This investigation shall commence by the submittal of a course of action plan(s) to the NNWSI Project Manager no later than 20 working days from the stop work notification letter date. This plan shall include the timetables, milestones, manpower requirements, and criteria necessary to both detail the extent of the deficiencies and outline the measures necessary to correct them.

Effective immediately, this stop work order is placed on the preceding USGS activities and subject to the conditions outlined above.

The activities affected by this stop work order are crucial to the successful completion of the site characterization at Yucca Mountain. WMPO is confident that USGS can and will develop the required course of action plan(s) and implement corrective actions expeditiously.

If you have any questions regarding this matter, please call me at FTS 544-7920 or James Blaylock at FTS 544-7913.

Carl P. Gertz, Project Manager Waste Management Project Office

WMPO:JB-3061

cc: M. E. Spaeth, SAIC, Las Vegas, NV S. H. Klein, SAIC, Las Vegas, NV Stephen Metta, SAIC, Las Vegas, NV H. H. Caldwell, SAIC, Las Vegas, NV James Blaylock, WHPO, NV E. L. Wilmot, WMPO, NV

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SUMMARY OF 20 USGS STANDARD DEFICIENCY REPORTS (SDRs)

- 142 o Certifications for certain USGS QA receiving inspectors were incomplete (Note: Receiving inspectors examine items before used in a study)
- 143 o Indoctrination and training needs not assessed annually as required
- 144 o No documented evidence of trend analysis performed to support statements in 1987 management assessment/no procedure for trending exists (Note: Trending is mechanism to determine if there are repeated QA deficiencies in a certain area)
- 145 o Position descriptions for QA staff do not exist
- 146, o Computer software does not identify quality levels,
- 147 & 148 software not properly certified as being verified and validated, i.e. software not properly documented and controlled
- 149 o Technical reviewers of scientific reports not properly certified
- 150 o No criteria letter available to specify the scope of REECo's responsibilities for calibration services at NTS
- 151 o Scientific Investigations Plans (SIP) did not reference all appropriate technical procedures
- 152 o Comments of technical review not maintained in QA files as required
- 153 o Entries into Scientific Notebooks are inadequate
- 154 o Procurement documents do not include required information
- 155 o Notebook entries for computer programs inadequate
- 156 o Procedures have not been updated to describe quality activities
- 157 o Procedure not properly controlled
- 158 o USGS QA office not notified of equipment calibration
- 160 o USGS internal deficiency documents not evaluated for unusual occurrence
- 161 o QA records not processed in accordance with procedure requirements
- 162 o USGS not performing external audits of its contractors as required

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#### WASTE MANAGEMENT PROJECT OFFICE

### **QUALITY MANAGEMENT PROCEDURE**

N-QA-015

	No. QMP-01-02	Rev. 0
STOP WORK	Effective Date 4/11/88	
	Page 1 of 7	

#### 1.0 PURPOSE AND SCOPE

This procedure establishes the Waste Management Project Office (WMPO) methodology and responsibilities for suspending a WMPO, Nevada Test Site (NTS) Support Contractor, Participating Organization, or WMPO supplier's activity that has been identified as a significant condition adverse to quality requiring correction prior to resumption of the affected activity.

#### 2.0 APPLICABILITY

This procedure applies to WMPO staff personnel who observe or are made cognizant of a significant condition adverse to quality regarding a Quality Assurance (QA) Level I or II activity performed by WMPO, NTS Support Contractor, Participating Organization, or a WMPO supplier.

#### 3.0 DEFINITIONS

3.1 STOP WORK ORDER (SWO)

A letter issued by authorized WMPO personnel to cause the suspension of an activity that is not being conducted in compliance with the applicable Nevada Nuclear Waste Storage Investigations (NNWSI) Project, WMPO, or QA Program requirement, plan, procedure, instruction, drawing, or procurement document, and requires correction prior to resumption of the affected activity.

3.2 CONDITION ADVERSE TO QUALITY

An all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, and nonconformances.

3.3 SIGNIFICANT CONDITION ADVERSE TO QUALITY

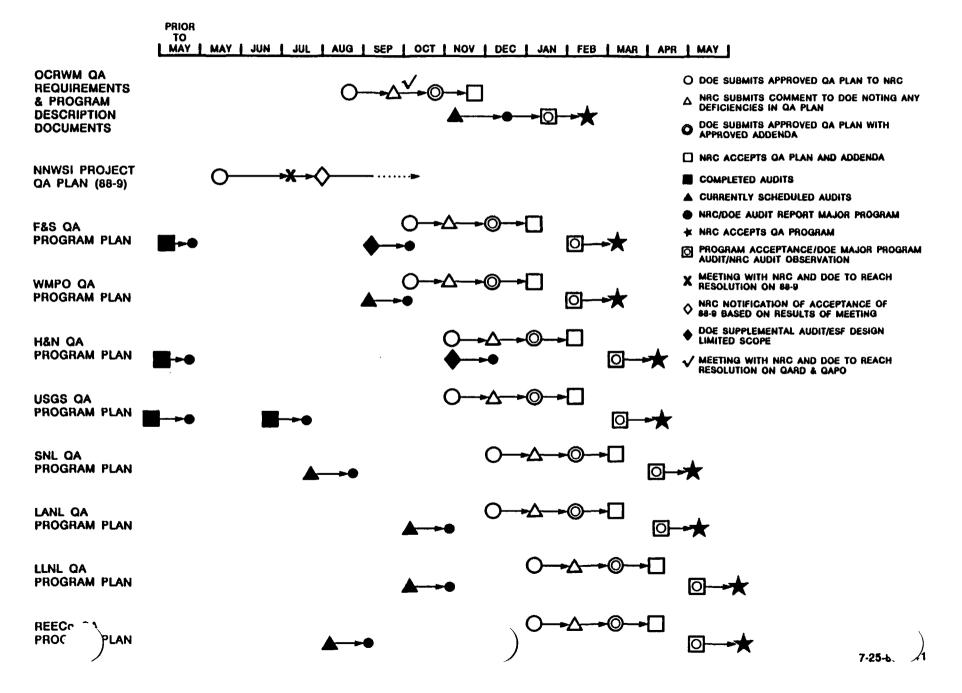
A condition adverse to quality which, if not corrected, could have a serious affect on safety or operability.

Project Manager, T&MSS	WMPO Project Quality Manager	WMPO Project Manager
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Date March 7 1988	Date 3/21/99	Date 5/21/87

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## SCHEDULE FOR NRC ACCEPTANCE OF DOE QA PROGRAM

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## NNWSI QA STRATEGY IS A THREE-PART PROCESS TO ENSURE FULL IMPLEMENTATION OF ALL APPLICABLE QA PROCEDURES ON PROJECT-RELATED WORK

- NRC APPROVAL OF NNWSI QA PLAN
- SEQUENTIAL APPROVAL OF PROJECT PARTICIPANTS QUALITY ASSURANCE PLANS
- IMPLEMENTATION AUDITS OBSERVED BY NRC

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20 DEFICIENCIES WERE IDENTIFIED DEALING WITH PROCEDURAL INCONSISTENCIES

Included in package:

- A. Letter from DOE to USGS issuing SWO
- B. Summary of SDRs
- C. Set of Standard Deficiency Reports (SDRs)
- D. NNWSI QA Stop Work Order Procedure



### **Department of Energy**

Nevada Operations Office P. O. Box 98518 Las Vegas. NV 89193-8518

JUL 26 1988

Larry R. Hayes Technical Project Officer for NNWSI U.S. Geological Survey Mail Stop 421 P.O. Box 25406 Denver, CO 80225

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If you have any questions regarding this matter, please call me at FTS 544-7920 or James Blaylock at FTS 544-7913.

Carl P. Gertz, Project Manager Waste Management Project Office

WMP0:JB-3061

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#### SUMMARY OF 20 USGS STANDARD DEFICIENCY REPORTS (SDRs)

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### **Department of Energy**

Nevada Operations Office P. O. Box 98518 Las Vegas, NV 89193-8518

Larry R. Hayes Technical Project Officer for NNWSI U.S. Geological Survey Mail Stop 421 P.O. Box 25406 Denver, CO 80225

WASTE MANAGEMENT PROJECT OFFICE (WMPO) QUALITY ASSURANCE (QA) STANDARD DEFICIENCY REPORTS (SDRs) RESULTING FROM QA AUDIT 88-4 OF THE U.S. GEOLOGICAL SURVEY (USGS) IN SUPPORT OF THE NEVADA NUCLEAR WASTE STORAGE INVESTIGATIONS (NNWSI) PROJECT (NN1-1988)

Enclosed are 20 SDR Nos. 142-158 and 160-162 that were generated as a result of WMPO QA Audit 88-4 of the USGS support of the NNWSI Project.

Provide responses to each SDR by completing Blocks 14 through 18 as appropriate on the first page of each SDR. Be advised that the audit checklist references provided on each SDR are for WMPO internal use and should have no bearing on your ability to respond to the cited deficiencies. Copies of the responses are due back to this office within 20 working days from the date of this letter. You are asked to send the original copy of each SDR response to Juanita J. Brogan of Science Applications International Corporation (SAIC), Las Vegas, Nevada.

If you have any questions, please contact Daniel A. Klimas of SAIC at FTS 794-7881.

James Blaylo&k Project Quality Manager Waste Management Project Office

WMPO: JB-3062

Enclosures: SDR Nos. 142-158 and 160-162

#### Larry R. Hayes

cc w/encls: S. W. Zimmerman, State of NV, Carson City, NV Lake Barrett, HQ (RW-40) FORS Ralph Stein, HQ (RW-30) FORS J. R. Willmon, USGS, Denver, CO S. H. Klein, SAIC, Las Vegas, NV H. H. Caldwell, SAIC, Las Vegas, NV E. P. Ripley, SAIC, Las Vegas, NV J. J. Brogan, SAIC, Las Vegas, NV B. A. Tabaka, SAIC, Las Vegas, NV E. W. Sulek, CER, Washington, DC J. J. Holonoch, NRC, Washington, DC P. T. Prestholt, NRC, Las Vegas, NV R. W. Gray, MED, NV M. B. Blanchard, WMPO, NV L. P. Skousen, WMPO, NV W. R. Dixon, WMPO, NV C. P. Gertz, WMPO, NV E. L. Wilmot, WMPO, NV R. E. Monks, WMPO, NV

	WMPO STANDARD DEFICIENCY REPORT						
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Rev. 0

8 Requirement ( continued )

SDR No. 142

- (a) Employer's name;
- (b) Identification of person being certified;
- (c) Activities certified to perform;
- (d) Basis used for certification that includes such factors as:
  - Education, experience, and training (when necessary),
  - Test results (where applicable), and
  - Results of capability demonstration (i.e., visual acuity, colorblindbess, etc.);
- (e) Results of periodic evaluation;
- (f) Results of physical examinations (when required);
- (g) Signature of employer's designated representative who is responsible for such certification;
- (h) Dates of certification and certification expiration.

9 Deficiency ( continued )

inspections of QA Level I items (i.e., MRIR #88-13 and MRIR #88-13). For the purpose of this audit, the items from MRIR #88-13 were traced to determine if these QA Level I items had been installed and were infact generating data for Scientific investigation. Two (2) pressure transducers SN #226110 and 226103, received by Alan Flint on MRIR 88-13, have been installed in USWG-3 on 3/24/88 and UE-25 WT #6 on 3/25/88 respectively. In follow up action during the audit, it was determined by discussion with the Assistant QA Manager of USGS that this condition was not isolated to these inspectors. The assistant QA Manager stated that the requirements in question (see 8 above) had not yet been implemented anywhere within the USGS.

BASIS FOR SDR

The basis for this SDR is already established above.

RATIONAL FOR FINDING

The purpose for developing a certification process for individuals performing activities which effect quality is to ensure that such individuals have suitable proficiency for accomplishing the task correctly. Additionally, a certification is a testiment that a specific individual has a specific body of knowledge and skills.

In the case of inspection (receipt or otherwise) specific requirements have been developed over the course of years of industrial experience. The requirements are intended to assure the inspection individuals have, (1) the knowledge of tools and set up processes for doing inspections; (2) a knowledge of the design attributes which the product must meet to assure conformance; (3) the physical ability of

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Page 3 of 3

9 Deficiency ( continued )

DR No. 142

inspectors to differentiate colors when necessary; (4) the visual acuity to discern sufficient details to assure product conformance; (5) sufficient experience to execute sound judgement during the inspection process in determining when products meet specified requirements. These abilities are necessary to perform the basic inspections and assure that items are conforming. Having a conforming product effects both the resultant quality of the task and its cost and schedule. (i.e., when the products are conforming, effort need only be expended once. Therefore, the cost of the task/effort is reduced by the amount necessary to correct and redue the task.

It is therefore necessary to define the knowledge, skills, experience, etc...that an inspector must have in order to perform inspections properly.

The lack of a basis for certification of inspection personnel is a deficiency which is of major importance. It will require remedial action to resolve the specified problems identified in the audit. Additional investigative actions will be required to determine the extent of personnel certified without benefit of a basis. Also, the impact on the project of having personnel perform inspection without benefit of udequate experience and or training must be determined. Corrective actions will be .ecessary to assure that individuals are trained and properly evaluated against an established standard which reflects both specified requirements and the needs of the project.

The fact that Quality level I items are currently being procured without benefit of properly trained personnel is an unacceptable risk to the project. The ability of regulatory authority to accept the results of the NNWSI Project is reduced as a result of our current practice.

10 Recommended Actions ( continued )

- (2) Implement fully or amend current inspection program.
- (3) Qualify & certify receipt inspection personnel in accordance with the approved QA Program.
- (4) Subsequent to amendment & implementation of inspection program, reinspect all QA Level I & II items.

		WMPO STANDARD DEFICIENCY REPORT N-QA-038 3/87							
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Rev.

Page 2 of 2

8 Requirement ( continued )

procedures.

143

9 Deficiency ( continued )

training exist, but a documented assessment of continuing indoctrination/training need was not provided.

In the area of software QA, no evidence of training of seismology personnel on USGS-QMP-3.03 has taken place for approximately 15-16 months.

BASIS FOR SDR

The USGS QAPP requires training of personnel performing activities which effect quality and those who verify the attainment of specified quality in order to assure correct performance of the activities. USGS has not maintained the training evaluation to assure that training is up to date.

RATIONAL FOR SDR

Properly trained personnel provide a greater measure of assurance that activities will be performed properly. In order to maintain the level of performance, training must be continuous.

10 Recommended Actions ( continued )

- 2.) Determine the impact on quality caused by personnel not receiving recurrency training.
- 3.) Retrain and document training of supervisory personnel as to QMP 2.02 Rev. 1 requirement.

	WMPO STANDARD DEFICIENCY REPORT N-QA-038 3/87										
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2	5	9 Deficiency Contrary to the above, no documented evidence was provided during the audit to demonstrate that an analysis of Nonconformance Reports had taken place to support the statements made in the 1987 Annual Assessment.									
Completed		10 Recommended	Action(s	): 🗓 Reme	dial X	Investigat	tive 🛛 Co	orrect	live		
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9 Deficiency ( continued )

DEFICIENCY

BASIS FOR SDR SDR

The applicant for NNWSI is the Director of OCRWM. OCRWM has deligated this authority to WMPO. WMPO requires "Management assessments are to be performed by the WMPO and each NNWSI Project Participant. Each organization is to develop its internal procedures for planning, organizing, performing, and documenting the management assessment conducted, including the analysis and reporting of the results and the tracking of recommendations. Copies of all management assessments are to be provided to the Project Manager, WMPO and the WMPO PQM. The Project Manager, WMPO will make appropriate submittals of canagement assessment reports to OCRWM. Although management above or outside the QA organization is responsible for the management assessment activity, the QA organization may participate in the actual conduct of the management assessments.

USGS requires "Performance of Management Assessments: The USGS shall develop internal procedures for planning, organizing, performing, and documenting the management assessment conducted, including the analysis and reporting of the results and the tracking of recommendations, Copies of all management assessments are to be provided to the Director, WMPO, and the WMPO PQM."

The internal USGS procedures for performing the management assessment is quoted above.

RATIONAL FOR THE SDR

To perform a trend analysis, documentation of the facts to be analysized must be accomplished. It is reasonable to assume that if an analysis was done, records or documentation of that analysis would exist. No such documents were provided during the audit. Additionally, USGS has no procedures to define how to perform trend analysis.

10 Recommended Actions ( continued )

- (2) Determine the impact of 1987 trending data in the annual assessment.
- (3) Train applicable personnel to trending anaylsis procedure and document same.

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	A Orga	5 Organization USGS-DENVER	6 Person(s) Joe Willmo	Contacted n, Susan Shipley	7 Response Due Date is 20 Working Days from Date of Transmittal						
C pating	ginating G	education and expe	l: USGS QAPP- erience requi	-01, R4, Section 2, Par	ished and documented in						
	Completed by Originating QA	9 Deficiency Contrary to the above requirement, minimum education and experience requirements are not established for Deputy QA Manager and other QA staff positions in position descriptions. Futhermore, no position descriptions were									
	Comple		prrective riptions for technical g activities.								
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8 Requirement ( continued )

activities that affect quality.

9 Deficiency ( continued )

provided for QA position titles named on the Quality Assurance Organization chart.

BASIS FOR SDR

SDR No. 145

This requirement is a WMPO requirement established NNWSI NV0.196-17 Rev. 5, para. 5.1.1. This requirement has been picked up by the current revision of the USGS QAPP, but compliance has not taken place.

RATIONAL FOR SDR

The minimum education and experience levels need to be established in order to assure that proper Project staffing is consistant with project needs. Since the minimum education and experience levels are not established, the proper staffing needs can not be determined.

10 Recommended Actions ( continued )

- (2) Determine impact of deficiency on quality activities, with emphasis on determining effectiveness of quality program implementation.
- (3) Assure position descriptions for each position title listed on the organization chart, which must include minimum education and experience requirements commensurate with the duties and responsibilities assigned
- (4) Evaluate currently assigned personnel against requirements specified in the position description.

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		5 Organization 6 USGS-DENVER To	Person(s) Co om Chaney/M	ontacted Mark Meremonte	20 Worki	Due Date is ng Days from ransmittal		
	Completed by Originating QA	8 Requirement (Audit Checklist Reference, if Applicable) (3-3) NNWSI-USGS-QMP-3.02, R1, Para. 6.1.3 states in part, "Data, documents, and computer codes shall have the same quality levels as the items or activities on which they are to be used or from which they result, unless						
	ted by Ori	9 Deficiency Contrary to the above, demonstrate compliance within the scope of th	with the	above requirement for	items or activi	ities		
L		10 Recommended Action(s): X Remedial X Investigative X Corrective (1) Review all data, documents and computer codes identified in all USGS SIPs for NNWSI work and assure that completed work to date is identified with						
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8 Requirement ( continued )

specifically exempted..."

SDR No. 146

9 Deficiency ( continued )

3233G-03; 3310G-01. NOTE: Reports USGS-0FR-76-408 andd 596 were issued as a result of SIP-3233G-02 Node T509 and T511. These documents have no quality level physically identified on the documents. All activities of SIP-3233G-03 are QA Level I.

The Software Summary Forms (Attachment 1 of QMP-3.03) do identify quality levels. However, during the audit, no traceability was established from the Software Summary Forms to the SIP they support. Additionally, all five SIPs within the scope of this audit were reviewed to determine what software was required by each SIP. Although software needs were identified within the SIP, no specific software was identified. All of the needed software in the SIPs was TBD.

Forty-three (43) auxiliary software programs resulting from SIP 3233G-03 are currently assigned QA Level III, although SIP-3233G-03 has no QA Level III activities and was classified by the WMPO as QA Level I.

#### DISCUSSION

According to the USGS QA Program Plan, Section 3.1.1.1, prior to the start of any scientific investigation, the SIP shall contain a description of the work to be performed...and...shall identify all factors...that relate to the...performance of the scientific investigation. Section 3.1.2 also states that QA levels need to be assigned to the items and activities in a plan that was prepared earlier. It is clear that extensive use of software is being made by USGS for this SIP without required reviews and approvals in an updated SIP. If this work were appropriately included in the SIP, proper assignment of QA levels would likely have occured. Unfortunately, this is not the case with the foregoing software, most of which has been prepared earlier outside the NNWSI Project. SIP 3233G-03, Rev. O should be updated promptly.

The root cause of the deficiency is not the improper use of software forms but the inadequate control over scientific investigations which include software use. USGS should determine whether or not other scientific work, other software and other data processing activities are being performed to support quality level I or II work without proper QA level assignment to the work per an approved SIP.

O Recommended Actions ( continued )

the appropriate QA level.

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10 Recommended Actions ( continued )

SDR No. 146

- (2) Develop and implement measures to assure compliance with this requirement in the future.
- (3) Determine the impact on quality of work done to date on NNWSI Project.
- (4) Reissue the SSF for the forty-three (43) software program versions currently covered by SIP 3233G-03.
- (5) Modify QMP-3.03 attachment no. 1 and 2, to provide traceability to applicable SIPs and require a QA approval signature to ensure that appropriate QA levels are identified for software affecting quality.

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٤	Contrary to the a Appendix A partic	9 Deficiency Contrary to the above requirments, USGS has published USGS-OFR-87-596 (see Appendix A particularly), dated 1987, which contains Quality Level I data generated by undocumented (i.e., no SCIF) computer program titled HYP071.FOR,						
Completed	activities prior	10 Recommended Action(s): X Remedial X Investigative X Corrective Modify QMP 3.03 to prevent the release for use of USGS software on NNWSI activities prior to the completion and certification of the SCIF.						
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8 Requirement ( continued )

all scientific and engineering software. In additiion, the SCIF must be "appropriate ly updated before the publication of any result depending on the software".

9 Deficiency ( continued )

Version 1.000. This Scientific and Engineering software, according to USGS staff, has been used to conduct QA Level I Regional Seismicity Studies (SIP 3233G-03) to locate earthquakes and their magnitude from Great Basin seismograph station data. However, an appropriately updated SCIF for HYP071.FOR was not presented during the au dit.

DISCUSSION

This SDR is based on an implementation deficiency identified during audit of USGS SIP 3233G-03, "Regional Seismicity Studies" and its related QA Level I Scientific and Engineering software, specifically USGS computer program HYP071.FOR. Publication USGS-OFR-87-596 is a clear violation of the USGS procedure and raises the question of acceptance of the data contained therein for licensing, since verification of the code and the changes made for the NNWSI Project are not documented, reviewed or approved.

10 Recommended Actions ( continued )

- (1) Complete the SCIF for HYP071.FOR computer program.
- (2) Document by Nonconformance Report that Publication USGS-OFR-87-596 contains data/results unqualified for use on the NNWSI Project.
- (3) Stop utilizing HYP071.FOR for scientific investigation until the SCIF is complete and certified.
- (4) Investigate to determine if other USGS Publications have been released utilizing USGS scientific software for which no SCIF has been completed and certified.
- (5) Determine the impact on the quality of publishing documents which contain unqualified data/results generated from uncertified software computer programs.

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Originating Q		8 Requirement (Audit Checklist Reference, if Applicable) The USGS QAPP, Section 3.3.1 states in part that computer software used to support a high level nuclear waste respository license application shall be documented and controlled. Section 3.3.2 also states that Users Manuals, code							
ه ا	Contrary to the abo "No documentation i		nt, USGS QMP-3.03, Sec or auxiliary software"	tion $6.3.1.1$ states that					
Completed	10 Recommended Action(s (1) Modify USGS QN activities for	10 Recommended Action(s): I Remedial I Investigative I Corrective (1) Modify USGS QMP-3.03 to require documentation for all QA Level I and II activities for which auxiliary software is required to conduct the work.							
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6 Persons contacted ( continued )

Z. Petermann, M. Meremonte, B. Szabo

8 Requirement ( continued )

No. 148

SDR

assessment and support, and continuing documentation and code listings shall be included as a minimum. Also QAPP, Section 3.3.3 states in part, "A software configuration management program shall be instituted for software including listings, chronology of revisions and descriptions of changes made".

Furthermore, Section III, Part 1.4 of the NNWSI QA Plan, states that "computer programs that are used for analysis shall be verified and controlled as specified in NNWSI Project...procedures..."

9 Deficiency ( continued )

DISCUSSION

bjective evidence of documentation for USGS QA Level I auxiliary software and data eduction software prepared for SIPs 3370G-02 (codes ANALYST, SR and CONTROL), SIP 3331G-01 (codes CVXYLL, REFORM1, CORALL, CORMP and NHP.HYDRO), and SIP 3233G-03 (codes INPUT.FOR, PTBPT, and 43 other codes), could not be provided by USGS staff. Minimum documentation of codes may consist of detailed user manuals, summaries of code verification and methods of calculation, or brief code descriptions depending upon the complexity of the method or code, or the number of users. The documentation should be complete enough to ensure that a knowledgeable person in the field could reapply the data reduction process or model effort and obtain consistent results. The documentation should also provide verification that the software performs the desired calculations correctly (i.e., computer codes for SR-isotope analysis, U-trend U-series dating, and Fission Track analysis, were apparently never verified) and changes made to existing codes for use on the NNWSI Project. Futhermore, no objective evidence was presented during the audit to document that software configuration changes are documented.

The NNWSI QA Plan (NV0-196-17) and the USGS QA Program Plan (NNWSI-USGS-QAPP-01) are consistent and congruent with respect to software documentation, but the authors of the USGS-QMP have taken exception with the requirements of the NNWSI QA Plan and the USGS QAPP. However, this exception is neither noted in the USGS QAPP nor recorded on checklists required by NV0-196-17, Section II, Parts 1.1, 1.2 and 1.3.

There is no justification why USGS-QMP-3.03 deviates from these requirements. Section II, Part 1.0 of the NNWSI QA Plan states that where deviations from the NNWSI QA Plan and Participant Plans/procedures exist, NVP-196-17 requirements shall

revail. Therefore, the USGS-QMP is not in compliance with the two controlling QA  $\sim$  lans. Such exceptions along with appropriate justification for non-compliance with



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9 Deficiency ( continued )

the NNWSI QA Plan requirements should have been reviewed by the WMPO prior to their implementation.

The NNWSI QA Plan (NVO-196-17) and the USGS QA Program Plan (NNWSI-USGS-QAPP-01), are very clear regarding the minimum requirements for software configuration management. These include:

- (1) Use of a unique identification, including version numbers, in the output.
- (2) Listings of the software.
- (3) A chronology of versions and description of changes made between versions.

The WMPO audit staff was provided no objective evidence that these minimum requirements were being met for the computer codes investigated.

10 Recommended Actions ( continued )

- (2) Determine the impact on quality of results/data published by USGS based on the use of auxiliary software without the required documentation.
- (3) Complete the required documentation for all auxiliary software in use which has resulted in publication of data/results obtained from USGS software.
- (4) Develop measures to assure that auxiliary software used by USGS will be documented in accordance with the QA requirements.
- (5) Institute a software configuration management program for all software developed or modified by USGS.
- (6) Document all software changes or modifications currently in use for NNWSI activities per QA software requirements.

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8 Requirement ( continued )

R1, para. 4.5, states in part regarding review of technical procedures, "The Review shall be in accordance with QMP-3.07 (Technical Review) regarding selection and certification of reviewer(s), specifications or criteria of review, and documentation."

9 Deficiency ( continued )

the audit. For three (3) of 11 Technical Reviewers on Technical procedures, no certifications were provided during the audit.

BASIS FOR SDR

SDR No. 149

This requirement is not a WMPO imposed requirment. Therefore, the basis for the SDR is the USGS implementing procedures.

RATIONAL FOR SDR

10CFR50 Appendiix "B" Criteria V requires procedures to specify how work activities are done and to have the work activity accomplished in accordance with the procedures. USGS did not implement their own procedures.

10 Recommended Actions ( continued )

NNWSI personnel except for Inspection, Non Destructive Examination, QA Auditors and performers of special processes as no NNWSI requirement exists for such certification except as noted. Response to the SDR will serve as the basis for future audit and surveillance activities.

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9 Deficiency ( continued )

DISCUSSION

The USGS-QAPP-01, Revision 4, Section 4.2, requires that when the USGS procures services from contractors or requests services from national laboratories and supporting Federal Agencies, the USGS shall prepare work agreements, memorandums of understanding, interagency agreements, management agreements, or other suitable documents.

The listed QMP-3.05, Revision 1, further amplifies this requirement in that criteria letters shall be prepared by the USGS organization requestIng NTS contractor services.

A request was made of the USGS-QA Manager to provide said objective evidence with respect to the scope of REECos work as related to calibration services provided by REECo to the USGS at the Nevada Test Site.

No documentation was presented during the course of the audit.

10 Recommended Actions ( continued )

(2) Determine the cause of the condition noted in this SDR and what action will be taken to prevent recurrence.

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SDR No.

9 Deficiency ( continued )

The USGS QAPP-01, Rev. 4., para. 3.1.1.1 requires that SIPs shall "identify all factors and concerns that related [SIC] to the planning or the performance of the scientific investigation." The implementing procedure referenced in 8 above, implement this QAPP-01 requirement. In the specific instance of SIP 3310G-01, the SIP failed to identify one procedure which was necessary to perform the work involved with the SIP scope of work.

RATIONAL FOR SDR

1.

The bifercation of the WMPO Criteria III program in to Scientific Investigation and Design Control is predicated upon the use of SIPs as the overall controlling document. Therefore, all sub-tier documents get their efficacy from the upper-tier SIPs. The SIP, in order to function properly as the controlling and authorizing document, must be maintained current.

10 Recommended Actions ( continued )

(2) Determine the impact on the quality of data gathered using procedures not referenced in this SIP.

(3) Review all SIPs to determine if similar situation exists.

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		5 Organization USGS-Denver	6 Person( Tom Chan	s) Contacted ley	7 Response 20 Workir Date of T	Due Date is ng Days from ransmittal							
	<b>Originating QA</b>	8 Requirement (Aud NNWSI-USGS-QM with copies of comments and a	P-3.04, R1, Para supporting do	ence, if Applicable) a. 6.5.1 - A printed copy cuments (Manuscript Rout , DOE/NV approval) shall	y of the document ing Sheet, review	together ers							
	à	The actual con		d for technical review o ailable in the QA record		the							
	Completed	<ul> <li>10 Recommended Action(s): X Remedial I Investigative Corrective</li> <li>(1) Obtain the actual comments generated as a result of the technical review done by the Geologic Division.</li> <li>N QAE/Lead Additor Date 12 Branch Manager Date 13 Project Quality Mgr. Date</li> </ul>											
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8 Requirement ( continued )

designated QA file in accordance with QMP-17.01.

9 Deficiency ( continued )

Basis for SDR:

152

All documents which meet the definition of QA records must be maintained in the QA records system. The documents involved with this SDR do in fact meet the definition of QA records. However, they are not included in the QA records system at USGS.

Rationale for SDR:

QA records included in the QA records system are maintained in a retrieval system for specified periods of time. The records in question were not subjected to any analysis as to the specific time period these records should be maintained.

10 Recommended Actions ( continued )

(2) Establish a method to assure continual compliance.

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9 Deficiency ( continued )

SDR No. 153

performing the geologic work in Trench #14. Scientific notebooks for the calcite and opaline silica (hydrogenic) deposits were observed to lack identification of the individual making the entry (e.g., Quaternary geologic and trenching work), lacking a date on which the work was performed, and widespread lack of a location for where the work was performed or a sample collected.

Further examples include:

- 1) Sample HD-16 has little sample description. Unit 1 and Unit 2 are mentioned with apparently no description of Unit 1 or 2. The description for this sample is brief and the sample location cannot be determined from the photographs.
- 2) Samples collected prior to 1986 for Quaternary geologic and trenching studies (calcite and opaline silica deposit work) are difficult to trace from the field notebook, to laboratory analyses, to soil stratigraphic units.
- 3) Samples HD-55-1 and HD-55-2 are not geologically described in the sample sheets or in the field notebook.

10 Recommended Actions ( continued )

- (2) Investigate to determine the impact on quality of the data collected for the calcite and opaline silica studies.
- (3) Reinstruct applicable personnel as to the requirements for entries into Scientific Notebooks.

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9 Deficiency ( continued )

SDR No. 154

to DOE for approval. Similar deficiencies were reported by USGS on several occasions; reference finding USGS-8701-6, NCR-88-09, NCR-88-12 and CAR-88-01, but to date, there has been no effective corrective action by USGS (Ref. page 2 of USGS CAR-88-01).

In addition, contract #GS-095-50007 from GSA to Martin Marietta, was piggy-backed by P0 #061311-86 dated 9/5/86, from USGS to GSA. The purchase requisition for this P0 and subsequent 5 modifications have not identified SIP No. or QA Level as required. The task order HF6603, which is part of this P.O., states that the function of the Instrumentation/Data-Acquisition System (IDAS) must be considered a QA Level I activity. Modification 4 to the P.O. contained a Technical Review Sheet which indicated that the Quality Level was "N/A", which is contrary to the task order HF 6603 instructions, and to the Quality Level Assignment Sheets which are attached to SIP #3343.

Discussion: This SDR was written because of the deficiencies found during the review of procurement documents which indicated that the requirements of NNWSI-USGS/QMP-4.01, Rev. 1, were not being met. USGS-CAR-88-01, dated 6/7/88, referenced 3 previous audits and surveillances with similar deficiencies and reported that procurement deficiencies in the referenced documents have not been resolved to date. Deficiencies which have been previously reported by the audited organizations are usually written as observations on WMPO audits, but because USGS had not resolved the deficiencies in a reasonable length of time, a decision was made to use the standard deficiency report. The SDR provides a means for WMPO to follow and verify the necessary corrective action as well as getting the attention of upper management.

10 Recommended Actions ( continued )

- (2) Investigate to determine the extent of the noncompliance and impact on quality.
- (3) Reinstruct applicable personnel as to the procedure requirements.

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	USGS technic calibration	al procedure SP- data be entered	rence, if Applicable) 11, Rev. O, Section in a notebook or othe l dated by the person	er organized documer	nt and that						
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8 Requirement ( continued )

and filed with the QA office." Section 7.1 of SP-11 also states that when such data are kept in loose-leaf form, each page will be numbered consecutively and chronologically, signed or initialed and dated by the investigator on a daily basis as entries are made. Section 7.2 also states that "all data collected...will be reviewed and cosigned by a peer or supervisor..."

9 Deficiency ( continued )

audit to demonstrate that methods and data generated by USGS computer program CALIBRATE.FOR have been entered, signed, numbered, reviewed, and cosigned according to procedural requirements.

CALIBRATE.FOR is a scientific computer program used to conduct QA Level I regional seismicity studies (SIP 3233G-03) Version 1.001 dated 2/22/88 per USGS QMP 3.03. The evidence examined indicated that this lack of compliance with specified requirements has existed since this NNWSI Program activity was started at USGS.

This SDR is based on an implementation deficiency identified during the audit of USGS SIP 3233G-03, "Regional Seismicity Studies" and its related QA Level I, Scientific and Engineering Software," specifically USGS computer program CALIBRATE.FOR, Version 1.001.

The deficiency resulted from non-compliance with the requirement(s) of SP-11: (1) Section 5.3 that calibration data be entered in a notebook or other organized document, (2) that entries shall be signed and dated by the person performing the calibration, (3) that when such data are kept in loose-leaf form, each page will be numbered consecutively and chronologically signed or initialed and dated by the investigator on a daily basis as entries are made, and (4) Section 7.2 that "all data collected...will be reviewed and cosigned by a peer or supervisor..."

10 Recommended Actions ( continued )

- (2) Investigate to determine if other NNWSI software activities have the same non-compliance.
- (3) Determine the impact on quality resulting from this deficiency.
- (4) Train applicable personnel to procedure requirements and document same.

SDR No. 155

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QA Orga	5 Organization USGS-Denver	6 Person(s) Darrell P	) Contacted Porter	7 Response Due Date is 20 Working Days from Date of Transmittal							
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8 Requirement ( continued )

circumstances.

SDR Ño. 156

9 Deficiency ( continued )

The lack of implementation of Rev. 4 of USGS QAPP resulted in other SDR problems, specifically (1) lack of trend analysis (SDR #144) - no objective evidence was presented during the audit that USGS has a deficiency document trending program in place as required by NNWSI-USGS-QAPP-01, Rev. 4, Section 15, Para. 15.5, (2) lack of position discriptions (SDR #145), (3) field notebook documentation (SDR #153), (4) lack of unusual occurance review and reporting (SDR #160).

10 Recommended Actions ( continued )

- (2) Develop/revise procedures implementing the Revision 4 QA program.
- (3) Perform comprehensive review of all project activities to determine impact on the QA program.

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8 Requirement ( continued )

signature and date denoting technical & QA compliance reviews", para. 4.2.3 states states in part "Each document will be reivewed by the Quality Assurance Office to check for compliance with the appropriate controls, and regulations in accordance with checklists established..."

9 Deficiency ( continued )

HP-61 Rev. O, were not reviewed by the QA office and they were not approved by USGS management.

These improperly approved procedures were physically located at the NTS (Test Cell C) and were the controlling documents for the individual work activities specified.

Discussion:

SDR No. 157

The NNWSI QAP requires that "The preparation, review, approval, and issuance of documents such as instructions, procedures, plans, and drawings, including changes thereto, shall be controlled through the implementation of methods that assure that only correct documents are used. Document control shall be applied to the following:

o Documents containing or specifying quality requirements

o Documents that prescribe activities affecting quality."

It was noted during the audit that USGS had developed measures to control the issuance of documents. A method to assure that only correct documents were used was in place. In fact the USGS QAPP, Rev. 4, required "Methods for Control: The preparation, review, approval, and issuance of documents, such as instructions, procedures, plans, and drawings, including changes thereto, shall be controlled through the implementation of methods that assure that only correct documents are used. Document control shall be applied to the following:

- o Documents that assure technical adequacy,
- o Documents containing or specifying quality requirements, and
- o Documents that prescribe activities affecting quality.

The document control system shall be documented and the QA office shall provide the appropriate review, resolution of comments, and concurrence with respect to quality related aspects of the documents."

Additionally, the USGS QAPP requires "Implementation of Document Control: Implementation of document control shall provide for the following:

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of 4

9 Deficiency ( continued )

DR No. 157

o A method for assuring that the correct and applicable documents are available at the location where they are to be used,

and it requires

o Identification of assignment of responsibility for preparing, reviewing, approving, and issuing documents."

All of the above requirements were included in the USGS implementing procedure, QMP 6-01, Rev. 1. However, as documented above, four of the technical procedures reviewed during the audit had not been subjected to the appropriate review and approvals.

A basic premise for licensing the NNWSI Project is that activities which affect quality are controlled through procedures. These procedures define the actions required to carry out tasks and assure that tasks are done in accordance with those procedures. When this basic premise is fulfilled, there is increased assurance that actions are done properly and in a controlled environment. In order to achieve this controlled environment, several subsystems are necessary: (1) procedures must be written and reviewed, (2) they must be approved, (3) they must be distributed, (4) there must be records that the work/task were accomplished in accordance with the procedure (QA records), and (5) the work is verified independently (QC inspection).

All of the attributes outlined above form an administrative system which supports the concept of quality of workmanship. As problems occur in the work place and specific controls are violated or invalidated, confidence is lost that the tasks were performed in a controlled environment.

In the case of this SDR, several of the control elements which should have been in place to create the controlled environment, were not operating effectively. Specifically: (1) Document Control, Criteria 6 - The review and approval cycle was not followed, (2) Document Control, Criteria 6 - The issuance process for controlled documents was not followed, (3) Document Control, Criteria 6 - No management control, (4) QA Program, Criteria 2 - The indoctrination of individuals in QA requirements was ineffective because the working level personnel doing the task were willing to work to improperly approved procedures indicating lack of knowledge. The approval process or lack of discipline in that they were willing to knowingly violate basic tenets of QA.

When these controlling elements were not in place as required, and confidence in proper performance of tasks is reduced. The ability of regulating quality to accept the resultant data in also reduced, and this reduced ability may severely challenge the successful compliance with the NWPA.



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9 Deficiency ( continued )

At the time of the audit only limited work activities were being accomplished at the NTS. These activities are limited to the monitoring of natural events and the measuring of ground water elevation. Only one SIP was used to audit the document control system used at NTS. The audit attempted to establish that controlled instructions which had been properly developed, reviewed, approved, and issued were available to the working level personnel. It was found that four of the 10 instructions reviewed by the auditor had not been subject to all of the appropriate controls required by the USGS management.

10 Recommended Actions ( continued )

- (2) Assess the impact on the quality of data gathered under unapproved procedures.
- (3) Determine if other unapproved procedures are in use.

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SDR No.	158	Rev.		Page	2	of	2

9 Deficiency ( continued )

Discussion: During the interview process, I asked the contacted person if she (a QA person) or the technical personnel could present to me any objective evidence that the technical personnel had notified the QA office/person when equipment is ready for calibration. The contacted person said that the technical personnel has never contacted the QA office. USGS QMP 7.02, Rev. 2, states that the notification will "be written or by copy of receiving papers." The procedure also states that "calibration activities shall not commence without USGS QA personnel in attendance."

10 Recommended Actions ( continued )

subsequent revisions.

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8 Requirement ( continued )

and Audit Findings to determine if further processing, as an unusual occurrence is required, per DDE/5000.3."

9 Deficiency ( continued )

documents for unusual occurrence status.

Rev.

Discussion: Prior to the audit, while reviewing the USGS QAPP, the auditor detected the stated requirement. Questions were added to three checklists. During the interview of each criteria (#15, 16, 18) the contacted person was asked the question three times. The question was "Have you evaluated each NCR, CAR, and AFR for unusual occurrences?" The contacted person said yes. When asked if the auditor could see and review the objective evidence, the contacted person said they didn't have any objective evidence. Good auditing practice indicated that without some form of objective evidence a deficiency existed.

10 Recommended Actions ( continued )

occurrences.

Investigative Action: Review all closed and present NCRs, CARs and Audit Findings to establish whether an unusual occurrence has or has not occurred.

T A		WMPO S	STANDA	RD DEFICIENCY REI	PORT		N-GA- 3/87	038
100	1 Date June	15, 1988	2 Seve	rity Level 🗌 1 🕅 2	3	Page 1	of	2
Organization	3 Discovered Audit 88-4	During 30 Identifi R. H. Kle		3b Branch Chief Concurrence Date		4 SDR No. 161	Rev	
OA Orea							Due Dat g Days ansmitta	from
Orininating O	8 Requirement (Audit Checklist Reference, if Applicable)							
ž	Contrary records	9 Deficiency Contrary to the above requirements, USGS has not been sending completed records to the USGS Records Processing Center within 120 days of completion. In addition, USGS has not been forwarding processed records to the Project						
Completed		lement the requi		X Investigative X ( of QMP 17-01.	Correct	tive		
Anrul	MICK IMAN 7-25-89 Martin Manager Date 13 Project Quality Mgr. Date							
5	14 Remedial/Inv	14 Remedial/Investigative Action(s)						
۲ ۲ ۲	16 Cause of the Condition & Corrective Action to Prevent Recurrence 17 Effective Date							
Completed	18 Signature/Da	ite						
Γ	19 Response	□Accept □Amer □Reject Resp		E/Lead Auditor/Date	E	Branch Manage	r/Date	
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8 Requirement ( continued )

SDR No. 161

Para. 6.5, The records will be processed at the USGS Records Center and will be forwarded to the PRC for microfilming once all QA reviews are complete.

9 Deficiency ( continued )

Records Center (PRC). These activities were interrupted early in 1987 by the high priority work on Discovery Records. Aside from record collection, very little processing of records has been resumed by USGS. Activities which have not been done include processing, examination of packages, evaluation, data entry, processing of data items, preparation for transmittal, and mailing records to the PRC.

While the USGS has not met the above requirements, it has been noted that processing activities are being reactivated. USGS has appointed a new Records Coordinator (as of 1/88) and are currently working to a plan which emphasizes the processing of 1987 records. A schedule has been established for the months of May, June and July, 1988.

AUDIT CHECKLIST REF: Audit Item 17-23, 17-24 and 17-25.

Discussion: This SDR was written because of the failure of USGS to collect and process records as required by USGS QMP 17.01, Rev. 1, during the period of time from early 1987 until the present. Although some activities have resumed within the past four or five months, it is apparent that USGS has not been able to resolve the problems which must be corrected prior to meeting the current records requirement documents.

10 Recommended Actions ( continued )

- (2) Investigate to determine if records in various stages of processing are intact and still in usable condition and determine the impact of this deficiency on quality.
- (3) Reinstruct applicable personnel as to procedure requirements.

R K	WMPO STANDARD DEFICIENCY REPORT N-QA-038 3/87							
	1 Date June 15, 198	8 2 Sev	verity Level 🗆 1 🕅 2 [	3 Page 1 of 2				
	3 Discovered During WMP0-Audit 88-4 5 Organization	30 Identified By W. B. Mansel	3b Branch Chief Concurrence Date	4 SDR No. <u>162</u> Rev. <u>0</u>				
	IUSGS-Denver I.A. M. Whiteside, J. K. Willmon, S. I. S. C. + T. Yurk							
Originating OA		8 Requirement (Audit Checklist Reference, if Applicable) Question 18-22, USGS QMP 18.01, Rev. 1, Para. 5.1.3 and 5.1.4; USGS-QAPP-01, Rev. 4, Para. 18.1.2.2, states that elements of an external organization's QA Program shall be audited at least annually or once during the life of the						
There is no available objective evidence that any other external organ: besides U.S. Bureau of Reclamation have been audited during FY 88 nor a								
Complet	organizations scheduled to be audited. 10 Recommended Action(s): I Remedial I Investigative I Corrective 1. Perform an audit of all USGS contactors on the approved vendors list.							
Anrvl	11 OAE/Lead Auditor Date 12 Branch Manager Date 13 Project Quality Mgr. Date and Junar 7-2598 Marth Arna 105/95 James Blaylork 7/25/86							
	14 Remedial/Investigative Action(s)							
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6 Persons contacted ( continued )

Shipley

SDR No. 162

8 Requirement ( continued )

activity, whichever is shorter, and when determined necessary, a supplier's facility shall have an initial audit to determine both technical and QA capability and adequacy of personnel and implementation of the QA program.

9 Deficiency ( continued )

Petty-Ray Geophysical, Martin-Marietta, and National Water Quality Lab have not been either initially or annually audited per the requirements stated in Section 18.0 in both the USGS-QAPP and USGS-QMP.

The provisions stated in USGS-QMP-7.01 and 7.03 do not provide relief from the requirements stated in Block 8 for the external organizations identified above.

10 Recommended Actions ( continued )

2. Investigate to determine the impact on quality.

3. Organizations performing work for USGS should be scheduled to be audited during FY 88 and FY 89 to verify implementation of the QA program.

	ITY MANAGEMENT PROJ	
: • STOP WORK		No. QMP-01-02 Rev () Effective Date - 11/88 Page 1 of 7
	1.0 PURPOSE AND	SCOPE
methodology and respons Support Contractor, Par that has been identifie	sibilities for suspendi rticipating Organizatio	ent Project Office (WMPO) ing a WMPO, Nevada Test Site (NTS on, or WMPO supplier's activity indition adverse to quality the affected activity.
	2.0 APPLICABI	ILITY
cognizant of a signific Assurance QA) Level I	cant condition adverse	er who observe or are made to quality regarding a Quality med by WMPD, NTS Support WMPD supplier.
	3.0 DEFINITI	IONS
3.1 STOP WORK ORDER (	SWO)	
activity that is not b Nuclear Waste Storage requirement, plan, pro	eing conducted in compl Investigations (NNWSI) cedure, instruction, dr	to cause the suspension of an liance with the applicable Nevada Project, WMPD, or QA Program rawing, or procurement document, of the affected activity.
3.2 CONDITION ADVERSE	TO QUALITY	
	used in reference to an acies, defective items,	ny of the following: failures, and nonconformances.
3.3 SIGNIFICANT CONDI	TION ADVERSE TO QUALITY	Y
A condition adverse to affect on safety or op		corrected, could have a serious
APPROVED BY Project Manager, T&MSS	WMPO Project Quality/Manager	WMPO Project Manager



# QUALITY MANAGEMENT PROCEDURE

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STOP WORK

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#### 4.0 RESPONSIBILITIES

#### 4.1 INITIATOR

WMPO staff personnel (hereafter referred to as Initiators) are responsible for immediately notifying the Manager of the Audits and Surveillances Division (A&SD) of a significant condition adverse to quality which may warrant a recommendation to stop all or specifically identified portions of work relating to the affected activity, and for preparing a Standard Deficiency Report (SDR) (see QMP-16-03, Standard Deficiency Reporting System). The Project QA Department Manager or WMPO Project Quality Manager (PQM) shall be notified of potential stop work conditions when the A&SD Manager is not available.

#### 4.2 AUDITS AND SURVEILLANCES DIVISION MANAGER

The ALSD Manager is responsible for convening and participating in meetings to evaluate SDRs to determine the need for issuing SWOs, and coordinating verification of corrective action measures prior to closing the associated SWO.

#### 4.3 PROJECT QUALITY ASSURANCE DEPARTMENT MANAGER

The Project QA Department Manger is responsible for evaluating SDRs to determine the need for issuing SWOs; preparing and approving stop work recommendation letters for NTS Support Contractors, Participating Organizations, and WMPO suppliers' activities; and preparing and approving stop work notification letters for WMPO activities.

#### 4.4 WMPO PROJECT QUALITY MANAGER (PQM)

The WMPO PQM is responsible for evaluating SDRs to determine the need for stopping affected work, approving stop work recommendation letters, and approving stop work notification letters (SWOs) for WMPO work.

#### 4.5 WMPO PROJECT MANAGER

The WMPD Project Manager is responsible for approving recommendations to issue or close SWDs, as appropriate. The WMPD Project Manager has been granted authority to act as the Contracting Officers Technical Representative (CDTR) to issue and close out SWDs for Lawrence Livermore National Laboratory (LLNL), Sandia National Laboratories (SNL), and Los Alamos National Laboratory (LANL). The actual stop work notification letter shall be signed, dated, and issued by the WMPD Project Manager. In addition, the WMPD Project Manager has been designated as the Contract Administration Representative (CAR) by the Contract Administration Representative Authority (CARA) with the authority to recommend to the U.S. Department of Energy Nevada Operations Office (DOE/NV)



# QUALITY MANAGEMENT PROCEDURE

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Assistant Manager for Administration (AMA) that Reynolds Electrical and Engineering Company (REECo), Holmes and Narver (H&N), Fenix and Scisson (F&S), or U.S. Geological Survey (USGS) activities be stopped or permitted to continue, as appropriate. The actual stop work notification letter and letter closing the SWD (see Section 5.10) shall be signed, dated, and issued by the AMA.

#### 5.0 PROCEDURE

#### 5.1 IDENTIFICATION

WMPO staff personnel who observe or are made cognizant of potential stop work conditions in the course of performing QA audits or surveillances of NNWSI Project Participants or WMPO suppliers, conducting document reviews, or during the normal course of business shall immediately notify the A&SD Manager. Potential stop work conditions should be reported to the A&SD Manager any time they are observed. This notification by the Initiator shall be made by personal contact, telephone conversation, or telex. The Initiator shall provide clear, concise, objective information, including the requirements violated and the reason the SWO should be issued. An SDR designated as Severity Level I (see QMP-16-03), shall be prepared by the Initiator within 24 hours of the notification.

#### 5.2 INITIAL EVALUATION

The SDR shall be promptly provided to the A&SD Manager who shall convene a meeting with the Project QA Department Manager and WMPO PQM to determine the need for the SWO. When the condition reported in the SDR is a technical concern, the cognizant WMPO Branch Chief shall participate in this evaluation. If the evaluation of the SDR reveals a significant condition adverse to quality or repeatedly unacceptable performance, and the WMPO PQM determines the affected activity must be stopped to preclude further degradation of the situation, a stop work recommendation letter shall be prepared (see Section 5.3.4 if the SDR applies to a WMPO activity).

#### 5.3 RECOMMENDATION TO STOP WORK

#### 5.3.1 Stop Work Recommendation Letter

When the SDR pertains to a Participating Organization, NTS Support Contractor, or WMPO supplier's activities, the stop work recommendation letter shall be prepared by the Project QA Department Manager and shall include the following information:

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3. 4.	to be stopped. Description of the deficiency. Responsible organization. Action required to resolve the ad- recurrence. Effective date of the SWO.	
5.3.2	Approval of Stop Work Recommendation	n Letter
Departm approva	p work recommendation letter shall ent Manager and forwarded with the 1. The WMPO PQM shall sign and data nsmit it and the associated SDR to 1.	related SDR to the WMPO PQM for e the stop work recommendation let
5.3.3	Stop Work Notification Letter	
authori issued as appr	WMPO Project Manager approves the size the preparation of a stop work no to the responsible organization as o opriate. The SWO notification lette corresponding stop work recommendat	otification letter which shall be outlined in Section 5.5, 5.6, or 5 er shall provide the same informat
5.3.4	Stop Work Notification Letter Issue	d to WMPO
shall p informa issued	e SDR pertains to a WMPO activity, repare and approve a stop work noti- tion required in Section 5.3.1. Th to the WMPO Project Manager followin oject Manager shall respond to the S	fication letter that contains the is notification letter shall be ng approval by the WMPO PQW. The
5.4 VO	IDING A RECOMMENDATION TO STOP WORK	
5.4.1	Justification for Voiding a Stop Wo	rk Recommendation Letter
	e WMPO Project Manager determines the indication of the second seco	hat a recommendation to stop work es) is not justified, he/she shall the justification for voiding the



# QUALITY MANAGEMENT PROCEDURE

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#### 5.4.2 Resolution of Disputes

Disputes between the WMPO PQM and others regarding the issuance or closure of the SWO shall be elevated to the WMPO Project Manager for resolution. In addition, the WMPO PQM has the authority to request that the DOE/NV Manager resolve disputes between the WMPO PQM and the WMPO Project Manager regarding the issuance or closure of the SWO. When the WMPO PQM is not satisfied with the DOE/NV Manager's resolution of a dispute, he/she shall notify the Office of Geologic Repositories (OGR) QA Manager and request resolution of the matter.

5.5 STOP WORK OF LLNL, SNL, AND LANL

The WMPO Project Manager shall issue the stop work notification letter and associated SDR (see Section 5.3) to the responsible organization's Technical Project Officer (TPO) and shall provide copies of the letter and associated SDR to the DOE/NV AMA and to the responsible DOE Operations Office Contracting Office; i.e., the DOE Contracting Officer, San Francisco Operations Office for LLNL, and the DOE Contracting Officer, Albuquerque Operations Office for SNL and LANL.

5.6 STOP WORK OF REECO, HEN, FES AND USGS

The WMPD Project Manager shall forward the stop work notification letter and associated SDR (see Section 5.3) to the AMA, who shall sign and issue the letter and associated SDR to the responsible organization's TPO and QA Manager

5.7 STOP WORK OF WMPO SUPPLIERS

The WMPO Project Manager shall issue the stop work notification letter to the affected supplier's management via the cognizant purchasing agent.

5.8 RESPONSE TO THE SWO

The SWO shall require the responsible organization to notify the WMPO Project Manager that activities within the scope of the SWO have been stopped. Additionally, the responsible organization shall be instructed to respond to the SWO and associated SLR within 20 working days of the effective date of the SWO. The responsible organization shall document the cause of the adverse condition, the corrective action planned and the estimated date of completion, and measures established to preclude recurrence of the adverse condition in the appropriate blocks of the SDR; and shall return the SDR to the WMPO PQM. Review and approval of responses shall be accomplished as described in QMP-16-03. When the responsible organization desires to revise the WMPO approved response to the SDR (e.g., request for a 30 day extension in regard to the completion date of corrective action), the proposed revision to the response shall be submitted to and approved by WMPO prior to implementation.

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QUALITY MANAGEMENT PROJECT OFFICE					
i e	STOP WORK	No. QMP-01-02 Rev. 0 Effective Date 4/11/38 Page 6 of 7			
5	.9 CLOSURE OF THE SWO				
5	.9.1 Verification of Corrective Action				
B t c t	he WMPO PQM, Project QA Department Manager, A ranch Chief, as appropriate, shall review the o determine the extent of required WMPO verif ate(s) established by the responsible organiz orrective action, the A&SD Manager shall sche he adequacy of required corrective action and ecurrence.	SWO, SDR, and related response ication activities. Based on the ation for completion of required dule and perform verification of			
5	5.9.2 Acceptance of Corrective Action Measures				
shall b PQM sha and the the WMF	hall be processed for closure. The Project Q QM shall review the documentation relating to nd the closed SDR. If all required actions h	completion of verification activities with acceptable results, the SDR be processed for closure. The Project QA Department Manager and the WMPD hall review the documentation relating to the SWO verification activities he closed SDR. If all required actions have been verified as acceptable, APD PQM shall notify the WMPO Project Manager of the acceptability of the ctive action measures.			
5	5.10 RESUMPTION OF ACTIVITIES The WMPO Project Manager shall take the necessary measures to ensure that the responsible organization is formally notified that the SWO and associated SDR have been closed and that continuation of the affected activities is permitted. The SWO close out letter with the associated SDR shall be processed and distributed to the responsible organization in accordance with Section 5.5, 5.6, or 5.7, as appropriate. When the SWO applies to WMPO activities, the WMPO PQM shall formally notify the WMPD Project Manager that the SWO and associated SDR have been closed and that continuation of the affected activities may continue.				
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	6.0 REFERENCES*				
Q	QMP-16-03, Standard Deficiency Reporting System.				
Q	MP-17-01, Quality Assurance Records.				
•	Latest Revision				

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### 8.0 QA RECORDS

The WMPD PQM shall ensure the following QA Records resulting from implementation of this procedure are processed and maintained in accordance with QMP-17-01, Quality Assurance Records:

- Stop work recommendation letters and associated SDRs. 1.
- 2. Stop work notification letters.
- 3. Letters voiding the SWO recommendations.
- 4. Notification letters to close the SWOs.
- 5. Other associated documentation relating to SWOs.